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NHS ENGLAND BOARD PAPER

Title: Items which should not be routinely prescribed in primary care: findings of consultation and next steps – for decision

Lead Director: Professor Sir Bruce Keogh, National Medical Director

Purpose of Paper:

- The Next Steps document, published on 31 March 2017, included as part of the NHS 10 Point Efficiency Plan a commitment to review the appropriateness of aspects of NHS-prescribing, including products deemed to be of 'low clinical value' and/or available to the public over the counter (OTC).
- In July 2017, the NHS England Board approved consultation on a set of proposals to limit the prescription of 18 products costing a total of £141million per year, which it was felt should not be routinely prescribed in primary care. NHS England and NHS Clinical Commissioners consulted publicly on these proposals between July and October 2017.
- The consultation also sought views on potentially limiting the prescribing of medicines that are available over the counter.
- This paper sets out the findings of the consultation and seeks the Board's agreement on proposed next steps.

The Board is invited to:

- Consider and note the findings of the public consultation in relation to the 18 items considered to be relatively ineffective, unnecessary, inappropriate or unsafe for routine prescription in NHS primary care, approve the final recommendations for these items and approve the publication and dissemination of final guidance to CCGs; and
- Note the findings of the public consultation in relation to the principles of limiting prescribing of products which are available over the counter, and note our intention to engage with patient groups ahead of formal public consultation on this.

Items which should not be routinely prescribed in primary care: findings of consultation and next steps

Context and Background

1. Last year, 1.1 billion prescription items were dispensed in primary care at a cost of £9.2billion. It is important that the NHS achieves the greatest value from the money that it spends. Across England there is significant variation in what is being prescribed and to whom. Often patients are receiving medicines which are relatively ineffective or for which there are other more effective and/or cheaper alternatives; there are also products which are no longer appropriate to be prescribed on the NHS.

2. In response to calls from GPs and Clinical Commissioning Groups (CCGs) who were having to take individual decisions about their local formularies, NHS Clinical Commissioners (NHSCC) surveyed their members during February and March 2017 to assess views as to whether a range of medicines and other products should be routinely available for prescription on the NHS.

3. CCGs asked for a nationally co-ordinated approach to the creation of commissioning guidance developed by NHS England and NHS Clinical Commissioners. The aim was a more equitable basis on which CCGs can take an individual and local implementation decision.

4. Together, NHS England and NHSCC established a clinical working group, chaired by representatives of these two organisations, with membership including GPs and pharmacists, CCGs, Royal College of General Practitioners, National Institute for Health and Care Excellence (NICE), Department of Health, the Royal Pharmaceutical Society and others. This clinical working group was tasked with identifying which products should no longer be routinely prescribed in primary care.

5. Work focused on developing guidelines for an initial list of eighteen products which fall into one or more of the following categories:

    - Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns;
    - Products which are clinically effective but where more cost effective products are available, including some products that have been subject to excessive price inflation; and
    - Products which are clinically effective but due to the nature of the product are deemed a low priority for NHS funding.

6. Consideration was also given to a wider list of medicines which, in addition to being available on prescription, are available over-the-counter and which are either of limited clinical effectiveness or used to treat generally time-limited or minor conditions which are suitable for self-care.

7. The Board agreed that NHS England should consult on specific proposals for the eighteen products and for a potential approach to over the counter medicines, and approval was given to run a three month consultation from 21 July to 21 October 2017. The consultation sought views on:

    - The proposed restrictions on the routine prescribing of 18 products, totalling £141m in NHS primary care spend, on which we published draft guidance to CCGs and an Equalities and Health Inequalities Impact Assessment for consultation;

    - The principle of restricting routine prescription of over the counter medicines. We set out that the NHS spent approximately £645m pa on prescriptions for so-called 'over the counter' (OTC) medicines and:

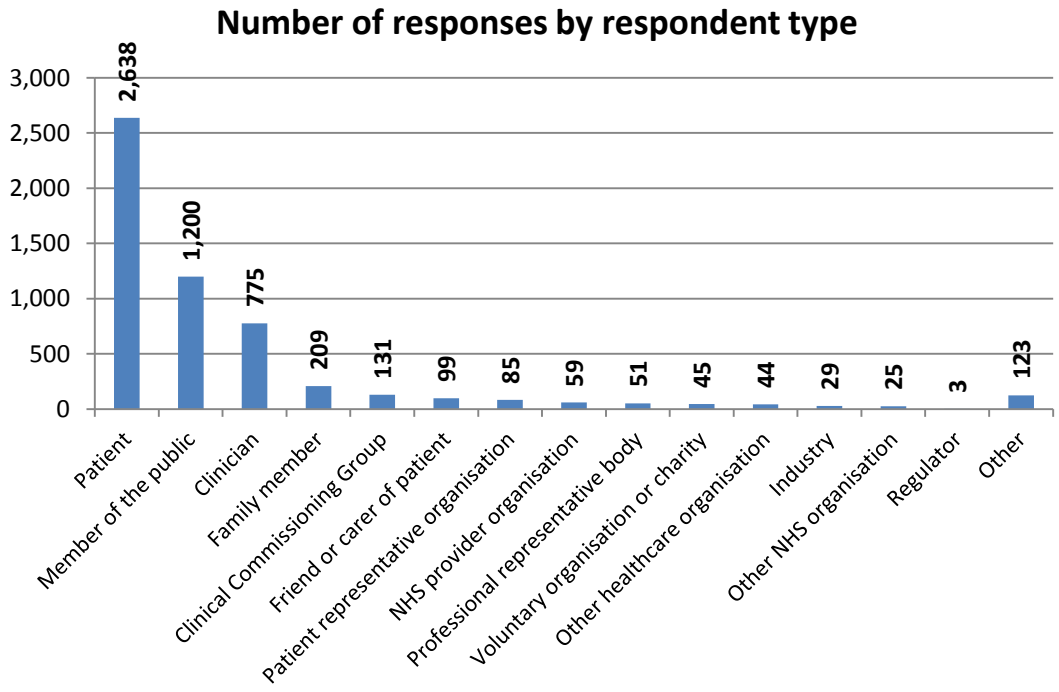
        - Listed a number of conditions which were generally time limited/short-term and/or suitable for self-care. We explained that NHS spending on prescriptions for these conditions amounted to £50m-£100m pa. We indicated that we were considering restricting prescribing and asked for general views and evidence on this proposal; and
        - Explained that the remainder of the spend (£545m pa) was accounted for by medicines used to treat longer term or chronic conditions. We again asked for general views and evidence on whether it would be appropriate to restrict prescribing in this area.

Conclusions on items which should not be routinely prescribed in primary care: the routine prescribing of eighteen products

8. A full analysis and report on the consultation responses is attached at **annex A**.

9. We received a total of 5544 responses through the online consultation survey, and a further 195 written submissions by post or email. In addition, we held 8 webinars for stakeholders, and 2 face-to-face public and patient stakeholder events in London and Leeds, alongside 3 individual meetings with key stakeholder groups including industry, pain management and mental health.

10. The chart below indicates the number of responses broken down by respondent type:



11. In terms of the 18 items under consideration, there were 6 items which generated over 500 responses each:

- Liothyronine
- Co-Proxamol
- Travel Vaccines
- Lidocaine Plasters
- Homeopathy
- Herbal Treatments

12. Immediate release Fentanyl also generated a significant amount of feedback from respondents and participants in the stakeholder engagement events.

13. We listened to what our stakeholders told us through the consultation and refined our draft guidance in light of the responses, discussion through the webinars and the engagement exercises, as well as recommendations from the joint clinical working group which considered the feedback in detail.

14. Whilst most aspects of the final guidance remain largely unchanged from the draft guidance shared with the Board in July, in the light of consultation there have been some important refinements and clarifications made in respect of the following items:

Liothyronine

15. Of those respondents who either agreed or disagreed with the recommendations, only 16% agree that CCGs should be advised that prescribers in primary care should not initiate Liothyronine for any new patients.

16. The main recurring theme – particularly from patients and organisational bodies - is that this is an effective treatment which can, in the appropriate circumstances contribute to patient wellbeing, quality of life and condition management. The impact on particular cohorts of patients was also highlighted - notably those who are unable to take Levothyroxine-T4, or whose metabolic pathway is impaired in some way.

17. The joint clinical working group therefore recommended the prescribing of liothyronine for any new patient should be initiated by a consultant endocrinologist in the NHS, and that de-prescribing in 'all' patients is not appropriate, as there are recognised exceptions. The recommendation would therefore be changed to advise prescribers to de-prescribe in all *appropriate* patients.

Co-proxamol

18. Of those respondents who either agreed or disagreed with the recommendations, 85% agree that CCGs should be advised that prescribers in primary care should not initiate Co-proxamol for any new patients, and 85% agree that CCGs should be advised to support prescribers in de-prescribing Co-proxamol in all patients.

19. The main theme, expressed particularly by patients and the public, CCGs and clinicians, was a concern around safety of the treatment.

20. The joint clinical working group considered that our initial recommendations not to initiate the treatment in new patients and to de-prescribe in existing patients should remain.

Travel Vaccines

21. Of those respondents who either agreed or disagreed with the recommendation, which was simply a restatement of current policy, 61% agree that CCGs should be advised that prescribers in primary care should not initiate the free provision of Travel Vaccines for any new patients.

22. While a commonly highlighted theme from patients, members of the public, clinicians and professional bodies was that the cost of a travel vaccination should be funded by the patient, there were also contrasting views from these groups that vaccines help to protect public health and that they provide a cost saving to the NHS overall. CCG responses were generally in favour of patients meeting

the costs of travel vaccines, but they highlighted that they wanted clarity on when vaccines should and should not be provided for free.

23. The joint clinical working group agreed that the recommendation (which is simply a reinforcement of existing policy) should remain unchanged, but the text of the guidance should be refined to make it clear and precise to practices that these vaccines should be still available for purposes other than travel. The items consulted on are not currently supposed to be commissioned in the NHS for the purposes of travel, therefore there should be no changes to currently commissioned vaccines.

Lidocaine Plasters

24. Of those respondents who either agreed or disagreed with the recommendations, 59% agree that CCGs should be advised that prescribers in primary care should not initiate Lidocaine Plasters for any new patients, and 58% agree CCGs should be advised to support prescribers in de-prescribing Lidocaine Plasters in all patients. A significant proportion of the respondents (approximately 44%) were clinicians.

25. It was noted that many of the current uses for patients are inconsistent with its licence and it was highlighted that treatment should only be prescribed by specialist teams.

26. However, some feel that the treatment is effective, particularly for palliative care and cancer patients. The Royal Pharmaceutical Society highlighted that they have seen benefits in patients using these, and The British Medical Association feel it would be inappropriate to de-prescribe in patients who have seen a good therapeutic response to treatment.

27. The Specialist Pharmacist Service reviewed additional evidence submitted through the consultation (**annex B**), and the outcome was that there is limited evidence of effectiveness available for use in unlicensed indications such as cancer and palliative care; however some evidence exists for the use of Lidocaine Plasters in Post Herpetic Neuralgia (PHN) only, for which it is licensed in adults.

28. The joint clinical working group therefore propose that the recommendations remain but be amended to include a specialist exemption for PHN, with detail about the circumstances in which it could be considered.

Immediate Release Fentanyl

29. Of those who either agreed or disagreed with the recommendations, 65% agree that CCGs should be advised that prescribers in primary care should not initiate immediate release Fentanyl for any new patients, and 59% of respondents agree

that CCGs should be advised to support prescribers in de-prescribing immediate release Fentanyl in all patients.

30. 76% agreed that CCGs should be advised that if, in exceptional circumstances, there is a clinical need for immediate release Fentanyl to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional.

31. Many respondents also felt that immediate release Fentanyl is an effective treatment especially in cancer patients, and that its use in palliative care is justified.

32. The joint clinical working group agreed that the recommendations should remain, while clarifying that use in palliative care by a recognised multi-disciplinary team professional is acceptable and that appropriate patients should therefore not be de-prescribed.

33. The group also recommended that the finalised guidance should also include helpful resources to ensure that services such as pain clinics, substance misuse etc, are commissioned to support de-prescribing.

Homeopathy

34. The responses to the consultation in relation to Homeopathy were split. Across all of the respondent groups, there was 46% support for the recommendation that CCGs should be advised that prescribers in primary care should not initiate homeopathic treatments for any new patients; 50% of respondents agreed with the recommendation that prescribers should be supported to de-prescribe homeopathy in all patients. CCGs particularly agreed with the recommendations, supporting the proposals by 94% and 93% respectively. Self-identified patient respondents were not supportive of the proposals, with only 27% and 37% respectively agreeing with the recommendations.

35. Whilst patients and several groups representing homeopathic practitioners and patients receiving the treatment felt that homeopathy was effective – and some suggested that the proposals would potentially increase costs to the NHS from replacing homeopathic treatments with more expensive items – a significant cohort of the public noted that there was a lack of evidence showing the effectiveness of homeopathic treatments.

36. The public generally were in support of the recommendations by margins of 55% and 57% respectively. Specialist homeopathy organisations took the opposite view and the British Homeopathic Association in particular submitted further evidence of the clinical effectiveness of homeopathy. NHS England commissioned an independent review of this additional evidence by the Specialist

Pharmacy Service (SPS). The SPS review showed that there was not a clear or robust evidence base for homeopathy (**annex C**).

37. Organisations representing groups within conventional medicine were generally in support of our proposals to restrict the availability of homeopathy in primary care on the NHS. Whilst some individual clinicians did support the use of homeopathy, we received responses from the Royal Pharmaceutical Society and the British Medical Association who told us respectively that they do not endorse homeopathy as a form of treatment and that homeopathy should be blacklisted. The National Institute for Clinical Excellence (NICE) also responded to our consultation stating that they have produced guidance across a range of conditions which showed no evidence of the effectiveness of homeopathy.

38. Having considered the wide range of responses to our consultation, and taking into account of the findings of the SPS review, the clinical working group was of the view that the scientific review of the evidence should be preferred to the anecdotal evidence from patients and, notwithstanding what we perceive to be marginal cost issues, that the initial recommendations should stand.

Herbal Treatments

39. Of those respondents who either agreed or disagreed with the recommendations, 46% agreed that CCGs should be advised that prescribers in primary care should not initiate herbal treatments for any new patients, and 52% of respondents agreed that CCGs should be advised to support prescribers in de-prescribing herbal treatments in all patients.

40. As with homeopathy, a large proportion of those who responded (approximately 40%) were self-identified patients, who expressed the view that herbal treatments are effective and safer than conventional medicines with fewer side effects. In contrast, 98% of CCGs and 66% of clinicians agreed that herbal treatments should not be initiated for new patients, and 93% of CCGs and 65% of clinicians agreed that herbal treatments should be de-prescribed for all patients. These groups highlighted that there is limited evidence of the effectiveness of herbal treatments.

41. The joint clinical working group reviewed the feedback and did not feel it necessary to amend the proposed recommendations for herbal treatments, and they remain unchanged.

Additional recommendations

42. The joint clinical working group did not feel it necessary to amend the proposed recommendations for de-prescribing prolonged release Doxazosin or Trimipramine; however the group felt that there would not be cases of

exceptionality that would warrant referral to a multidisciplinary team so removed that recommendation.

43. In relation to a number of drugs, the consultation feedback included requests that the particular drug should be formally placed on the 'blacklist'. This is not a matter for NHS England, but rather one for the Secretary of State to consider. Subject to the Board's agreement to the recommendations in this report, it is proposed that NHS England recommends that the Secretary of State formally consider blacklisting the following drugs:

    - Co-proxamol
    - Glucosamine and Chondroitin
    - Herbal Treatments
    - Homeopathy
    - Lutein and Antioxidants
    - Omega-3 Fatty Acid Compounds
    - Rubefacients (excluding topical NSAIDS)

44. If the Secretary of State decides to proceed with any such recommendation, there will be a further formal consultation on the proposals.

Recommendations for Items which should not be routinely prescribed in primary care: the routine prescribing of eighteen products

45. The final proposed guidance for CCGs is attached at **annex D** for the Board's consideration and approval to publish. This is accompanied by an Equalities Impact Assessment, attached at **annex E**.

46. The Board is asked to:

    - **Consider and note the findings of the public consultation in relation to the 18 items considered to be relatively ineffective, unnecessary, inappropriate or unsafe for routine prescription in NHS primary care; approve the final recommendations for these items; and approve the publication and dissemination of final guidance to CCGs.**

47. CCGs will be expected to take this guidance into account in formulating local polices, and prescribers should reflect these local policies in their prescribing practice. This guidance does not remove the clinical discretion of the prescriber in accordance with their professional duties.

Conclusions on items which should not be routinely prescribed in primary care: over the counter items

48. The consultation on items which should not be routinely prescribed in primary care sought views on restricting the prescribing of medicines which are readily available over the counter and indicated an indicative list of 26 minor acute/self-limiting conditions where prescribing restrictions could be considered.

49. As feedback from the consultation was broadly supportive, we now believe that it is appropriate for NHS England to work with partners to develop formal and far more detailed guidance to CCGs.

50. These are for prescriptions for medicines which could otherwise be purchased over the counter from a pharmacy and/or other outlets such as petrol stations or convenience stores. These include products that:

- Can be purchased over the counter, and sometimes at a lower cost than that which would be incurred by the NHS;
- Treat a condition that is considered to be self-limiting and so does not need treatment as it will heal/be cured of its own accord; and/or
- Treat a condition which lends itself to self-care, i.e. that the person suffering does not normally need to seek medical care and/or treatment for the condition.

51. The NHS also wishes to promote the concept of appropriate self-care and increase awareness amongst the public that there are alternatives to making GP appointments in relation to conditions for which over the counter medicines are typically prescribed.

Proposed Approach to consultation

52. We consulted our clinical working group on several proposed approaches to restricting the prescription of over the counter (OTC) medicines. Based on their guidance, we mapped OTC products to the conditions for which they are typically prescribed. We refined our approach to develop restrictions based on severity of condition rather than product name or type, as the number of OTC products (c. 3,200) and the frequency of product name changes over time would make it difficult to apply any restrictions based on product name or type. Nevertheless, many of the criteria that we would normally use to assess products are still relevant to condition-based restrictions and have been incorporated into our thinking.

53. Following our mapping exercise, 8 additional minor conditions (in addition to the 26 conditions outlined in July 2017) were identified which could be scoped for inclusion. The full list of indicative conditions identified is attached at **annex F.**

Vitamins/Minerals and Probiotics have also both been included as a standalone category given that they have been identified as high cost in terms of OTC spend, although their use cannot be mapped to one single condition.

54. We propose that over the counter products could be classified within the three condition categories below:

- ***Products that are used to treat minor conditions****:* An ailment or condition which can be classified as being minor and/or self-limiting. For self-limiting conditions medical advice is not usually necessary, so they can be promoted for self-care without need for NHS prescribing. Some drugs used for such conditions in this category may have a limited evidence base for their use. An example would be cough medicines, where the evidence behind their use is weak and there is no evidence to say that they will reduce the duration of illness. Other conditions in this category are suitable for self-care, and treatments for them can be purchased over the counter.

- ***Products that can be used to treat both minor and non-minor conditions***: Some drugs, whilst used purely for minor ailments, may also be used for a chronic illness or in response to a side effect of another drug that is required for treatment of more complex disease. An example could be drugs used to treat constipation. Simple constipation due to lack of fibre in the diet can be considered minor and treated with an OTC product; however, laxatives could also be prescribed to prevent constipation in patients with chronic pain who are taking opiate analgesics (morphine). Some patients may also be prescribed these drugs for inflammatory bowel disease. We therefore expect around 20% of OTC prescribing for drugs in this category to be for minor conditions. We do not propose restrictions on OTC prescribing for non-minor conditions.

- ***Products that are used to treat non-minor conditions***: OTC drugs in this category are being prescribed for non-minor conditions. An example would be nitrates (GTN Spray) which are prescribed for the symptomatic relief of angina. We do not propose restrictions on OTC prescribing for conditions in this category.

55. Having identified those OTC drugs which we considered to be prescribed for minor conditions, we believe we can group each condition as either:

a) A condition that is self-limiting and does not require medical advice or treatment as it will clear up on its own; or
b) A condition that is a minor ailment and is suitable for self-care and treatment with items that can easily be purchased over the counter from a pharmacy.

56. In the case of vitamins/minerals and probiotics, these are considered to be items of limited clinical evidence of effectiveness.

57. We then propose that for each condition we could make one of the following recommendations to CCGs:

    a) Advise CCGs to support prescribers that a prescription for treatment of **[condition]** should not routinely be offered in primary care, as the condition is self-limiting.
    b) Advise CCGs to support prescribers and patients that a prescription for treatment of **[condition]** should not routinely be offered in primary care, as the condition is appropriate for self-care unless one or more general exemptions apply.

58. In the case of vitamins/minerals and probiotics we propose to make the following recommendation:

    - Advise CCGs to support prescribers that **[item]** should not be routinely prescribed in primary care due to limited evidence of clinical effectiveness.

59. We have not included vitamins or probiotics within our final guidance on items which should not be routinely prescribed in primary care, as we would need to consult on this proposal in due course.

60. We initially consider that the cases below are examples of exceptions which may apply to the proposed restrictions:

    - People who lack the appropriate level of cognitive capacity to be able to independently purchase items over the counter (for example patients with learning disability or with conditions such as dementia).
    - Groups of people who are commonly refused the sale of OTC medicines because of cautions or contraindications in the product licence e.g. pregnancy and breastfeeding and babies and young children (although this may depend on the condition)
    - Patients with a minor condition suitable for self-care that has not responded sufficiently to treatment with a purchased OTC product.
    - More severe forms of some conditions e.g. recurrent cystitis,
    - Those in conditions of detention unable to visit a retail outlet or pharmacist (eg HM Prisons, IRC establishments); and/or
    - Where the GP believes that in their clinical judgement, exceptional circumstances exist that warrant deviation from the recommendation to self-care.

61. We estimate that up to **£190m pa** could potentially be saved on prescribing of OTC items using the approach set out above.

62. It is important that we engage and consult with patient groups in developing and refining these draft proposals and, in particular, exemptions which may apply to our guidance. We therefore propose to seek individual meetings with key patient groups including Healthwatch England during late November and early December to further shape and refine the draft proposals set out above.

63. Subject to NHS England Board approval at this meeting, we propose to publish draft guidance in January 2018, with the intention of consulting with CCGs, patients, clinicians, professional and other stakeholder bodies, and the public.

64. This consultation would be intended to provide a consistent, national framework, in the context of which local CCGs will be able to decide whether and how to implement the national clinical commissioning guidance, with due regard to both local circumstances and their own impact assessments.

65. The Board is asked to:

- Note the findings of the public consultation in relation to the principles of limiting prescribing of products which are available over the counter, and note our intention to engage with patient groups ahead of formal public consultation on this.

ANNEX A

Items which should not be routinely prescribed in primary care: Consultation Report of Findings

NHS England

Items which should not be routinely prescribed in primary care: Consultation Report of Findings

Version number: 1

First published: 30 November 2017

Prepared by: Midlands and Lancashire Commissioning Support Unit

Classification: OFFICIAL

This information can be made available in alternative formats, such as easy read or large print, and may be available in alternative languages, upon request. Please contact england.medicines@nhs.net

1 Contents

2 Background

2.1 The issue to tackle

NHS England has partnered with NHS Clinical Commissioners (NHSCC) to support Clinical Commissioning Groups (CCGs) in ensuring that they can use their prescribing resources effectively and deliver best patient outcomes from the medicines that their local population uses. CCGs asked for a nationally coordinated approach to the development of commissioning guidance in this area to ensure consistency and address unwarranted variation. The aim is that this will lead to a more equitable process for making decisions, addressing unwarranted variation, and provide clear guidance on medicines. CCGs, however, will need to take individual decisions on implementation locally.

Last year 1.1 billion prescription items were dispensed in primary care at a cost of £9.2billion. This cost coupled with finite resources means it is important the NHS achieves the greatest value from the money that it spends. We know that across England there is significant variation in what is being prescribed and to whom. Often patients are receiving medicines which have been proven to be relatively ineffective or in some cases dangerous, for which there are other more effective, safer and/or cheaper alternatives.

The 'Items which should not routinely be prescribed in primary care – a consultation on guidance for CCGs' - ran between 21 July and 21 October 2017. Responses to our proposals were received through the online survey, webinars, public events and correspondence in the form of letters and emails.

NHS England and NHSCC, alongside their joint clinical working group, have reviewed the consultation findings contained in this report and developed finalised commissioning guidance for approval by the NHS England Board. The guidance will then be published with the expectation that CCGs should 'have regard to' it in accordance with the Health and Social Care Act 2012.

The NHS England and NHSCC led clinical working group developed guidelines regarding a list of 18 products which they considered to be ineffective, unnecessary, inappropriate or unsafe for prescription on the NHS.

The 18 items were categorised under three headings:

- *Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns:* Co-proxamol, Omega-3 fatty acid compounds, Lidocaine Plasters, Rubefacients, Dosulepin, Glucosamine and Chondroitin combination product, Lutein and Antioxidants combination product, Oxycodone and Naloxone combination product, Homeopathy, Herbal Medicines

- *Products which are clinically effective but where more cost-effective products are available (this includes products that have been subject to excessive price inflation):* Liothyronine, Prolonged-release Doxazosin, Perindopril Arginine, Immediate-release Fentanyl, Once Daily Tadalafil, Trimipramine, Paracetamol and Tramadol combination product

- *Products which are clinically effective but deemed a low priority for NHS funding:*

Travel Vaccines (Public Health England will be undertaking policy work on this).

The group also sought views generally on the potential restriction on prescription of over the counter medicines used for generally minor and/or self-limiting conditions. These included:

- Products that can be purchased over the counter, and sometimes at a lower cost than would be incurred by the NHS
- Products that treat a condition that is considered to be self-limiting and so does not need treatment as it will heal or be cured of its own accord, and/or
- Products that treat a condition which lends itself to self-care, i.e. that the person suffering does not normally need to seek medical care and/or treatment for the condition.

NHS England commissioned NHS Midlands and Lancashire Commissioning Support Unit (MLCSU) to collate and analyse all of the feedback from this consultation and produce this report which has been considered in full by NHS England.

3 Engagement methodology and feedback

Engagement was structured around the following channels and feedback mechanisms:

Breakdown of responses according to feedback method		
Feedback methods	**No. responses from feedback method**	**Action taken**
Online survey (comprising 75 closed questions and 26 open questions)	5,544	Closed questions are tabulated by respondent type. Open questions are coded, key quotes identified and tabulated by respondent type.
Patient and public correspondence (email and letters)	95	Each correspondence was read and coded against the online survey coding frame. The data was then coded and a summary report was written.
Organisational correspondence (email, letters and formal correspondence)	80	Each correspondence was read and summarized.
Letters from MPs including one parliamentary briefing	20	Each correspondence was read and summarized.
Webinars (professional and industry)	5	Summaries have been written for each of the products mentioned in the discussion.
Webinars (patient and public)	3	Summaries have been written for each of the products mentioned in the discussion.
Engagement events	2	Summaries have been written for each of the products mentioned in the discussion.
Events and meetings (professional and industry)	3	Summaries have been written for each of the products mentioned in the discussion.

Analysing feedback received

The consultation survey included a combination of ‘open text’ questions (e.g. If needed, please provide further information) where respondents could share their views and opinions as well closed questions where respondents ‘ticked’ a response to a set of preset responses (e.g. ‘To what extent to do you agree with X’ and the answers are: agree, disagree, neither or unsure). The closed questions were tabulated and responses shown by respondent type.

The ‘open text’ questions were handled differently. A random sample of around 200 responses for each ‘open text’ question was initially read in order to create and list key themes (codes) raised by respondents. This was undertaken for every question. Some codes were replicable across more than one response (e.g. ‘NHS funds should not be used to pay for this’) whilst others were specific to a particular product or question. This means that every comment was coded because the list of themes/codes was not predetermined but instead emerged dynamically from the responses received.

The coding frame was then used to read, code and analyse every single response received from patients and the public. **This has ensured that all responses can be considered by NHS England and be compared and analysed together**. Supporting evidence, reports, academic papers etc. which were submitted by organisations are being reviewed by NHS England separately as appropriate.

Responses from specific organisations were read and summarised. These summaries have been referred to in this report.

3.1 Survey respondent types and patient demographics

Overall 5,544 individuals completed the survey, with the majority (69%) of responses coming from patients and members of the public. However responses were also received from other respondent types, including; Clinicians, Clinical Commissioning Groups, NHS Provider Organisations, Professional Representative Bodies and Industry.

Focussing on the patients specifically, the majority were; women, heterosexual, aged between 30 and 79 and of British ethnicity.

Respondent types and patient demographics			
Respondent type (total)	**No.**	**Gender**	**No.**
Patient	**2,638**	Female	2,041
Member of the public	1,200	Male	496
Clinician	775	Non binary	9
Family member	209	Trans	6
Clinical Commissioning Group	131	Intersex	1
Friend or carer of patient	99	Prefer not to say	64
Patient representative organisation	85	*Total*	*2,638*
NHS provider organisation	59		
Professional representative body	51	**Sexual orientation**	**No.**
Voluntary organisation or charity	45	Heterosexual	2,095
Other healthcare organisation	44	Bisexual	48
Industry	29	Gay	28
Other NHS organisation	25	Lesbian	21
Regulator	3	Prefer not to say	356
Other	123	*Total*	*2,638*
Total	*5,516*		
Age	**No.**		
Under 18	3	60 – 69	599
19 – 29	74	70 – 79	218
30 – 39	347	80+	33
40 – 49	581	Prefer not to say	33
50 – 59	702	*Total*	*2,638*
Disability	**No.**		
Yes	847	Prefer not to say	230
No	1,529	*Total*	*2,638*
Religion/beliefs	**No.**		
Christian	1,068	Jewish	19
No religion	916	Hindu	10
Prefer not to say	270	Sikh	6
Atheist	143	Any other religion	87
Buddhist	30	*Total*	*2,638*
Muslim	22		
Ethnicity	**No.**		
White: Welsh/ English/ Scottish/ Northern Irish/ British	2,181	Mixed: White and Asian	7
Other White background	217	Black or Black British: Black - Caribbean	6
White: Irish	41	Asian/Asian British: Bangladeshi	5
Other ethnic background: Any other ethnic group	33	Black or Black British: Black - African	5

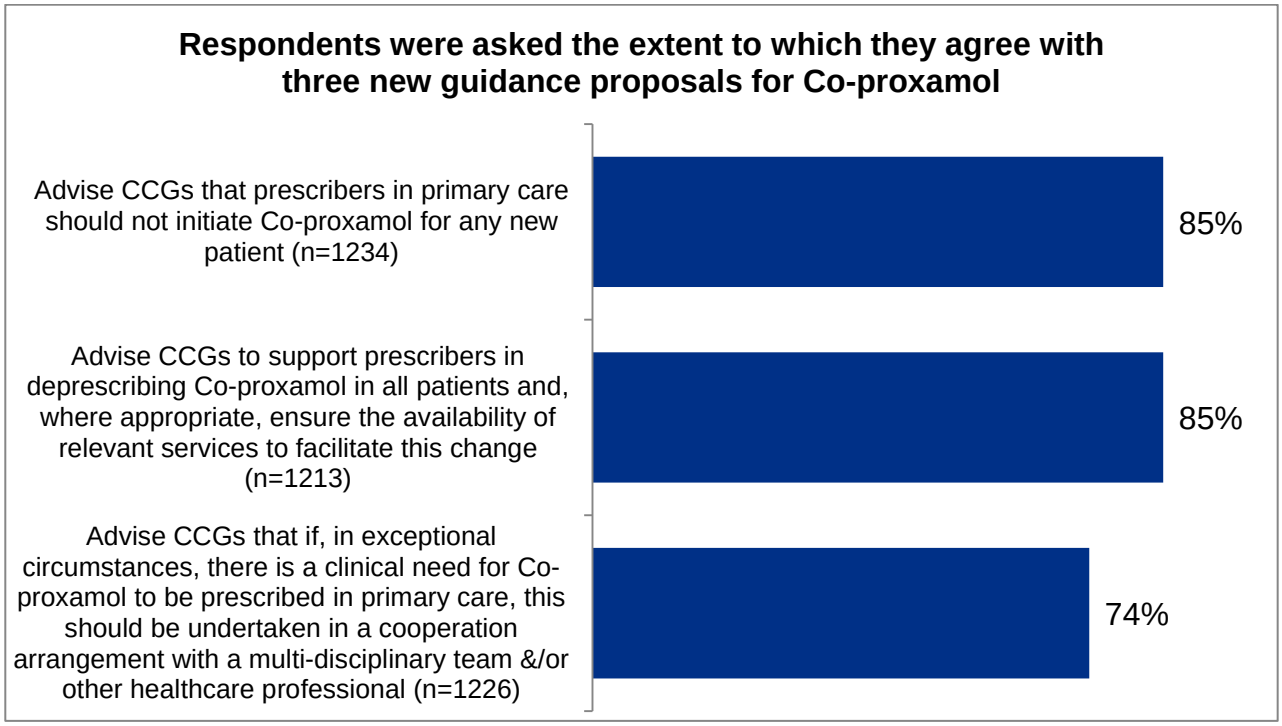
Asian/Asian British: Indian	28	Mixed: White and Black African	4
Any other mixed background	19	Black or Black British: Any other Black background	2
Asian/Asian British: Pakistani	10	White: Gypsy or Irish Traveller	1
Mixed: White and Black Caribbean	10	Other ethnic background: Chinese	0
Asian/Asian British: Any other Asian background	7	*Total*	*2,638*

4 Responses by item

4.1 Co-proxamol

Co-proxamol is a painkiller that was previously licensed in the UK until being fully withdrawn from the market in 2007 due to safety concerns. All use in the UK is now on an unlicensed basis. The inclusion of Co-proxamol within this consultation is due to the significant safety concerns associated with it (fatal overdoses).

The chart below presents the extent to which all survey respondents agree with the two new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



N.B. Respondents were asked whether they 'agree', 'disagree', 'unsure' or 'don't know' to the proposal questions. The bars show percentages calculated as a proportion of those who 'agree' /'disagree' and excludes those who said 'unsure' and 'don't know'. A full breakdown by respondent type can be found in the annex.

The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

Some patients state that Co-proxamol is an effective treatment that has provided patients with long-term relief and ask NHS England to consider the additional demand that will be placed onto healthcare professionals if it is removed. It is more likely to be used in older patients who have been using it for a long period of time and are, therefore, most likely to be affected by this proposal.
"Co-proxamol used to be the best painkiller I had. It was as effective as codeine without making me drowsy. It was the only painkiller I could function on."

However, some patients (10) suggested that Co-proxamol should be blacklisted because of safety concerns.

Members of the public and family members

This cohort voices concern about the safety of Co-proxamol and supports the motion of blacklisting the treatment. Additionally, some state that there are alternative treatments available with similar efficacy.

"Blacklist Co-proxamol – should not be available under any circumstance."

CCGs

Responses from this group generally support the proposal. They state the guidance around Co-proxamol should be strengthened and the treatment blacklisted. They express safety concerns with the use of Co-proxamol and state there are alternatives available with similar efficacy.

"CCGs and clinicians do not need any further 'guidance' or 'recommendations' on prescribing. We need a change in NHS regulations to prevent prescribing. Medicines Optimisation teams have worked to review and stop Co-proxamol prescribing since the original safety warnings, but we cannot eliminate prescribing due to small numbers of patients exerting pressure on clinicians. Bury has an excellent record in the implementation of cost-effective prescribing guidance, but we still struggle to eliminate inappropriate prescribing across all practices and clinicians."

Clinicians

Clinicians generally also support the proposal, expressing safety concerns and also stating that it is an expensive treatment. Using stronger wording in the guidance and blacklisting the treatment are also prominent themes amongst this cohort. A small sub-set of this group states Co-proxamol is an effective treatment, and there may be scope to prescribe it in exceptional circumstances.

"Previously, I was a PCT chief pharmacist, and during my 10 years in post we managed to work with our GPs to stop prescribing Co-proxamol for all but one patient in our PCT area. I am surprised that we are still spending over £9 million on Co-proxamol. It has no place in therapy, and presents significant safety concerns. While I understand that it can be difficult to convince some patients of the need to stop using Co-proxamol, there is no excuse for not trying. I would consider raising performance concerns about any prescriber who has initiated Co-proxamol since it was withdrawn in 2007."

Patient representative organisations, voluntary organisations and charities

The key themes to emerge amongst this cohort are the requirement to consider the impact on healthcare professionals as a result of this treatment not being available; multi-disciplinary team involvement in the prescription of this treatment not being a good use of resources; safety concerns around Co-proxamol's use; and the requirement for clearer definitions in the guidance. There is also a need to consider the impact this proposal will have on those for whom Co-proxamol has been effective in providing long-term relief.

Other NHS organisations, provider organisations and professional bodies

Comments from other organisational bodies convey their support for the proposal, expressing concern around safety of this treatment and a need for clearer guidance to avoid any misunderstanding and inappropriate patient expectations that it is still available in exceptional circumstances.

This group also suggests an additional reason for not prescribing it at all is because there are a number of safer, effective alternatives.

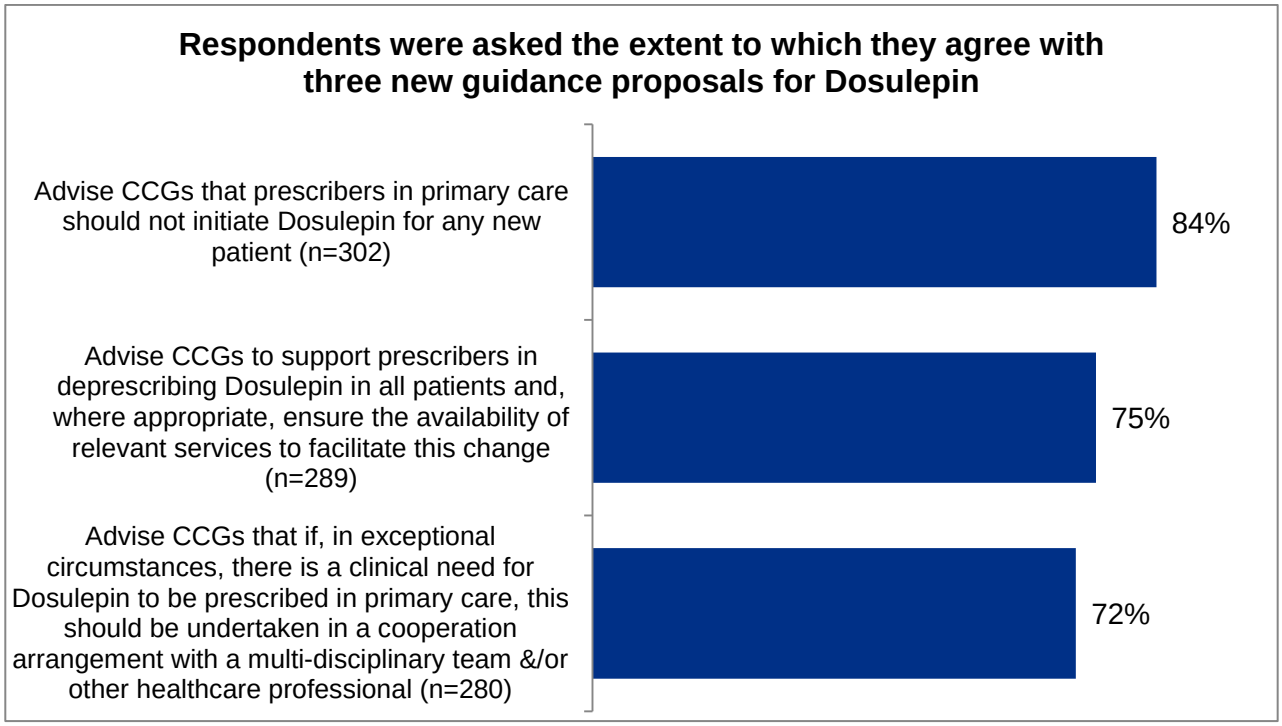
NICE agrees with all of the proposed guidance in relation to Co-proxamol.

The Royal Pharmaceutical Society also agrees with the proposal, citing safety concerns and the availability of alternatives. The British Medical Association disagree that CCGs should be advised that if, in exceptional circumstances, there is a clinical need for co-proxamol to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional. The BMA think that due to its toxicity, co-proxamol should either be placed on the blacklist of drugs unavailable on the NHS or be restricted to prescription by a specialist.

4.2 Dosulepin

Dosulepin is an anti-depressant. NICE includes Dosulepin in its 'do not do' recommendation because it has a high chance of causing heart problems, is toxic in overdose and there are other anti-depressants available which are safer to use.

The chart below presents the extent to which all survey respondents agree with the two new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



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The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

Themes raised by patients in their comments were that: this is an effective treatment; and alternatives don't suit all patients, therefore Dosulepin is the only suitable medication for them.

"If I cannot be prescribed Dosulepin, I will not be able to function. I will have to give up work and social activities. I will be in constant pain."

Members of public and family members

The majority of members of the public agree with the proposals mainly because they feel that if there are safety risks associated with taking Dosulepin, it shouldn't be prescribed or available at all. They also feel that there should be clear guidance and explanation

about what constitutes an exceptional circumstance.

"Has a 'do not use' warning, significant risks of use, and there are numerous other medications which could be prescribed instead. Risks outweigh benefits."

CCGs

CCGs believe prescribing of Dosulepin should stop and it should be blacklisted. However, one of the top five themes from this group is that patients who currently use the Dosulepin should be able to continue to use it.

"New patients should not be initiated, however it is felt that where patients are currently prescribed the treatment and are stable – then they should remain on treatment, as there may be implications which cost more to the system, and could result in poor patient outcomes/patient experience by trying to stop treatment."

Clinicians

Clinicians make a number of comments in agreement with the proposals. Some state that as this is the only medication that works for some patients, those who currently use it should be able to continue to do so.

"This drug has a very small role and is useful in a tiny number of patients."

Patient representative organisations, voluntary organisations and charities

The majority of this group agrees with the recommendations for new patients. However, just a quarter agree with the recommendations for deprescribing Dosulepin for all patients, with others stating that for some patients it is the only option that works.

Other NHS organisations, provider organisations and professional bodies

Other organisations think that the prescribing of Dosulepin should be reviewed and deprescribed where appropriate. Where this is not deemed possible there should be a coordinated approach between primary and secondary care. Some organisations support this proposal stating safety concerns about the use of Dosulepin.

The Royal Pharmaceutical Society says that Dosulepin should continue to be prescribed for the small number of patients, mainly elderly, who benefit from it. They may not be able to tolerate switching to an alternative which could lead to increase costs to the NHS. Phasing out Dosulepin over time may be a more realistic approach.

"Patients already on this medicine have been stabilised … for many years. We are going to take them into an unknown state. Where appropriate, the clinicians should be able to prescribe this [if] in their opinion [it] would be the most suitable for their patients." (NHS provider organisation)

Industry

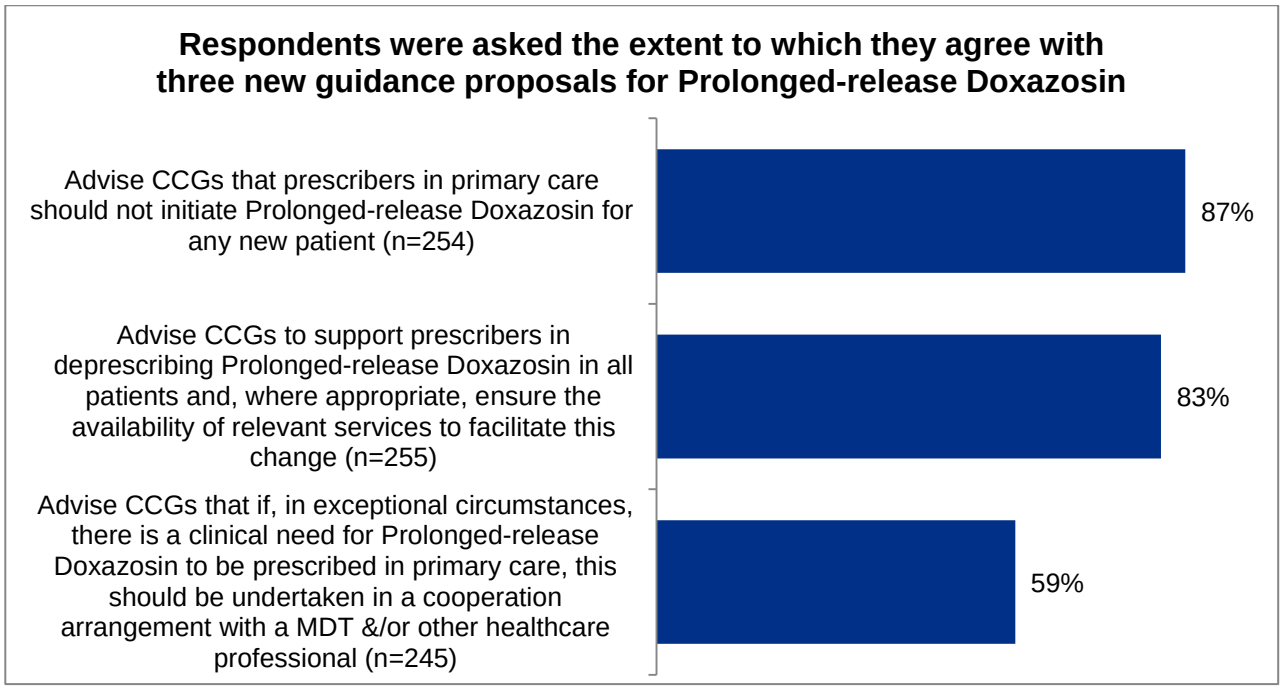
The one response from industry neither agrees nor disagrees.

"Agree that there may be suitable alternatives however for those patients who are currently on treatment; to be continued with support. Agree for use in new patients in exceptional circumstances. However exceptional circumstances should be pre-defined in NHS guidelines."

4.3 Prolonged-release Doxazosin

Prolonged-release Doxazosin is a drug that can be used to treat high blood pressure/hypertension (in men and women) or prostate problems in men (benign prostatic hyperplasia). There are two oral forms of the medication (immediate-release and prolonged-release) and both are taken once daily. The inclusion of Prolonged-release Doxazosin within this consultation is due to the fact that it is approximately six times the cost of Immediate-release Doxazosin, which is also more readily available.

The chart below presents the extent to which all survey respondents agree with the two new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



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The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

This cohort is divided in support for these recommendations, some quoting the side-effect profile of Immediate-release Doxazosin as the main contributing factor.

"Some patients have resistant-controlled high blood pressure, whichever medication they are prescribed. To remove this tablet and put them on the standard release one could totally upset their blood pressure long-term."

Members of the public and family members

Some respondents agree with the proposal however, some state that the treatment should be prescribed with input from primary and secondary care.

"This item is likely to be on hospital prescribing formularies and therefore there must be a joined-up approach between primary and secondary care."

CCGs

Most comments from CCGs state that they feel this product should be blacklisted. This group would welcome a robust definition of exceptional circumstances as well as clearer guidance and education material from NHS England to support the implementation of these recommendations, including the role of the multidisciplinary team.

"No clinical need for Prolonged-release Doxazosin, however significant use so will be difficult to implement. Some clear guidance regarding 'no clinical rationale for use' will be essential to get GPs to agree."

Clinicians

Like CCGs, clinicians agree that this treatment should be removed or blacklisted. This group would also welcome a robust definition of exceptional circumstances as well as clearer guidance and education material from NHS England to support the implementation of these recommendations, including the role of the multidisciplinary team.

"Immediate release is once daily, no value in MR therefore should be unavailable for prescribing and blacklisted."

Patient representative organisations, voluntary organisations and charities

One respondent from this cohort observes that Prolonged-release Doxazosin and Immediate-release Doxazosin are both taken once daily – so there is no need for Prolonged-release Doxazosin.

Other NHS organisations, provider organisations and professional bodies

The majority of organisations are in support of the proposals. Like CCGs and clinicians, they would welcome further guidance on the proposal in regards to implementation. A small number of these bodies are against the proposal or just an aspect of it.

"Evidence from practice and dealing with patients would suggest that many patients cannot tolerate Immediate-release Doxazosin."

NICE agrees with all three recommendations, and also notes that when exercising their judgement, health professionals are expected to take guidance fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in NICE guidance is at the discretion of health professionals and their individual patients and does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

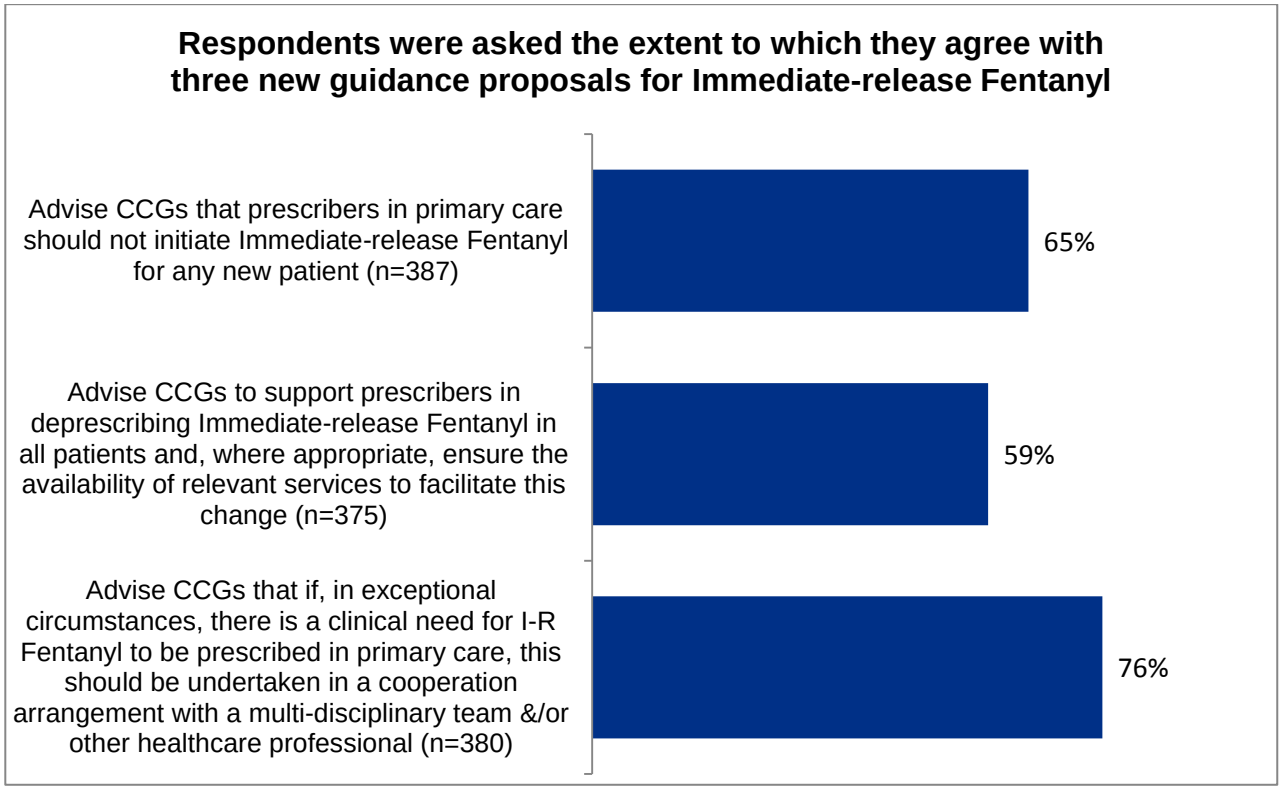
Middlesex Pharmaceutical Group of Local Pharmaceutical Committees mildly disagrees with this proposal. However, they say that CCGs should be advised that if, in exceptional

circumstances, there is a clinical need for Prolonged-release Doxazosin to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional.

4.4 Immediate-release Fentanyl

Immediate-release Fentanyl is a painkiller, similar to Morphine. It is available in various forms, such as tablets, lozenges, film and nasal spray, and is licensed for the treatment of breakthrough pain in adults with cancer who are already receiving at least 60mg oral morphine daily or equivalent. NICE CG140 Opioids in Palliative Care states 'Do not offer fast-acting Fentanyl as first-line rescue medication'. Consensus of the working group is that the small number of people this would apply to does not justify current prescribing volumes. Due to the recommendations from NICE and Immediate-release Fentanyl being only licensed for use in cancer, the group considers it suitable for inclusion in the proposed guidance. This recommendation does not apply to longer sustained release versions of Fentanyl which come in patch form.

The chart below presents the extent to which all survey respondents agree with the two new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



N.B. Respondents were asked whether they 'agree', 'disagree', 'unsure' or 'don't know' to the proposal questions. The bars show percentages calculated as a proportion of those who 'agree' /'disagree' and excludes those who said 'unsure' and 'don't know'. A full breakdown by respondent type can be found in the annex.

The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

Patients highlight that if this product were removed there would have to be a plan in place for those needing to be managed off it because it is the only effective treatment for some patients.

"Immediate pain relief, especially for cancer suffers, is important. If it is being routinely prescribed, than we should assume that GPs are doing this for a good reason. No-one should have to endure unnecessary pain."

Members of the public and family members

Similarly to patients, this cohort also feels Immediate-release Fentanyl is an effective treatment, and therefore a plan must be in place for those who must be managed off it. Additionally, respondents feel that the prescribing decision should remain with healthcare professionals, giving them the option to also prescribe alternative forms of the treatment where required.

CCGs

CCGs largely support the recommendations but caveat there may be exceptional circumstances when it is appropriate to prescribe in primary care. They argue the use of this treatment in palliative care is justified. CCGs highlight safety concerns with the misuse of this treatment, therefore it should be restricted for those who show a genuine clinical need and this is where further guidance and education from NHS England is required to ensure it is implemented effectively.

Clinicians

Clinicians state the use of this treatment in palliative care is justified as they feel it is an effective treatment. They say that therefore the impact on palliative care patients must be considered when considering this proposal.

Regarding deprescribing Immediate-release Fentanyl, some clinicians feel they may need to consult with specialists before attempting to withdraw this medication. However, some feel the prescription of this treatment in palliative care should continue.

Patient representative organisations or voluntary organisations and charities

The key themes to emerge from this cohort are that it is an effective treatment that should be prescribed to whoever requires it regardless of whether it's primary, secondary or palliative care; and that it is beneficial to have numerous treatment options available rather than relying on a select few.

Patient representative organisations also stress the potential impact on patients if this treatment is removed, with some feeling this guidance has come about due to the cost of the treatment. The Patients Association feels this treatment should only be prescribed following the input of multi-disciplinary teams or a specialist. Marie Curie adds that patients with conditions which lead to poor renal function have been overlooked. Unlike some other opioids, Fentanyl is expelled from the body through the liver rather than the kidneys, making it an important pain control drug for those with poor renal function.

Other NHS organisations, provider organisations and professional bodies

This cohort considers that although this treatment is effective, its use should be restricted to those with a major clinical need, such as palliative care and cancer patients. Therefore, this group requires clear guidance and education from NHS England to ensure the proposed guidance is effectively implemented.

NICE agrees with the proposed guidance for this treatment and recommends Immediate-release Morphine for breakthrough pain, which is also used and cited by the Royal Pharmaceutical Society. The British Medical Association disagree and say that Immediate-release Fentanyl is an extremely effective analgesic whose mode of action is much more rapid than oral morphine and this avoids the need to teach families how to administer morphine or diamorphine by injection. Furthermore, the availability of immediate analgesia may avoid unnecessary hospital admission. They suggest that Immediate-release Fentanyl is classified as an ‘amber’ drug suitable for prescribing in primary care only for palliative patients under formal shared care arrangements

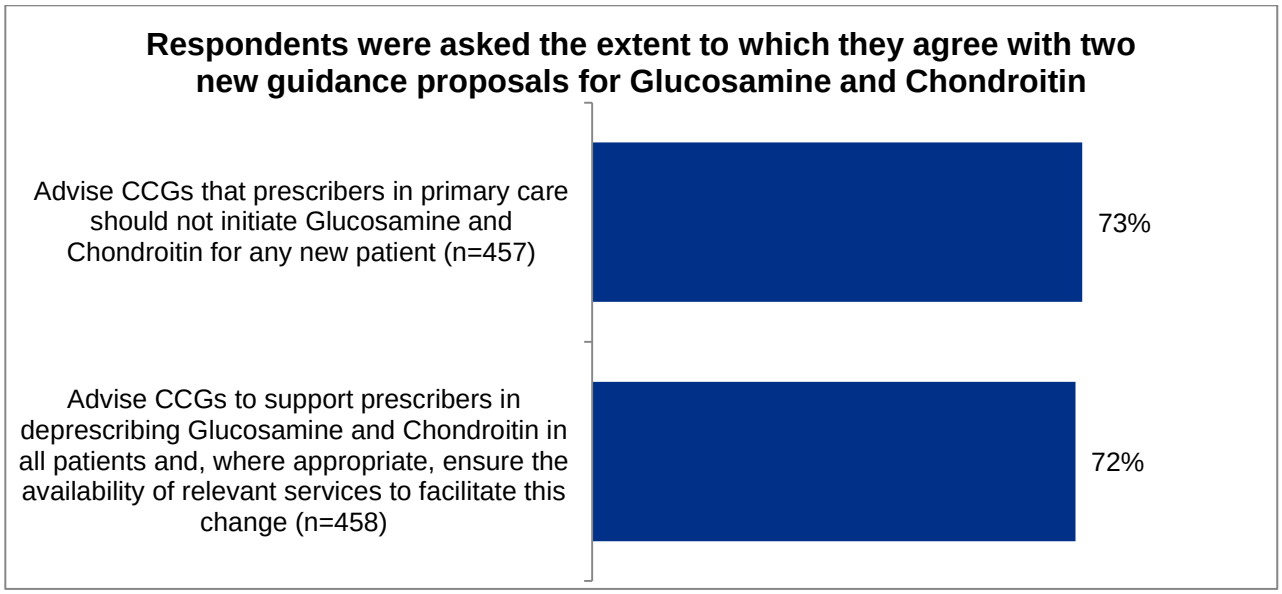
Industry

Some industry representatives feel restricting primary care access to this drug would have unintended consequences that will have a detrimental impact on outcomes and experience of care, particularly for terminal cancer patients being cared for at home, in the community and hospice units. Teva disagrees with the recommendations, citing the impact on patients as they are taken off this treatment and the potential commercial implications if manufacturers of alternative products increase their costs.

4.5 Glucosamine and Chondroitin

Glucosamine and Chondroitin are dietary supplements used to improve pain associated with osteoarthritis; a condition that causes joints to become painful and stiff. Osteoarthritis is the most common type of arthritis in the UK. Glucosamine and Chondroitin can be bought over the counter from pharmacies, supermarkets and health food stores. Their inclusion in this consultation is due to the lack of evidence to show they are effective in the management of osteoarthritis.

The chart below presents the extent to which all survey respondents agree with the two new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



N.B. Respondents were asked whether they 'agree', 'disagree', 'unsure' or 'don't know' to the proposal questions. The bars show percentages calculated as a proportion of those who 'agree' /'disagree' and excludes those who said 'unsure' and 'don't know'. A full breakdown by respondent type can be found in the annex.

The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

Patients feel that Glucosamine and Chondroitin are effective treatments. However, some state there is a lack of evidence that proves their effectiveness. Points are also raised about the availability of these treatments over the counter and how they should not be funded by the NHS but by the patient if it is their choice of treatment or a lifestyle choice.

"I meet people who swear by these. To remove [them] would be psychologically damaging if nothing else."

Members of public and family members

Like patients, this respondent group point out that Glucosamine and Chondroitin are effective treatments. They also note that these treatments are available over the counter and some responses demonstrate support for them not being prescribed.

CCGs

Common themes from CCGs are a lack of evidence for the effectiveness of these treatments and the view that they should not be prescribed. Some CCGs also highlight that this treatment is available over the counter and should be funded by the patient not the NHS as it is a lifestyle choice.

"The same argument is still valid that in order for something to be valid for a prescription there needs to be an evidence base to back it up."

Clinicians

Like CCGs, some clinicians state that Glucosamine and Chondroitin should not be

prescribed. This group also highlights the availability of these treatments over the counter and that they should be patient-funded if they choose to use them. Some clinicians also mention the lack of evidence for their effectiveness.

"Patients can be directed to purchase these items over the counter."

Patient representative organisations, voluntary organisations and charities

Most of this cohort agrees with the proposal, citing the availability of the treatments over the counter; lack of evidence for their effectiveness; and belief that the treatments, as a lifestyle choice, should be funded by the patient not the NHS. One organisation argues that the treatments are effective.

Other NHS organisations, provider organisations and professional bodies

This group raises points about the availability of the treatments over the counter; lack of evidence for their effectiveness; and belief that the treatments, as a lifestyle choice, should be funded by the patient not the NHS. NICE and the Royal Pharmaceutical Society are some of the organisations that support the recommendations. A small group of organisations say it is an effective treatment.

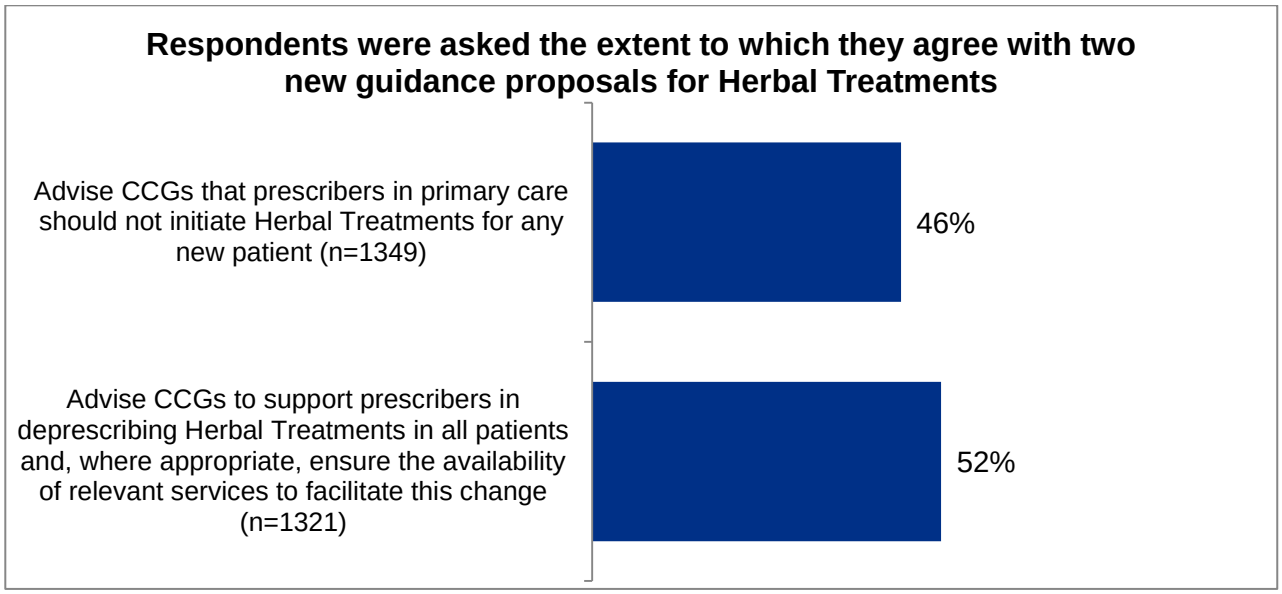
Some call for clearer guidance from NHS England and say the impact on those from a lower socioeconomic background should be considered.

"Limited evidence of its effectiveness and other medications available." (Other healthcare organisation)

4.6 Herbal Treatments

Herbal Treatments are currently available in the UK to help with minor health conditions that do not require medical supervision. This is a very wide category and includes things like St John's Wort, Black Cohosh and Chinese medicines. Herbal Treatments can come in a variety of formulations, such as tablets, capsules, powders and sprays. These items can be bought over the counter. The inclusion of Herbal Treatments within this consultation is due to the lack of robust evidence of their clinical effectiveness.

The chart below presents the extent to which all survey respondents agree with the two new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



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The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

The most commonly mentioned themes from this cohort are that Herbal Medicines are an effective treatment; the proposal goes against the patient's freedom of choice; there is evidence that shows the effectiveness of Herbal Medicines; and this form of treatment is less expensive than orthodox medicines and could save the NHS money compared to alternative treatments and conventional medicines. Alongside this, there is concern that those on low incomes would not be able to purchase these treatments if not provided by the NHS.

"Anthroposophical herbal remedies are very helpful and effective, and it would really limit patient choice if the few anthroposophical doctors who do prescribe on the NHS were to be prevented from doing so."

Members of public and family members

This group's most commonly mentioned themes are also that Herbal Medicines are an effective treatment; the proposal goes against the patient's freedom of choice; there is evidence that shows the effectiveness of Herbal Medicines; and this form of treatment is less expensive. Additionally, this cohort also states there is a low risk of addiction and side effects with this type of treatment.

CCGs

CCGs express their support for the proposal, with individuals stating that these products should be blacklisted. There is also the belief that because there is limited evidence into the effectiveness of this treatment it should not be prescribed by the NHS. This cohort also believes if patients choose to use this form of medication, they should fund it themselves.

“There is insufficient high-quality evidence to demonstrate clinical effectiveness of complementary and alternative medicines. Some complementary and alternative medicines or treatments are based on principles and an evidence base that are not recognised by the majority of independent scientists. There is absolute lack of well-conducted systematic reviews that permits any basic analyses of these therapies.”

Clinicians

Most clinicians state that they agree with the proposals. They state that: the NHS should only be providing evidence-based medicines, side effects and interactions of Herbal Treatments are unknown and herbal treatments are a waste of NHS money and resources

However herbalist clinicians were not supportive of the proposals and state that this is an effective treatment and that there is evidence to support this. Other key themes to emerge amongst this group are that this proposed guidance goes against the patient’s freedom of choice; it would impact on those from lower socioeconomic backgrounds and their ability to afford this treatment if it were no longer available; and that herbal medicines are less expensive than orthodox medicines.

Patient representative organisations, voluntary organisations and charities

The key themes to emerge from this cohort are that Herbal Medicines are effective and could assist in other areas such as antibiotic resistance; they pose less risk of side effects and addiction; the proposal goes against the patient’s freedom of choice; and Herbal Medicines are relatively less expensive.

Some organisations, such as The Nightingale Collaboration, support the proposed guidance outlined for Herbal Treatments citing the lack of evidence for their effectiveness. Humanists UK believe greater education is required to protect patients from this form of treatment.

“Herbal Treatments cost very little, have amazing patient outcomes and could save the NHS money if more widely used. This consultation has not taken on board patient experiences which vouch for effectiveness and how Herbal Treatments can keep drug costs at a minimum. Herbal Treatments offer a solution to the NHS's problems and it would be short-sighted and unscientific to cut Herbal Treatments due to lack of proper evaluation of current NHS services offering said treatments.”

Other NHS organisations, provider organisations and professional bodies

Some bodies state that Herbal Treatments are effective for patients and believe that evidence of this treatment does exist. Other responses from this group support the proposals and doubt effectiveness.

NICE agrees with both recommendations. Although NICE has never been referred to in any guidance around Herbal Treatments, it does have guidance that indicates no evidence of effectiveness in conditions such as endometriosis. The Royal Pharmaceutical Society also supports the recommendations, stating a lack of evidence for the effectiveness of these products which are also freely available over the counter.

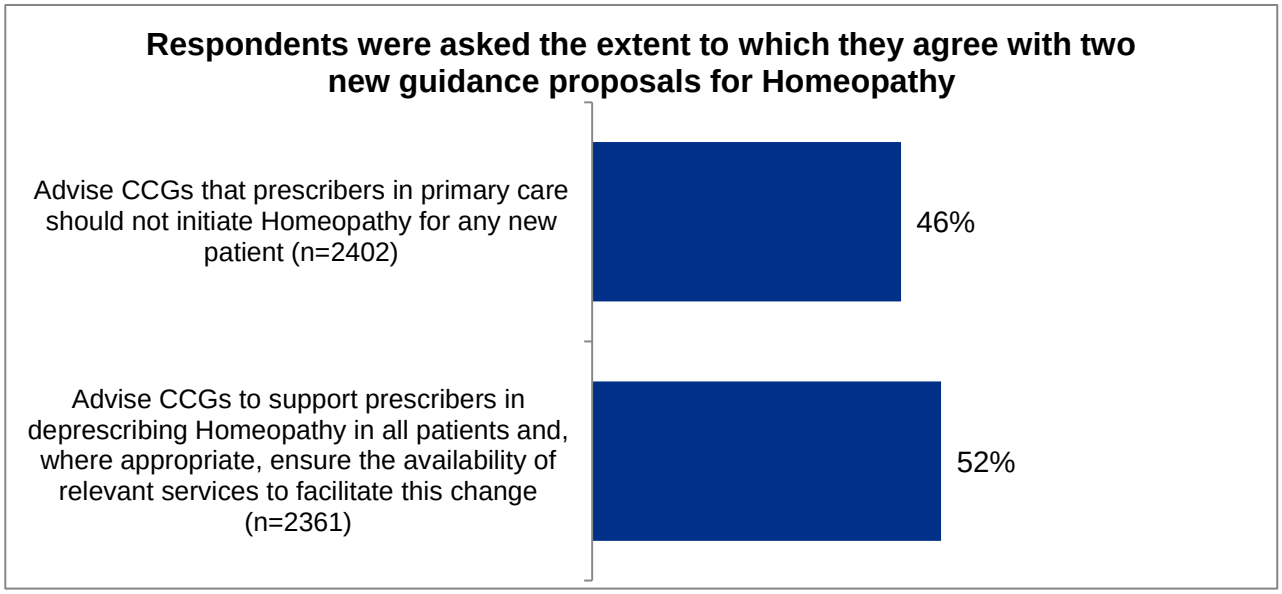
Industry

The main themes to emerge amongst this cohort are that Herbal Medicines are an effective treatment and there is evidence that shows this. This group also states that Herbal Medicines are safer (less risk of side effects and addiction) and cheaper than traditional medicines and healthcare professionals should be given the freedom to advise their patients as to whether they are necessary.

4.7 Homeopathy

Homeopathy seeks to treat patients with highly diluted substances that are administered orally. Homeopathy is mainly available in tablet form but also comes in drops, capsules and powders. These items can be bought over the counter. The inclusion of Homeopathy within this consultation is due to there being a lack of robust evidence for its clinical effectiveness.

The chart below presents the extent to which all survey respondents agree with the two new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



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The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

Patients who responded critically on this item said that in their view homeopathy is an effective treatment; it is cheaper than conventional medicine; it can replace ineffective medicines; the proposal goes against a patient's freedom to choose their treatment; and homeopathic treatments save the NHS money.

"Homeopathy works for a lot of people. Even if this is only the placebo effect shouldn't it not be explored? After all, the placebo effect is free!"

Members of the public and family members

This group makes similar comments to patients with most saying it is ineffective and some saying it is effective. Reasons given against homeopathic treatment include the lack of proven evidence and that they are a waste of NHS money.

"Homeopathy has been demonstrably disproved. Starting from a position of implausible benefits from diluted ingredients, the overwhelming negative evidence should be enough for any reasonable person to see that this is a con."

CCGs

CCGs are in full support of the proposals. They say that homeopathy products should be blacklisted, there is a lack of proven evidence, and the NHS should prioritise evidence-based medicines and treatments.

"These should be blacklisted to enable a consistent and equitable approach across the country on these medicines of very limited clinical value."

CCGs recognise there is no benefit beyond a placebo effect but some say that placebo can be a useful tool in exceptional circumstances.

"*We consider that Homeopathy is no more than a placebo which should not be available at NHS expense. A patient leaflet should be produced explaining the reasons why it is not available on the NHS to counter the mystical science that is advertised alongside these products.""*

Clinicians

Comments were received from Homeopathic clinicians and orthodox medicine clinicians and reflect both sets of views. Homeopathic clinicians give similar views to patient respondents. Conventional clinicians are either in favour of the proposals (due to lack of clinical evidence and therefore inappropriate for NHS money to be spent on this) or say that homeopathic medicines are harmless and their benefit is as a placebo.

"Prescribing Homeopathic products seems to me a clear breach of Good Medical Practice. It is shambolic that in this day and age the NHS is still paying for such sham treatment."

"Homeopathy has been conclusively shown to be of no benefit for any medical condition via detailed meta-analyses of many clinical trials. The mechanisms of efficacy promulgated by Homeopathy advocates lack prior plausibility – to accept them would require ignoring large chunks of chemistry and biology. It is utter bunkum and a waste of taxpayers' money to fund such quackery."

"I am a GP of more than 30 years' experience and also use Homeopathy at times within my practice … I tend not to offer Homeopathic medicines if there is a safe, effective and acceptable conventional treatment available but for many forms of distress I see in my patients, conventional treatments may be ineffective or not acceptable."

Patient representative organisations, voluntary organisations and charities

This cohort of respondents is against the proposal. Responses were mainly from societies and associations in favour of homeopathy. They make the same comments as the patients.

Other NHS organisations, provider organisations and professional bodies

This group includes Homeopathic organisations which are against the proposals for reasons already given (see above) – such as the Society of Homeopaths, Homeopathy Research Institute, and British Homeopathic Association. Responses from other NHS organisations, provider organisations and professional bodies including NICE, BMA, Royal Pharmaceutical Society, Association of the British Pharmaceutical Industry, Humanists UK, The Royal Society, the Academy of Medical Sciences and the Good Thinking Society, are in agreement with the proposal.

NICE agrees with both recommendations. They note that they have never been referred any guidance topics specifically on Homeopathic treatments. NICE has produced guidance where the evidence shows no evidence of effectiveness across a range of conditions, including otitis media, lower urinary tract symptoms in men, induction of labour, neonatal jaundice and eczema.

The RPS does not endorse Homeopathy as a form of treatment because there is no scientific basis for Homeopathy nor any evidence to support the clinical efficacy of Homeopathic products beyond a placebo effect. We do not support the prescribing of Homeopathic products on the NHS. (Royal Pharmaceutical Society)

[Homeopathy is] better dealt with by inclusion in the blacklist of drugs unavailable on the NHS. (British Medical Association)

NICE has never been referred any guidance topics specifically on Homeopathic treatments, and therefore they have not been the subject of a specific NICE evaluation. However, NICE has produced guidance where the evidence shows no evidence of effectiveness across a range of conditions, including otitis media, lower urinary tract symptoms in men, induction of labour, neonatal jaundice and eczema. (NICE)

Industry

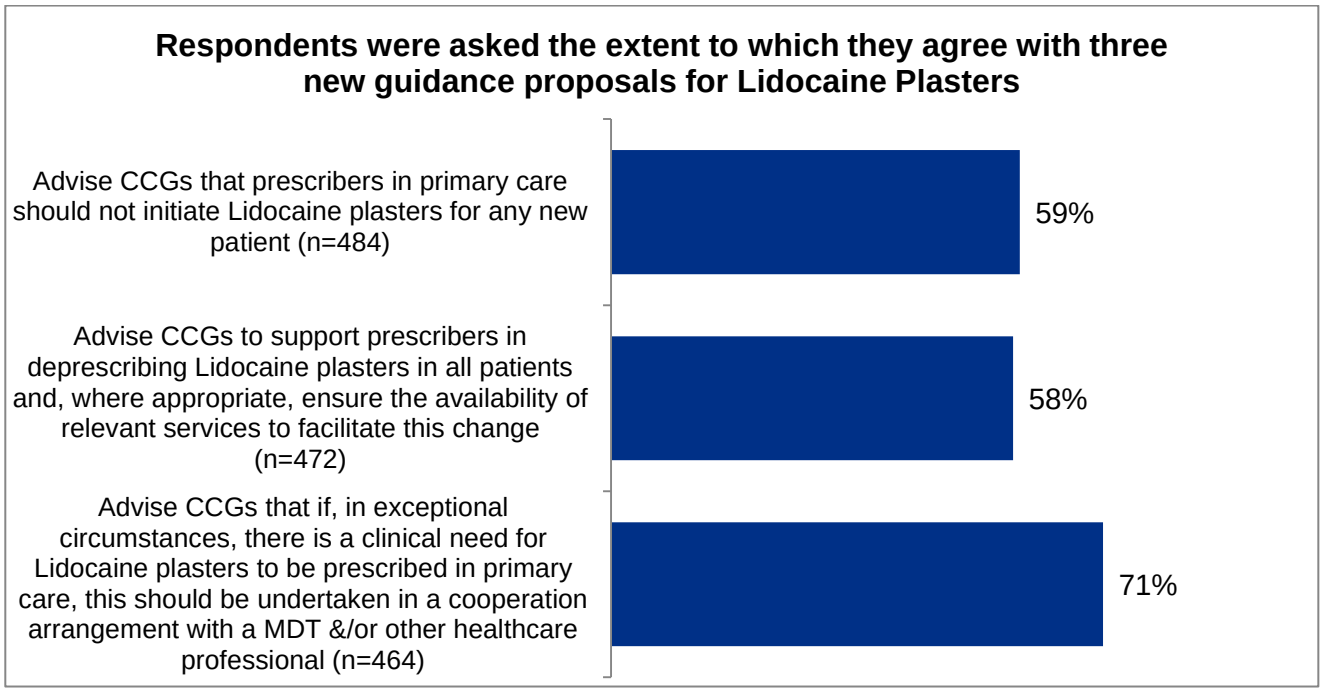
The only response was from the Association of the British Pharmaceutical Industry which welcomes the proposal to stop prescribing Homeopathic remedies that have not been subject to the same stringent conditions required of licensed medicines.

4.8 Lidocaine Plasters

Lidocaine Plasters (patches) can be applied for pain relief and are licensed for symptomatic relief of neuropathic/ nerve pain associated with shingles in adults. NICE guidance does not recommend Lidocaine Plasters for treating neuropathic pain. Due to its non-inclusion in NICE guidance, the group considered Lidocaine Plasters suitable for

inclusion in the consultation.

The chart below presents the extent to which all survey respondents agree with the three new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



N.B. Respondents were asked whether they 'agree', 'disagree', 'unsure' or 'don't know' to the proposal questions. The bars show percentages calculated as a proportion of those who 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and 'unsure. A full breakdown by respondent type can be found in the annex.

The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

The key themes emerging from patient comments are: that Lidocaine Plasters are an effective treatment; the guidance should consider the impact on the patient's quality of life if this treatment is removed and the impact on patients who are unable to take alternative medicine; and cost should not be considered when decisions are being made around the prescription of Lidocaine Plasters. Some also query the use of evidence and guidance from sources like PrescQIPP and NICE and the consistency with NHS England views.

"If the patches are withdrawn, there needs to be a viable alternative. Surely it is better to prescribe something that has little side effects and provides excellent pain relief, than anti inflammatories and pain killers that a patient can build up tolerance to or have side effects that can impact on health in the future. This could end up costing the NHS more if side effects cause medical problems …"

Members of the public and family members

This group raises similar comments to patients. Their key themes in response to this proposal are: that it is an effective treatment; the effect on patients' quality of life and

those who are unable to take alternative medications should be considered; and there should be clearer guidance around use in exceptional circumstances. A small group feel this treatment should be blacklisted.

"My sister has been chronically Ill and needs a high level of pain relief, other painkillers did not work. These have meant she had a higher quality of life and can get out and about. If you see someone in awful pain you wouldn't not help them, you know these are vital for some people."

CCGs

Although some feel this is an effective treatment, the majority of CCGs are in agreement with the proposed guidance. Additional themes to emerge amongst this group include: Lidocaine Plasters should be blacklisted; further clarification is required around use in exceptional circumstances; the prescribing process should involve input from both primary and secondary care professionals, and prescription should only be restricted to the conditions Lidocaine Plasters are indicated for as currently it is being used outside of its product license.

"There should be no need to prescribe within primary care under the licensing and NICE guidance. Prescribing is short-term in limited patient groups and therefore should be prescribed via secondary care only."

Clinicians

Clinicians say that Lidocaine Plasters are an effective treatment for a niche group of patients, i.e. palliative care and cancer patients. They also highlight that the prescription of this treatment should involve both primary and secondary care professionals.

"I accept that they are very much for a niche only, and I have only had to use them in two or three patients, but in those patients where nothing else was working, they have been extremely effective."

Patient representative organisations, voluntary organisations and charities

This cohort feels Lidocaine Plasters are an effective treatment for a niche group of patients so should not be deprescribed. Rather, prescriptions should be reviewed and the efficacy of treatment monitored by specialist teams and coordinated with primary care.

Other NHS organisations, provider organisations and professional bodies

Organisations make a range of comments, including: that Lidocaine Plasters are effective; they should be blacklisted; the prescription process should be reviewed; and a more coordinated approach between primary and secondary care professionals should be implemented.

NICE agrees with all three of the proposals, also noting that when exercising their judgement, health professionals are expected to take the guidance fully into account alongside the individual's needs.

The Royal Pharmaceutical Society and the British Medical Association do not support the proposals. They cite similar reasons around it being inappropriate to deprescribe in patients who have seen a good therapeutic response to treatment.

*"This is approved on the formulary for focal neuropathic pain with allodynia, and for PHN where patients cannot tolerate oral medicines. For some patients this is invaluable as can reduce escalating doses of other analgesics with systemic ADRs which can cause significant problems. The Trust want to continue to be able to ask GPs to prescribe in those patients benefitting from treatment when being used for the criteria for use that is locally agreed. There is also some use in post-operative patients as part of multimodal analgesia (to assist opioid dose reduction and faster discharge), but it is reasonable to expect that ongoing supplies are not requested from the GP." (*NHS Provider Organisation)

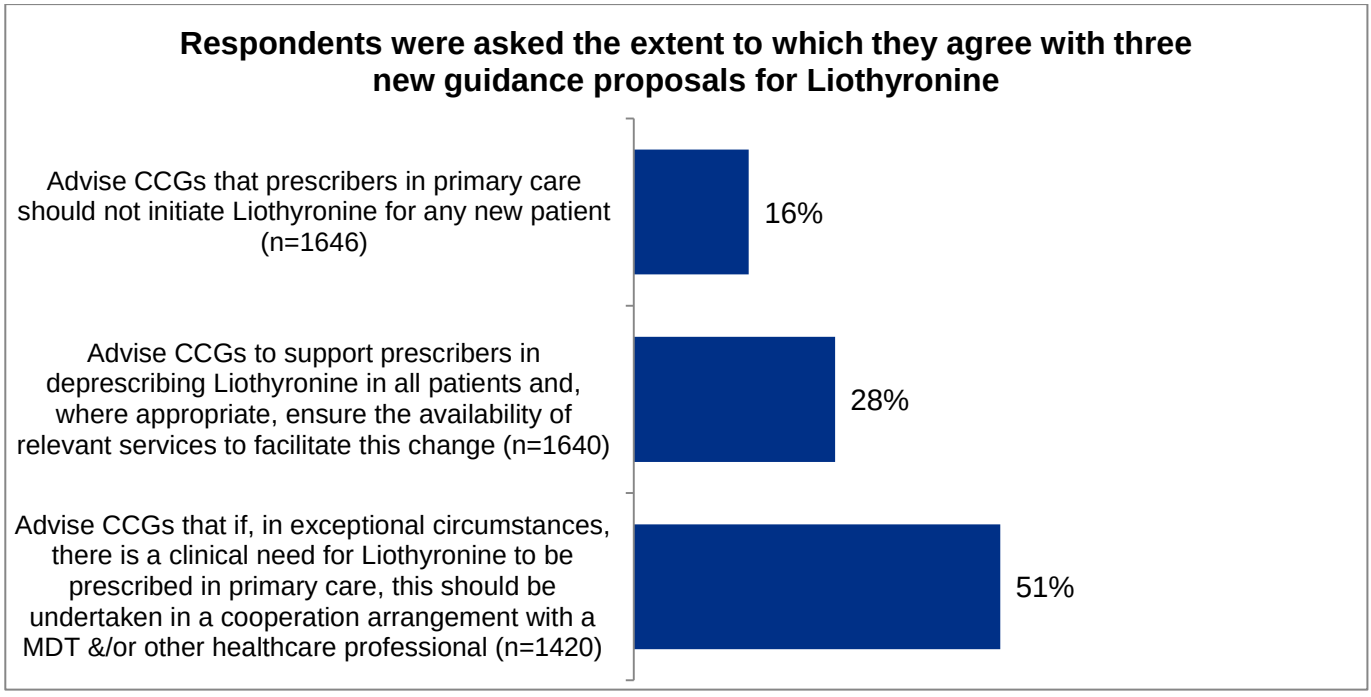
Industry

Grünenthal Ltd states Lidocaine Plasters are an effective treatment for a number of conditions. In relation to the proposed guidance, there is some concern around the impact on pain and palliative care patients and the fact that restricting prescribing will disadvantage patients as these are not available over the counter, forcing patients to attend hospital clinics to obtain a prescription.

4.9 Liothyronine

Liothyronine is used to treat Hypothyroidism (when the thyroid produces less thyroid hormone than it should). It has a similar action to Levothyroxine but is more rapidly broken down in the body and has a more rapid effect. Liothyronine is available as a tablet and also available as Liothyronine + Levothyroxine combination products e.g. Armour Thyroid.

The chart below presents the extent to which all survey respondents agree with the three new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



N.B. Respondents were asked whether they 'agree', 'disagree', 'unsure' or 'don't know' to the proposal questions. The bars show percentages calculated as a proportion of those who 'agree' /'disagree' and

excludes those who said 'neither agree nor disagree' and 'unsure. A full breakdown by respondent type can be found in the annex.

The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

Patients raise a number of concerns against the proposal including: that Liothyronine is an effective treatment: the impact on those with a genuine clinical need; before deprescribing the product the quality of life for Hypothyroid patients must be considered if treatment is removed; and that Liothyronine is cheaper abroad but very expensive privately in the UK.

"One only has to go onto the Thyroid UK website to find a world of patients who self-medicate and arrange their own blood tests because they feel so unwell taking Levothyroxine only. As both a patient and a registered nurse I cannot believe that there is such gross unawareness of the need for Liothyronine. For years I was needlessly suffering severe symptoms and would have been unable to continue working as a nurse had I not started self-medicating with Liothyronine – when I did my symptoms fled and within 20 minutes of taking it I had my energy and life back – it is simply not true that Levothyroxine does the same thing."

Members of the public and family members

This cohort raises the same concerns as patients. They also say that there should be better knowledge amongst healthcare professionals around Hypothyroidism so they understand when and how to prescribe Liothyronine.

CCGs

CCGs make a range of comments including: little support for allowing prescribing in exceptional circumstances; that the treatment should be blacklisted; the proposal is based on cost; and if prescribing is stopped no one should be allowed to access it. They also requested clear guidance on what constitutes exceptional circumstances.

"Our CCGs have been actively pursuing a reduction in Liothyronine prescribing in recent months. It has become apparent that local endocrinologists and head and neck clinicians are willing to continue to support some patients who petition for continued treatment with Liothyronine and so the support of a multi-disciplinary team has not led to a discontinuation of the medication … If prescribing is to be allowed to continue, there should be clear guidance in terms of the thyroid function test results and significant pressure on manufacturers to reduce the price to a reasonable level. At a lower cost, there would be less need to pursue deprescribing of a medication that some patients feel very strongly have had a positive effect on their quality of life."

Clinicians

Comments from clinicians reflect the view that Liothyronine should be available for new patients but that the product should be available in exceptional circumstances and to support prescribers in deprescribing. Their comments focus on: the effectiveness of the

treatment; the need to improve knowledge about Hypothyroidism amongst GPs/healthcare professionals and allow them to prescribe Liothyronine; blacklisting the product; and if treatment is removed, no-one should be allowed to access it.

Patient representative organisations, voluntary organisations and charities

Organisations representing patients with Thyroid conditions that disagree with the proposals include: British Thyroid Association, Thyroid UK, Improve Thyroid Treatment (ITT) Campaign, and Thyroid Association of New Zealand Incorporated. The Patients Association also felt that patient concerns about the proposals should be considered. Feedback from these organisations reflects themes in patient responses.

Other NHS organisations, provider organisations and professional bodies

This group mostly disagrees with the proposals. Those disagreeing include the Royal College of Psychiatrists, Royal Pharmaceutical Society, British Medical Association (BMA state that it should be consultants and not primary care making deprescribing decisions) and the British Generic Manufacturers Association (they believe new generic entrants will make Liothyronine cost-effective for discrete groups of patients).

Other comments made by organisations include: that Liothyronine is an effective treatment; there is a need for more testing and research to prove effectiveness; there needs to be better knowledge and understanding amongst healthcare professionals around Hypothyroidism to enable better prescribing as well as clearer guidance on what constitutes ‘exceptional’; and that the proposal is based on cost.

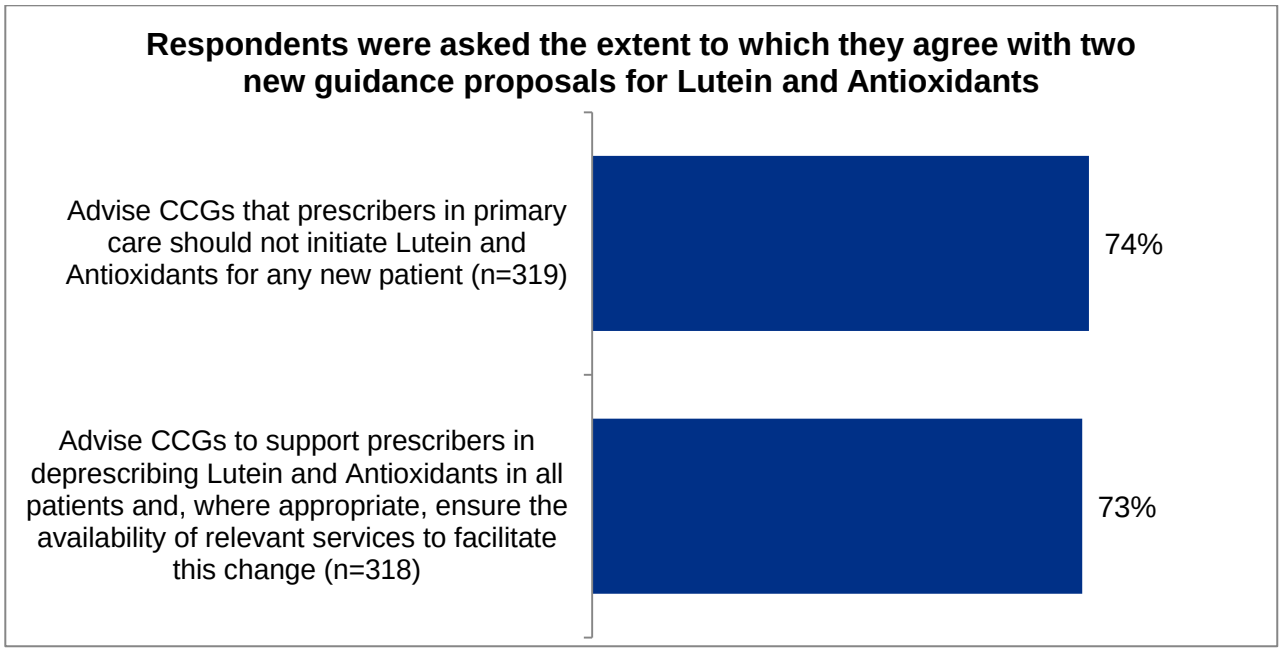
Industry

Industry respondents support the continued prescribing of Liothyronine in accordance with NICE guidelines which state that T3 is not initiated in primary care but “*may be considered by endocrinology specialists… in people who have persistent symptoms despite compliance with Levothyroxine treatment and a TSH value in the normal range.”* (https://cks.nice.org.uk/hypothyroidism#!scenario)

4.10 Lutein and Antioxidants

Lutein and Antioxidants (e.g. vitamin A, C, E and zinc) are supplements recommended for age-related macular degeneration (AMD; a condition that causes loss of central vision, usually in both eyes). PrescQIPP CIC has issued a bulletin which found no evidence to support routine prescribing of Lutein and Antioxidants. These items can be bought over the counter.

The chart below presents the extent to which all survey respondents agree with the two new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



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The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

Patients say Lutein and Antioxidants are effective treatments and there is evidence to support this. They say it is considered to be beneficial in cases where patients suffer from age-related macular degeneration. A chief concern raised is that people on low incomes would find it difficult to afford these supplements if they were removed from prescriptions.

"From my own experience, I believe that the use of Lutein supplements (Occuvite in my case) has helped to stabilise my vision and probably reduce the number of injections needed. However these supplements are expensive to buy privately."

Members of the public and family members

Members of the public also feel that Lutein and Antioxidants are effective treatments and there is evidence available that show the effectiveness. They also say the impact on people with low incomes should be considered.

CCGs

CCGs make comments in agreement with the proposals and say that there is very limited or insufficient evidence to demonstrate the effectiveness of Lutein and Antioxidants and that patients should purchase these supplements over the counter if they want them.

"Could be purchased over the counter. The CCG supports self-care for this type of product."

Clinicians

Clinicians raise concerns about the limited evidence to demonstrate the effectiveness of Lutein and Antioxidants.

Patient representative organisations, voluntary organisations and charities

These organisisations make similar comments to patients and the public, highlighting the effectiveness of this product.

"I have personal experience of the positive effects of taking Macushield. OCT results show improvements in my eye health during the time I have been taking this medication. My doctor refused to prescribe it last year and since then I have funded this myself, because as a full-time carer for a disabled husband I cannot afford to go blind, but I am also struggling to pay to fund it. Imagine the cost to the health and social care budget if I did go blind, not only would it be devastation for me personally but there would be two people who would need full-time care. Not cost-effective." (Voluntary organisation or charity)

Other NHS organisations, provider organisations and professional bodies

Other NHS organisations agree with the recommendations saying that: the NHS should only provide evidence-based medicines, there is a lack of proven evidence showing the effectiveness of Lutein and Antioxidants, and that the treatment is available over the counter.

"Lutein and Antioxidants are included in our local prescribing for clinical need policy and are not recommended for prescribing because of the lack of evidence relating to their efficacy and cost effectiveness." (other NHS organisation)

The Royal Pharmaceutical Society agrees with the recommendations. The British Medical Association says it would be better dealt with by blacklisting this item.

Industry

The one industry body to comment on the recommendations disagrees with them and is concerned that if the treatment is not available it may lead to wider health problems.

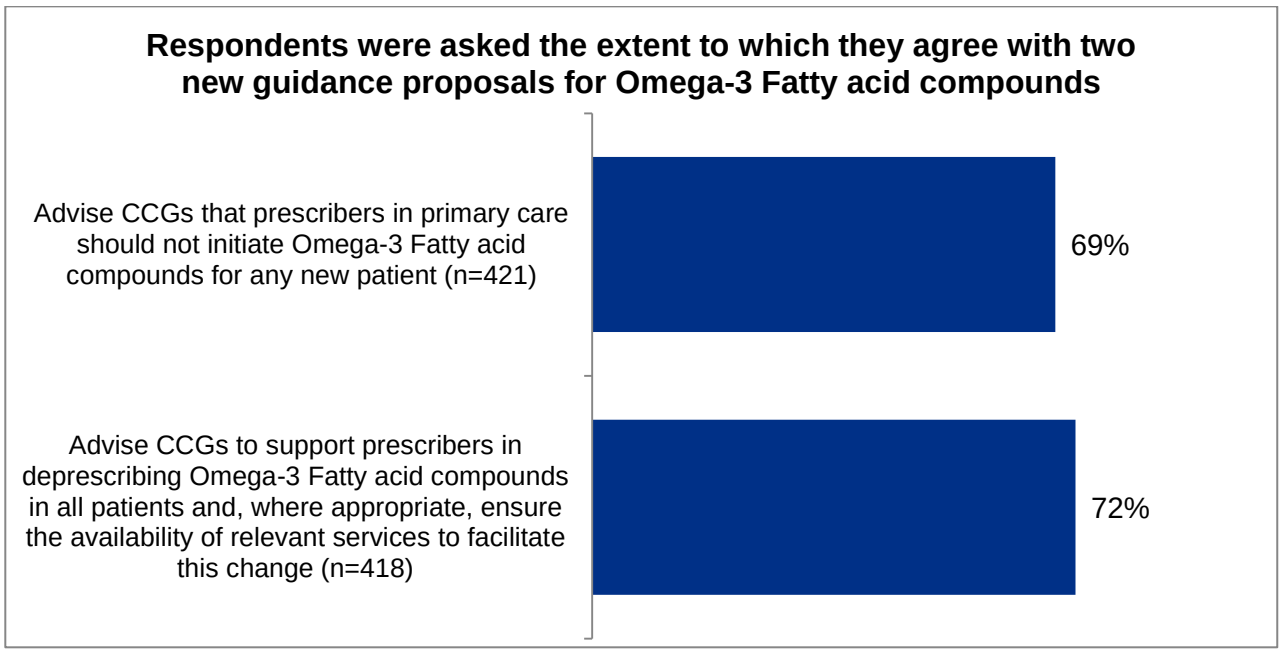
"Food supplements should not be ignored as a potential health benefit in those where pharmaceutical agents don't exist, are not preferred by the patient, and could be cheaper than managing the latter consequences of possible poor health."

4.11 Omega-3 fatty acid compounds

Omega-3 fatty acid compounds are essential fatty acids which can be obtained from the diet. They are licensed for adjunct to diet and statin in hypertriglyceridemia; adjunct to diet in type IV hypertriglyceridemia and adjunct in secondary prevention in those who have had a myocardial infarction in the preceding three months. Omega-3 fatty acid compounds are available as capsules under the brand name Omacor or Prestylon and can be bought over the counter. There is no good quality data for their use in prevention of dementia, pre-menstrual syndrome, attention-deficit hyperactivity disorder (ADHD), atrial fibrillation, eczema, osteoarthritis or age-related macular degeneration. The

inclusion of Omega-3 fatty acid compounds within this consultation is due to there being a lack of robust evidence for clinical effectiveness.

The chart below presents the extent to which all survey respondents agree with the two new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



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The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

Some patients comment on the effectiveness of Omega-3 fatty acids, the availability of the product over the counter, and that public/patient communication or education is required to explain how these compounds can be gained through a balanced diet.

"Omega-3 is available over the counter probably a lot cheaper than on prescription."

Members of the public and family members

This group makes similar comments to patients noting that Omega-3 fatty acid compounds are an effective treatment for a number of conditions, they are readily available over the counter and emphasis/communication is needed on the importance of eating a balanced diet.

CCGs

Most CCGs are in full support of the proposals and say that prescribing of all Omega-3 fatty acid compounds should be stopped, not least because they are readily available

over the counter and there is lack of clinical evidence.

"These should be added to the blacklist due to lack of clinical evidence."

Clinicians

Again most comments are in agreement with the proposals, suggesting blacklisting of the treatment and mentioning its availability over the counter. However, some clinicians also cite its effectiveness for a number of conditions.

"At clinical doses and with good and pure formulas, Omega-3 oils have been shown to be very effective. It reduces inflammatory-type responses which tend to be the root cause of most disease. It is not harmful and has far better health implications than other anti-inflammatory-type drugs. Helpful for pain, blood cholesterol levels, dementia etc."

Patient representative organisations, voluntary organisations and charities

Most of these groups agree with the principles, making comments similar to those raised by patients and the public. One organisation comments that taking Omega-3 is a lifestyle choice, and should therefore be funded by the patient.

Other NHS organisations, provider organisations and professional bodies

Some organisations are supportive of the proposals and some say that the product should be blacklisted. However, some feel it is an effective treatment for a number of conditions.

"NHS England should issue clear, national advice on how changes should be made and how to transition to alternative products. This will enable clear advice to be followed in primary care, reducing the need for secondary care involvement… The committee has some concerns that the guidance is largely focused on primary care prescribing and not secondary care. It is felt that this still leaves an open door for prescribing these items and while it is recognised that they might need to be prescribed in specific cases, they shouldn't be used in the vast majority of patients in any sector." (Other NHS organisation)

"The 'do not do' recommendations are accepted; however these are agreed on formulary in SE London for management of hypertriglyceridemia for use where fibrates are not tolerated (not covered by the 'do not do' recommendations). The recommendation should be explicit that usage for this indication may be appropriate, and a blanket rule of not prescribing in primary care is therefore not helpful as patients appropriate for treatment may struggle to receive it." (NHS provider organisation)

NICE, the North Central London Medicines Optimisation Committee and the Royal Pharmaceutical Society are amongst those who support the proposals, with the Royal Pharmaceutical Society commenting that the products are readily available to buy for patients who choose to supplement their treatment in this way.

The British Medical Association feels that Omega-3 fatty acid compounds would be better dealt with by inclusion in the blacklist of drugs unavailable on the NHS.

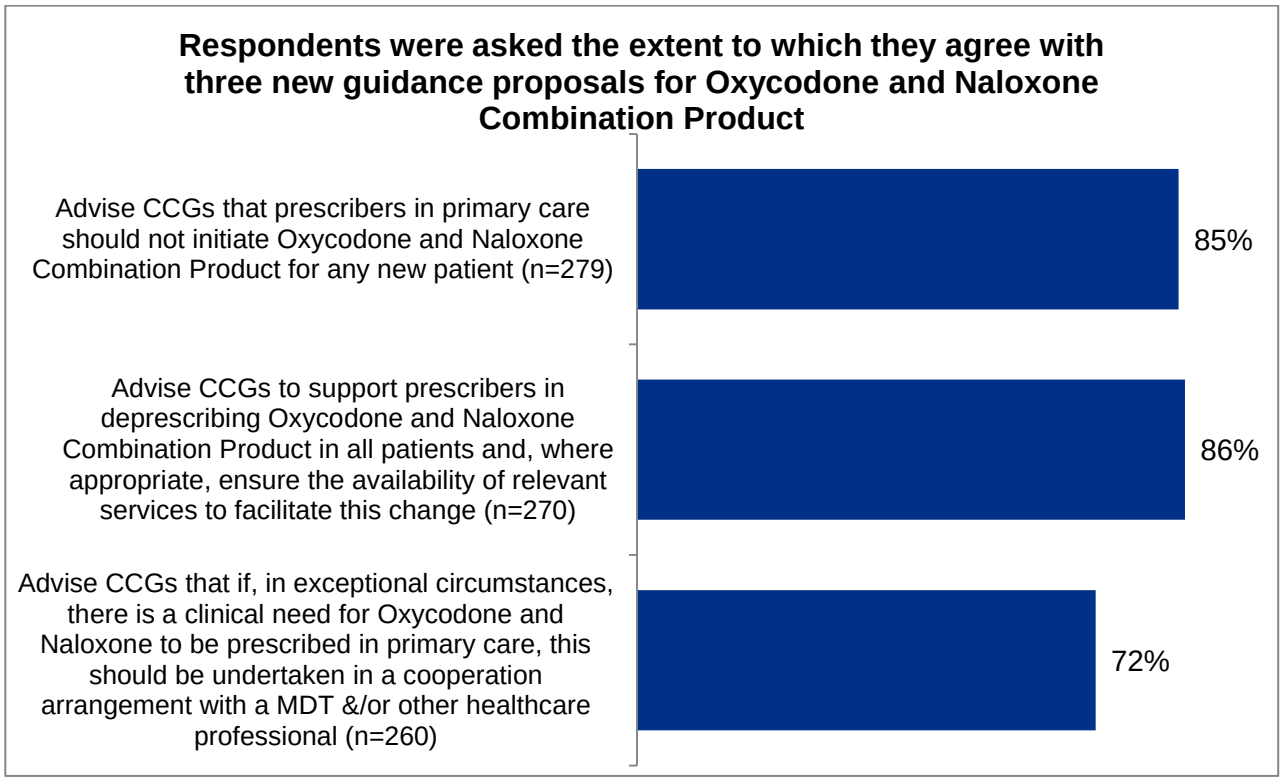
Industry

Just one industry responded to the consultation; they are in full support of the proposals.

4.12 Oxycodone and Naloxone combination product

Oxycodone and Naloxone Combination Product is available under the brand name Targinact and is used to treat severe pain. The inclusion of Oxycodone and Naloxone within this consultation is due to the fact that there is no clear benefit of this single treatment over other painkillers that are combined with laxatives when required. The product is also considered suitable for inclusion due to its significant cost and unclear role when compared with individual products.

The chart below presents the extent to which all survey respondents agree with the three new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



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The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

The comments raised by patients include: that this product is an effective treatment for a small group of patients; the need to consider patients for whom other medications (e.g. morphine, opiate-based drugs) are ineffective; and that prescribing of this product requires a coordinated approach between primary and secondary care:

"As a former Palliative Care healthcare assistant, Oxycodone and Naloxone are useful in

patients with advanced cancer. I am of the view that it should only be made available to patients on Palliative Care grounds. It should not be made available to any other users as there is no clinical need."

Some note that there are safety concerns with Oxycodone and Naloxone in relation to side effects or addiction.

Members of the public and family members

This cohort agrees that there are safety concerns with Oxycodone and Naloxone but that it is an effective treatment for a small group of patients.

CCGs

CCGs support the medications being added to the blacklist as alternative treatments are available and there is a lack of proven evidence showing the effectiveness of Oxycodone and Naloxone, and no-one should be allowed to access the treatment.

"It needs to be consistent and the only way is by blacklisting. This removes duplication of time and effort at CCG level."

Clinicians

Clinicians say that this combination product is not required and can be prescribed as separate products. They also say that the treatment should only be prescribed by specialists and secondary care and acknowledge that it is an effective treatment for a small group of patients.

"Traditional laxatives are not always effective or tolerated by patients and so there are occasions when this drug is the only option. It needs to be used in moderation and when all other efforts have failed. However should not be deprescribed as a blanket rule, needs to be assessed on a patient-by-patient basis."

Some clinicians say that they would support the product being added to the blacklist.

Patient representative organisations, voluntary organisations and charities

One respondent says that Oxycodone and Naloxone is an effective treatment for a small group of patients. Another suggests that patients for whom other medications are ineffective should be considered for it.

"Finding the best pain relief combinations for patients can be a difficult exercise and an individualised approach to prescribing is needed in order to accommodate the needs and sensitivities of different patients to different medications and combinations of medications. Removing this drug combination as an option would be counter-productive as it will leave some without effective pain relief or with considerable side effects."

Other NHS organisations, provider organisations and professional bodies

Several respondents say that the combination product is an effective treatment for a small group of patients. Others urge NHS England to consider the quality of life for patients who require Oxycodone and Naloxone, including availability for palliative care patients.

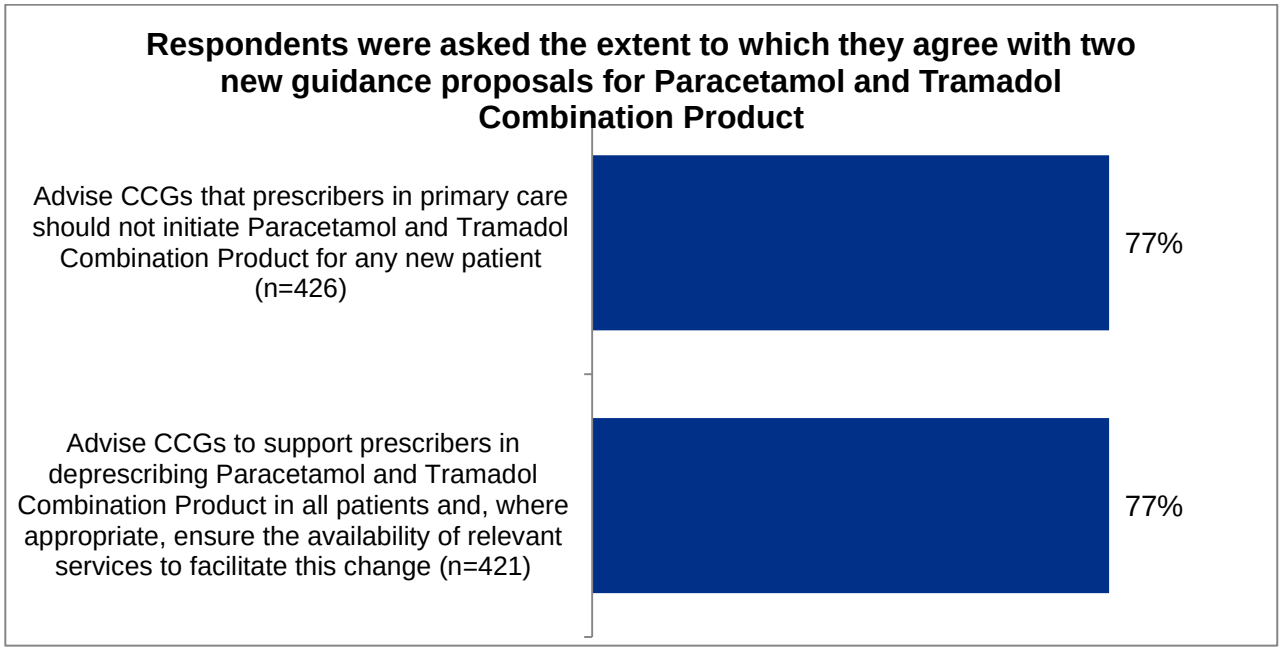
The British Medical Association argues that for terminally ill patients who experience

severe constipation on opioids, the combination of Oxycodone and Naloxone can greatly improve their quality of life.

4.13 Paracetamol and Tramadol combination product

Paracetamol and Tramadol are both commonly available painkillers. This recommendation relates to where both chemical ingredients are used together in a single combination product. They are available as tablets and effervescent tablets, with the brand name Tramacet. Paracetamol and Tramadol combination products are more expensive than the products with the individual components. They are included in this consultation because there are more cost-effective products available.

The chart below presents the extent to which all survey respondents agree with the two new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



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The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

The key themes raised by patients include: the ready availability of Paracetamol at a low cost over the counter and safety concerns in relation to side effects or addiction. The key theme against the proposal focuses on the effectiveness of this combination treatment, particularly for those who have difficulty in taking other treatments.

"I also object to the removal of pain killers. As someone who suffers chronic pain I can tell you that many medications can be intolerable to patients with complex conditions,

or interact badly with other meds/symptoms and so choice is necessary. Additionally there are many types of pain that only different types of painkiller can help."

Members of the public and family members

Like patients, a common theme raised by this cohort is around the availability of some of the individual components over the counter at low cost. Additional themes in support of the proposal also include the suggestion to blacklist this product and that taking Paracetamol and Tramadol separately is more effective.

The key themes against the proposal focus on the effectiveness of the treatment, particularly for those who have difficulty with other treatments and concern regarding the impact on the quality of life should this be removed.

Comments are also made around the implementation of the proposal, such as the need for clearer guidance on what constitutes 'exceptional circumstances'.

CCGs

The key themes raised by CCGs include: blacklisting this product; and that some of the individual components (Paracetamol) are available at low cost and that taking them separately is more effective. There are also comments relating to the need for clearer guidance from NHS England to implement this effectively.

"It should be blacklisted in the Drug Tariff."

Clinicians

Clinicians raise similar themes to CCGs: that this product should be blacklisted; that some of the individual components (Paracetamol) are available at low cost and effective when taken separately; and that alternatives are readily available.

On the contrary, the key theme to emerge against the proposal is around the fact that this combination product is an effective treatment.

"Separate prescribing allows more versatility in dosing both for providers and patients. It should also be possible to deliver this medicine at a lower cost this way."

Patient representative organisations, voluntary organisations and charities

The key themes in favour of the proposal include: safety concerns with the use of this combination product and the availability of some of the individual components over the counter (Paracetamol). The key themes against the proposal focus on the need to consider the impact on those in lower socioeconomic groups.

Other NHS organisations, provider organisations and professional bodies

The common themes in support of the proposal amongst this cohort relate to availability of some of these products at a lower cost (Paracetamol), safety concerns and that the treatment should be blacklisted and no longer prescribed.

Other key themes amongst this cohort include: the need for clearer guidance on what constitutes exceptional circumstances and the recommendation to lift restrictions on the amount of Paracetamol that can be purchased over the counter.

"This product is available as individual components which are cheaper than the combined version." (Other NHS organisation)

Industry

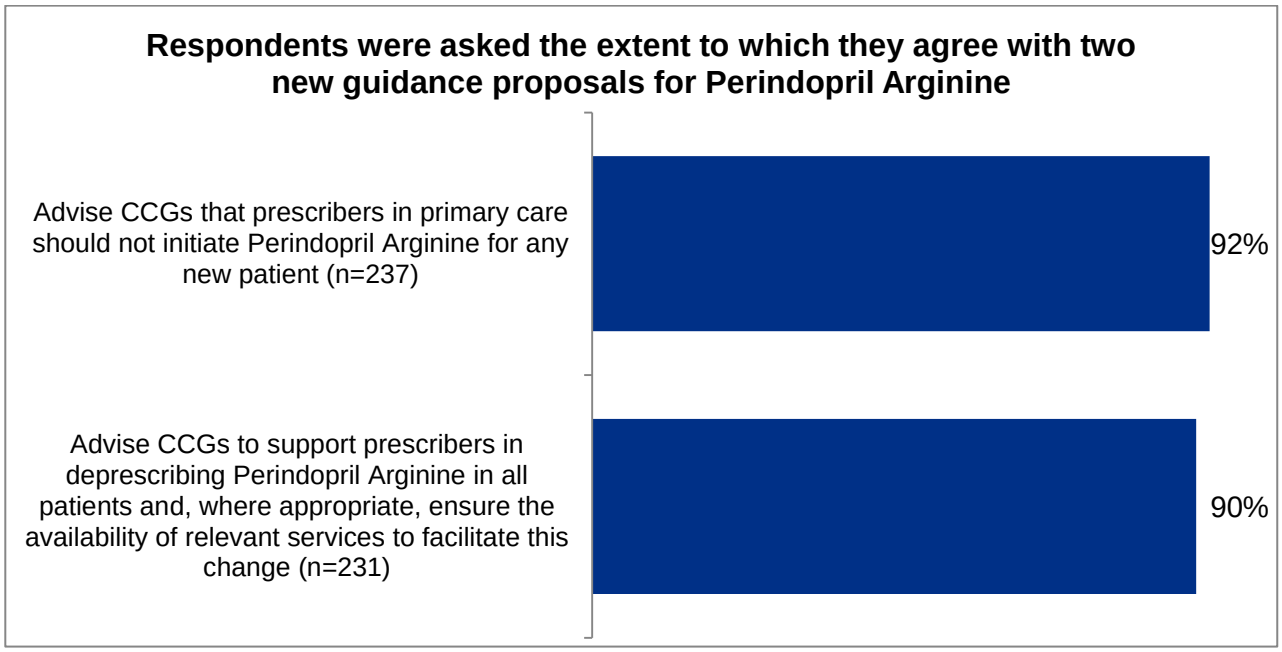
The key themes raised by industry bodies include the availability of suitable alternatives at low cost to the NHS, the effectiveness of taking these products separately and also the possible impact on market dynamics and costs should this product be removed.

"Agree that there may be suitable alternatives, however for those patients who are currently on treatment; to be continued with support."

4.14 Perindopril Arginine

Perindopril Arginine is an ACE inhibitor used in heart failure, hypertension, diabetic nephropathy and prophylaxis of cardiovascular events. The Perindopril Arginine Salt version was developed as it is more stable in extremes of climate than the Perindopril Erbumine Salt, which results in a longer shelf-life. Perindopril Arginine is available as a tablet, under the brand name Coversyl Arginine, and is also available as a combination with a diuretic (water table) as Coversyl Arginine Plus. Perindopril Arginine is included in the consultation because it is significantly more expensive than Perindopril Erbumine and there is no clinical advantage of the Arginine Salt.

The chart below presents the extent to which all survey respondents agree with the two new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



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The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

The key themes raised by patients supporting the proposal include the availability of suitable alternatives and that the treatment should be blacklisted. The key themes not in favour of the proposal include: that it is an effective treatment; it should be available to those unable to tolerate alternative treatments; and that the proposal does not take into account evidence showing its effectiveness.

"This medication controls my blood pressure better than other types of medication. I have taken it for many years without side effects. I don't want to have to start having to try various medications to find one that suits me."

Members of the public and family members

This cohort raises the same themes as patients in support of and against the proposal. The key themes supporting the proposal include the availability of alternatives and that the treatment should be blacklisted. The key themes raised against the proposal include: that it is an effective treatment and that it should be available to those unable to tolerate alternatives.

"It is dangerous having two products with different salts but very different in price as a mix up could be easy to do and different treatment for patients, maybe even cause hospitalisation if patient is sensitive to products."

CCGs

The key themes raised by CCGs include: the treatment is not required; alternatives are available and the guidance should be expanded to include secondary care.

Comments not in favour of the proposal focus on the fact that this is an effective treatment.

Another theme to emerge amongst CCGs is the suggestion that the Arginine Salt is an attempt by the manufacturer to negate the generic market and extend the life of their product.

"Agree that there may be suitable alternatives however for those patients who are currently on treatment; to be continued with support."

Clinicians

Similarly to CCGs the key themes to emerge amongst clinicians include: the fact that the treatment is not required; there are suitable alternatives available; the product should be blacklisted; and there is a need to expand the guidance to include secondary care.

The key theme raised against the proposal is that it is an effective treatment.

Other NHS organisations, provider organisations and professional bodies

Again the key themes from this cohort call for the expansion of the guidance to include secondary care and state that the treatment is not required and there are suitable

alternatives available.

The key theme not in favour of the proposal focuses on the fact that this is an effective treatment.

"NHS England should issue clear, national advice on how changes should be made and how to transition to alternative products. This will enable clear advice to be followed in primary care, reducing the need for secondary care involvement. There is a risk that prescribing will be transferred to secondary care unnecessarily and as such the clear guidance mentioned previously should articulate the relevant clinical strategies. This should be done once at a national level to provide clear support to this change." (Other NHS Organisation)

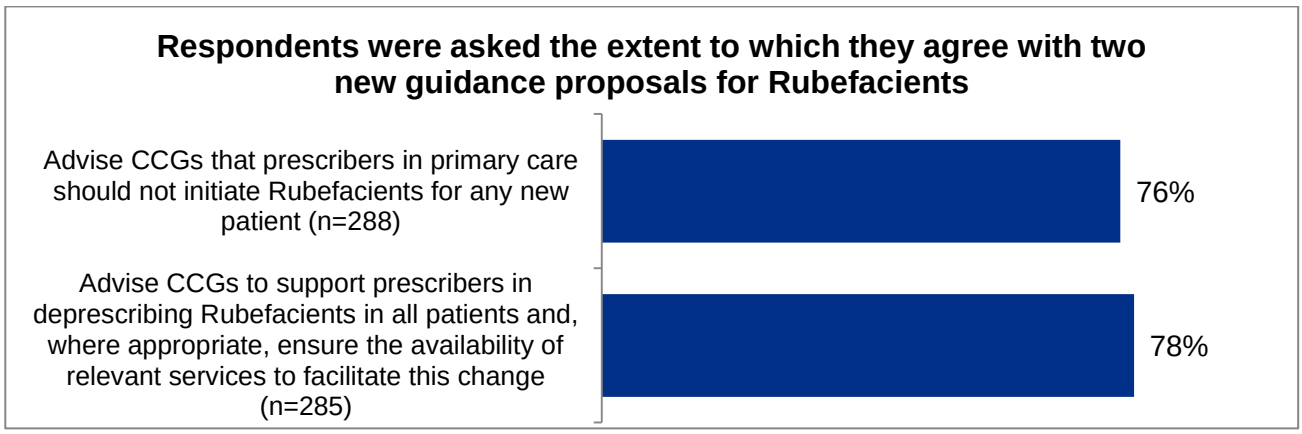
Organisations supporting the proposals include NICE and the Royal Pharmaceutical Society. NICE also notes that when exercising their judgement, health professionals are expected to take guidance fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in NICE guidance is at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

The BMA would prefer to see the product blacklisted so they are unavailable on the NHS.

4.15 Rubefacients

Rubefacients are topical preparations that cause irritation and reddening of the skin due to increased blood flow. They are believed to relieve pain in various musculoskeletal conditions and are available on prescription and in over the counter remedies. They are currently available as ointments, creams, lotions and sprays. The inclusion of Rubefacients within this consultation is because of their low clinical effectiveness.

The chart below presents the extent to which all survey respondents agree with the two new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



N.B. Respondents were asked whether they 'agree', 'disagree', 'unsure' or 'don't know' to the proposal questions. The bars show percentages calculated as a proportion of those who 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and 'unsure'. A full breakdown by respondent type can be found in the annex.

The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

The key theme raised in support of the proposal relates to the availability of this treatment over the counter at a low cost.

The key themes not in favour of the proposal include: Rubefacients are an effective treatment; removal will have a negative impact on quality of life for patients, including vulnerable groups; and the decision to prescribe should be left to GPs and healthcare professionals.

"Perfectly good over the counter products available. No need to prescribe."

Members of the public and family members

The key themes demonstrating support for the proposal amongst this cohort include: this treatment is readily available over the counter; use of this treatment should be funded by the patient rather than the NHS; Rubefacients should be blacklisted; and there is a lack of evidence demonstrating the effectiveness of the treatment.

The key themes opposing the proposal focus on the effectiveness of the treatment and that GPs and healthcare professionals should be left to decide whether to prescribe it.

CCGs

Key themes mentioned by CCGs indicate support for the proposal. Themes indicate a belief that these treatments should be blacklisted and that they are readily available over the counter at a low cost. A key theme raised that is not in support of the proposal is that Rubefacients can be suited to some patients not suited to other medications.

An additional theme raised by this cohort focuses on the effect of the proposed changes, such as the potential increase in the prescription of alternatives which would negate any potential savings

"Rubefacients should be blacklisted and should no longer be available to prescribe via the NHS. The medicines should be placed on the Drug Tariff blacklist. Within our CCG we have deprescribed Rubefacients and identified alternatives. However patients are still aware that other CCGs have not taken this action. It needs to be consistent and the only way is by blacklisting. This removes duplication of time and effort at CCG level."

Clinicians

Key themes in support of the proposal include: the lack of evidence demonstrating the effectiveness of Rubefacients; availability of alternatives; and the suggestion to blacklist these products.

Key themes not in support of the proposal include: that these are more effective and safer than other treatments; and the potential increase in the prescription of alternatives which would negate any potential savings

"Whilst I agree that Rubefacients have limited efficacy for osteoarthritis, there is longstanding evidence to show their tremendous efficacy in rheumatoid-arthritis,

rheumatism and especially in chronic acute rheumatism. This is especially of worth in children, adolescents as well as adults and the elderly as a safe alternative to NSAIDs (oral or topical) and oral analgesics which are often less effective…"

Patient representative organisations, voluntary organisations and charities

The key theme to emerge from this group is the need to conduct further research to see which form of the compound is most effective and/or provides the greatest cost benefit.

Other NHS organisations, provider organisations and professional bodies

Whilst there is acknowledgement that Rubefacients are an effective treatment the key themes to emerge from this group focus on the concerns around the effectiveness of these treatments and accompanying evidence that demonstrates this and the need for clearer guidance relating to the implementation of the proposal.

NICE and the Royal Pharmaceutical Society support the proposal. NICE specifically highlights that health professionals are expected to take guidance fully into account, alongside the individual needs, preferences and values of their patients. They endorse that healthcare professionals are to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

"We are concerned that GPs will be pressured to prescribe and will therefore prescribe a topical NSAID instead which will increase the cost base." (Professional Representative Body)

Similarly to CCGs and clinicians, another theme raised by this group focuses on the potential knock-on effects as a result of the changes, such as the prescription of more expensive alternatives

Industry

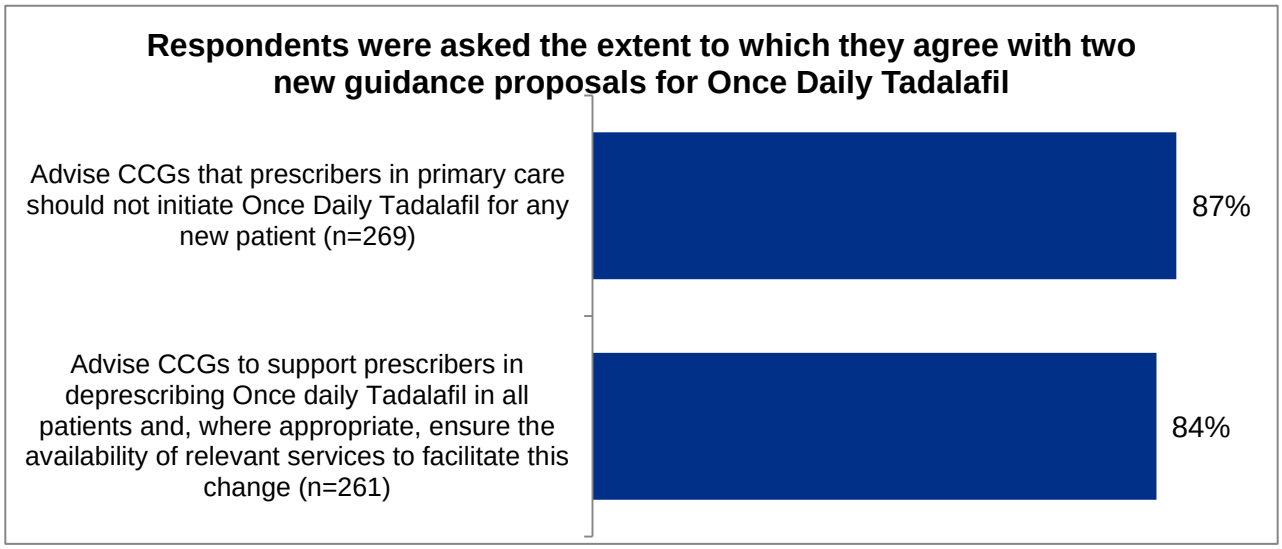
There was only one industry response and that highlights that the inclusion of a product in this category needs to be reviewed as PrescQIPP has incorrectly classified salicylate-containing topical products as Rubefacients; it should be classified as a topical NSAID and excluded from this consultation. It is not available to purchase over the counter unless the sale is supervised by a pharmacist.

4.16 Once Daily Tadalafil

Once Daily Tadalafil is used to treat erectile dysfunction in circumstances as set out in part XVIIIB of the Drug Tariff. Tadalafil is a phosphodiesterase-5-inhibitor and is available in strengths of 2.5mg, 5mg, 10mg and 20mg. In addition, 2.5mg and 5mg can be used to treat benign prostatic hyperplasia. Only 2.5mg and 5mg should be used once daily. 10mg and 20mg are used in a 'when required fashion'. The inclusion of Once Daily Tadalafil within this consultation is due to there not being enough evidence to routinely recommend once daily preparations in preference to 'when required' preparations.

There is also a 20mg once daily preparation, branded Adcirca, which is used to treat pulmonary hypertension. This recommendation does not apply to this product, however it should only be prescribed by specialist centres and not routinely prescribed in primary care.

The chart below presents the extent to which all survey respondents agree with the two new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



N.B. Respondents were asked whether they 'agree', 'disagree', 'unsure' or 'don't know' to the proposal questions. The bars show percentages calculated as a proportion of those who 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and 'unsure'. A full breakdown by respondent type can be found in the annex.

The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

The key theme in favour of the proposal is that Tadalafil should not be funded by the NHS. The key theme not in favour of the proposal is that Tadalafil is an effective treatment and is required for a number of conditions.

Comments from participants at the patient and public engagement events largely focus on clarity around the provision of this treatment under schedule 2 and the effects of it not being provided (e.g. the cost to patients, equity of access). Cancer patients in particular are a group considered to be affected if this is removed.

"I feel that the removal of this prescribed medication, will have an effect on the quality of my life, and I would urge that it be kept available on prescription."

Members of public and family members

The key themes raised by this group include the availability of cheaper or more cost-effective alternatives, and that if a patient chooses to have this treatment, they should fund it themselves, possibly through private prescriptions.

CCGs

The key themes raised by CCGs are in agreement with the proposal, with comments focusing on how this treatment should be blacklisted and should not be funded by the NHS. There are also some comments highlighting the lack of proven evidence for the product's effectiveness.

"If the price of Once Daily Tadalafil could be reduced to the cost of On Demand Sildenafil following patent expiry then there would be no need to decommission Once Daily Tadalafil. The recommendations included in the consultation are concerned with treatment of BPH and ED, as per the product licence. However, locally, urology teams have tended to start Once Daily Tadalafil following surgery as 'penile rehabilitation' and in addition to on demand PDE5 inhibitors. If this continues to be accepted practice among urology specialists, it is unlikely that the results of the consultation will remove variation in prescribing. In addition, it would help CCGs reduce prescribing of Once-Daily Tadalafil to have some clearer guidance on the amount of support that the NHS overall considers appropriate for treatment of ED. Many GPs have interpreted previous guidance that the NHS would provide treatment for one episode of sexual activity per week, thus limiting prescriptions to four per month (with some even providing private prescriptions for quantities higher than this). Where patients have challenged the guidance and requested more on demand treatments, there is a point at which the monthly cost of on demand and daily treatment equals out. To implement this guidance, therefore, I think the NHS should be explicit in that it agrees to fund either up to a threshold monthly cost (beyond which the patient self funds) or a total number of episodes of sexual intercourse (beyond which the patient self funds)…"

Clinicians

The key theme raised in favour of the proposal focuses on the lack of evidence for the effectiveness of the treatment. However, some comment that this is an effective treatment.

Additionally, one clinician says that Tadalafil does not meet the criteria to be included in this consultation, commenting around the treatment's clinical effectiveness, cost effectiveness and NHS funding priorities.

CCGs, clinicians and other healthcare organisations think that when Once Daily Tadalafil comes off patent in November 2017[1] the cost of treatment will no longer be an issue as the generic price will be much lower.

Patient representative organisations, voluntary organisations and charities

Two respondents say that Tadalafil prescriptions are not an effective use of NHS resources and that it should not be funded by the NHS, whilst one argues that it is effective.

"Community Pharmacy Lancashire (CPL) supports these proposals, as these items are either dangerous or not the most effective treatment available. CPL believes that the national NHS prescribing blacklist should be used to restrict these products."

Other NHS organisations, provider organisations and professional bodies

Respondents broadly agree that Tadalafil treatment is required for a number of conditions including benign prostatic hyperplasia and think NHS England should provide additional support for those suffering from erectile dysfunction.

NICE agrees with both recommendations and also notes that when exercising their judgement, health professionals are expected to take guidance fully into account,

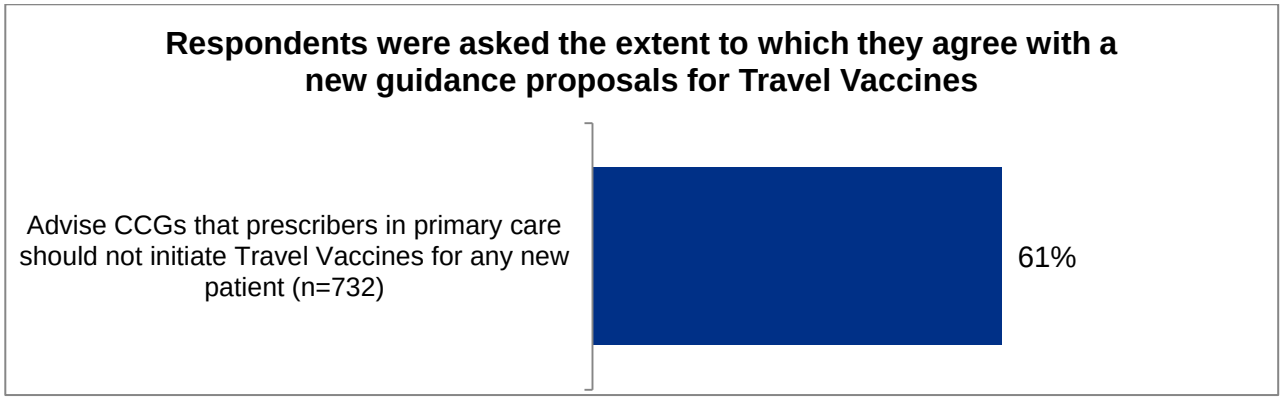
[1] NHS England have confirmed that the patent for Tadalafil once daily expires in April 2020 (correct at date of publication)

alongside the individual needs, preferences and values of their patients.

4.17 Travel Vaccines

Travel Vaccines are injections that are available to prevent illnesses abroad. Some Travel Vaccines are available on the NHS and others are not available on the NHS. Travel Vaccines not available on the NHS are sometimes inappropriately administered for the purposes of travel, due to them being available for prevention of illness in other circumstances. The inclusion of Travel Vaccines within this consultation is due to them being a low priority for NHS funding.

The chart below presents the extent to which all survey respondents agree with the new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



N.B. Respondents were asked whether they 'agree', 'disagree', 'unsure' or 'don't know' to the proposal questions. The bars show percentages calculated as a proportion of those who 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and 'unsure'. A full breakdown by respondent type can be found in the annex.

The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

Some comment that the cost of Travel Vaccines should be met by patients, whilst others state it should be funded by the NHS. Those against the proposal state that there is a cost saving overall for the NHS by not having to treat people returning with holiday diseases which could have been vaccinated against.

"The cost of a travel vaccination should be met by the patient. A patient who is able to afford travel should budget for vaccines as part of the cost."

Members of the public and family members

Responses from this cohort mirror those from patients. The key themes raised include: the cost of travel vaccines should be met by the patient; vaccines should remain on the NHS to provide valuable protection to the public's health; and vaccines provide a cost saving overall.

CCGs

CCG are generally in favour of the proposal, with participants commenting that patients should meet the cost of vaccines themselves. Some comments also request clear guidance on use in exceptional circumstances (e.g. patients working abroad, doing voluntary work) and when vaccines would and would not be provided for free, especially for combination vaccines. An example was for Hepatitis B when patients are in a high risk group.

"If Travel Vaccine not provided; future cost in case of infection is projected to be high, treating disease."

"There needs to be clarity on the use of combined Hep A and B products as there is a lot of variation

nationally."

Clinicians

Clinicians agree with the proposal, with comments such as the cost should be met by patients being made. Some also suggest patients should be required to meet some of the cost or a proportion of cost for Travel Vaccines.

Some comment that the proposal would lead to increases in costs for the NHS because vaccines provide an overall cost saving and valuable public health protection.

"There is no reason why these should not be prescribed in primary care. They may prevent diseases that will be a burden on the NHS and there is intrinsically no difference between any of these and medication taken whilst travelling to prevent a pre-existing condition."

"Access to some of these vaccines is almost impossible in some areas, and primary care is the easiest place to access. If it was made simpler to charge and claim for these vaccines with a clear remit from Public Health, we could continue to provide Travel Vaccines appropriately."

Patient representative organisations, voluntary organisations and charities

The key themes amongst this group are similar to the comments provided by clinicians – the cost of Travel Vaccines should be met by the patient, they provide a cost saving overall and it is in the interest of public health.

Other NHS organisations, provider organisations and professional bodies

Some comment the cost should be met by the patient whilst others say it should remain on the NHS (e.g. the Royal Pharmaceutical Society). Those who argue the cost should be met by the NHS (e.g. Public Health England) highlight the extra costs of treating people who are not vaccinated, and the overall impact on public health and risk to public safety.

The British Medical Association neither agrees nor disagrees.

"These vaccines may be expensive for patients to obtain privately and adequate consideration needs to be given to the possible consequences and costs involved should appropriate vaccines not be given and a chronic disease is contracted. The

burden of managing this disease will far outweigh any costs to the system of the initial vaccination programme."

Industry

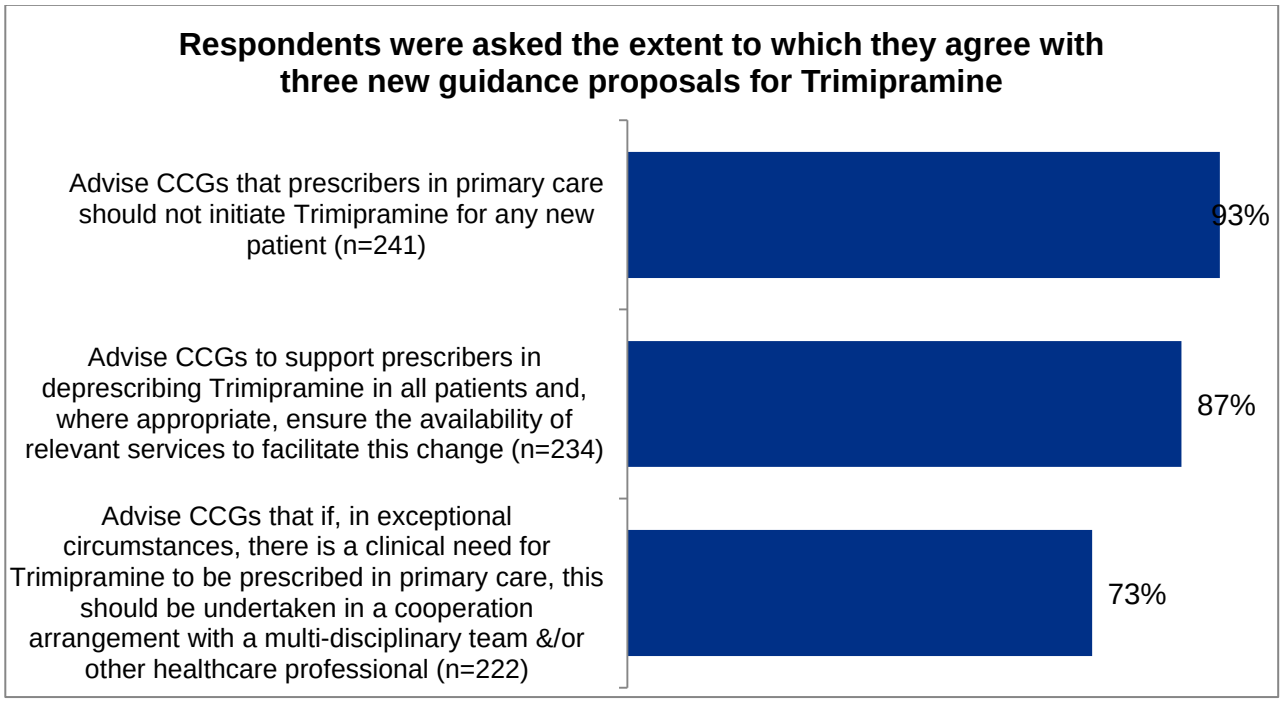
Companies who responded to the consultation voice their disagreement with the proposal.

"Preventative medicine is always cheaper than active treatment. A person infected with any of these diseases uses more resources and costs more to treat than the vaccines do."

4.18 Trimipramine

Trimipramine is an antidepressant (TCA) with the brand name Surmontil. The cost of Trimipramine is significantly more expensive than other antidepressants. NICE CG90: Depression in Adults recommends selective serotonin reuptake inhibitor (SSRI) antidepressants first line medicines are indicated as they have a more favourable risk to benefit ratio compared to TCA. However, if a TCA is required, there are more cost-effective TCAs available. Due to the significant cost associated with Trimipramine and the availability of alternative treatments, the group considered Trimipramine suitable for inclusion in the consultation.

The chart below presents the extent to which all survey respondents agree with the three new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



N.B. Respondents were asked whether they 'agree', 'disagree', 'unsure' or 'don't know' to the proposal questions. The bars show percentages calculated as a proportion of those who 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and 'unsure'. A full breakdown by respondent type can be found in the annex.

The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

This cohort comments there are a number of readily available, suitable alternatives but consideration should be given to patients who are stable on Trimipramine. Some also request reassurance that the treatment can be re-prescribed if alternatives aren't effective.

"It is vital that GPs are given sufficient resources to spend time with patients discussing alternatives and managing the transition from Trimipramine to an alternative, with close monitoring and several follow-up appointments."

Members of the public and family members

Similarly to patients, this cohort also comments that here are a number of readily available, suitable alternatives but seeks reassurance that the treatment can be represcribed if alternatives are not effective. The comments from this group also show they are conscious there are cheaper or more cost-effective alternatives available.

"There are precious few, if any, good clinical reasons for still using tricyclic anti-depressants when more effective and safer alternatives have been available for decades."

CCGs

CCGs generally agree with the proposal and comment that the treatment should be blacklisted for all patients and that there are suitable alternatives available. Some are keen for prescribers to be given specialist guidance and education when changing treatments.

"Prescribers would need clear national advice on how to implement any changes and transition to alternative products, ensuring that both primary and secondary care are adopting the same approach."

Clinicians

Similarly to CCGs, clinicians generally agree with the proposal, commenting that the treatment should be blacklisted for all patients and that there are suitable alternatives available, including many that are cheaper and more cost-effective.

"Perfectly suitable alternatives that are much more cost effective. The cost of Trimipramine to the NHS is ridiculous."

Patient representative organisations, voluntary organisations and charities

Comments in favour of the proposal focus on the availability of suitable alternatives. Comments not in favour of the proposal cite the requirement to consider the effect on patients who have been taking this treatment for a long time and are stable on this treatment.

"…an expectation that any change to an alternative is completed via face-to-face consultation and agreement with the patient. This is because they may have been stable

on this treatment for a long time and there is a risk of deterioration in their mental health wellbeing if the change is made without a full partnership between the patient and the prescriber."

Other NHS organisations, provider organisations and professional bodies

Comments from other organisational bodies convey their support for the proposals, again highlighting suitable alternatives, whilst comments not in favour of the proposals include the consideration for patients who have been taking the treatment for a long time.

NICE agrees with the recommendations in line with guidance and individual patient needs, however the Royal College of Psychiatrists and Royal Pharmaceutical Society do not agree as they believe it is effective for some patients. The Royal Pharmaceutical Society argues that Trimipramine is a strong antidepressant with strong anti-anxiety effects, it does not interfere with normal sleep patterns and it is helpful in managing withdrawal from alcohol or narcotics.

5 Over the counter medication

In addition to the detailed recommendations made by the joint clinical working group for the list of 18 products, another area of NHS prescribing that has been suggested for consideration regards those products which can also be purchased over the counter.

5.1 Views and relevant evidence that NHS England should consider

Respondents were asked to provide their views and relevant evidence that NHS England should consider when developing proposals to potentially restrict items that are available over the counter. In total 5,543 respondents provided feedback on the questions in this section.

Top themes

From the comments, the three main themes overall from all respondent types regarding the proposal to stop prescribing medicines available over the counter are:

1) Treatments available over the counter should not be prescribed
2) Over the counter medicines should not be prescribed unless there is a specific need from the individual
3) Restriction of over the counter medicines just because of the cost to the NHS is unfair on vulnerable groups.

The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

Patients also comment that readily available treatments that are cheap to buy over the counter should be considered for prescribing restriction.

"I think there needs to be clear guidance when items can be prescribed to avoid any mis-interpretations by prescribers or patients, items should be restricted as we do not have the funds to support self-care and items are available much cheaper than it would cost NHS."

Members of the public and family members

This group also comment that readily available treatments that are cheap to buy over the counter should be considered for prescribing restriction and treatments with evidence of clinical effectiveness should not be restricted just because of the cost to the NHS.

"Agree in general, but for medicines that are effective, there should be prescription for those who cannot afford to buy them – those on free prescriptions linked to being on benefits (but not pensioners who are not receiving benefits other than the state pension)."

CCGs

Other themes raised by CCGs include the requirement for clear guidance and education from NHS England to implement this effectively and the effect this proposal will have on patients who require a large amount of prescribed over the counter medication.

"Items which are readily and inexpensively available should be recommended to be purchased by patients if for short-term conditions or covered by the over the counter licence."

Clinicians

The additional key themes emerging from clinicians are that considerations must be made for those who require a large supply of over the counter medication (e.g. to manage a chronic/long-term condition) and those items that are readily available over the counter cheaply should be considered for prescribing restriction.

"Happy as long as people needing long-term treatment can still get on prescription e.g. paracetamol, where there is a restriction on amount that can be sold."

Patient representative organisations, voluntary organisations and charities

This group also comments that when making decisions, consideration must be made for those with long-term conditions who require a large supply of over the counter medicine, and that the deprescription of these items could result in patient compliance and clinician monitoring issues. Some also comment that treatments that are available over the counter cheaply should be considered for prescribing restriction.

"Some patients with a long-term condition, taking aspirin as an example for heart conditions, may not continue their treatment if it is no longer prescribed. Surely the doctor is best to make the decision and sadly many prescribe for things that the patient should not even present for. They must …ensure both a reduction in unnecessary prescribing and consultations."

Other NHS organisations, provider organisations and professional bodies

Organisational bodies cite similar themes – considerations have to be made for those with long-term conditions who require a large supply of over the counter medication and

items that are readily available at a low cost should not be prescribed. This cohort also comments that there should be greater utilisation of community pharmacies in aiding patients to source treatments needed.

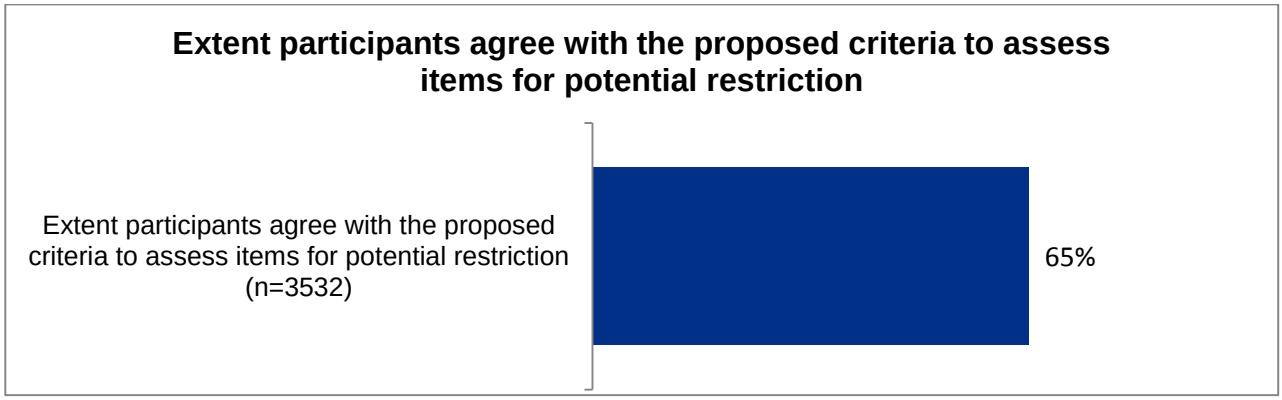
Industry

Industry bodies also comment healthcare professionals should be able to advise on whether these treatments are necessary – the deprescription of these items could result in patient compliance and clinician monitoring issues and the impact on healthcare professionals as a result of these changes should also be considered.

5.2 Agreement with proposed criteria

Respondents were asked to identify the extent to which they agree with the proposed criteria to assess items for potential restriction and identify products, which are either clinically ineffective or available over the counter, for prioritising for early review.

The chart below presents the extent to which all survey respondents agree with the proposed criteria to assess items for potential restriction. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



N.B. Respondents were asked whether they 'agree', 'disagree', 'unsure' or 'don't know' to the proposal questions. The bars show percentages calculated as a proportion of those who 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and 'unsure. A full breakdown by respondent type can be found in the annex.

The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

The common themes discussed amongst this cohort relate to concerns and queries around the evidence consulted when informing the proposal, that the proposal goes against patients' freedom of choice and that items not available over the counter should not be removed.

"Freedom of choice and for doctors to be allowed and be encouraged to exercise their judgment and experiment outside the highly restrictive tick-box guidelines."

Members of public and family members

Common themes mentioned by this cohort include: concerns or questions around the evidence consulted when informing the proposal; decisions should be based on more

than just the cost of the treatment to the NHS; the proposal goes against patients' freedom of choice; and assessments must be made on the requirements of individual patients and their needs.

CCGs

The key themes raised by this cohort include: concerns some may not want to pay or be able to afford the treatment; the restrictions on the quantities that can be purchased over the counter should be reconsidered; the requirement for clearer guidance; and that consideration should be given to the impact on vulnerable groups.

"Often people request a prescription as it is cheaper than purchasing products if they get free prescriptions. We should consider a small token fee for all prescriptions. Entitlement to free prescriptions should be reviewed e.g. wealthy elderly, working retired, and people with endocrine disorders getting all prescriptions free."

Clinicians

The common themes discussed amongst this cohort relate to concerns around the evidence used. Clinicians also voiced concerns around patient freedom of choice and the belief that these decisions should be made on more than the cost of the treatment to the NHS.

Patient representative organisations, voluntary organisations and charities

Comments from this group focus on the consultation process and guidance, including that: clearer guidance and education is required to implement this effectively; the effectiveness of treatments should be considered by speaking to users of the treatments; and there are concerns around the evidence used to formulate the proposal. There are also comments relating to the requirement to carry out assessments based on patient needs, the impact on vulnerable groups and concerns that some patients may not be able to afford treatments.

"I agree that the NHS needs to save money but the whole consultation and any resulting alteration of the guidelines needs to be done fairly, taking each patient's needs into consideration." (Voluntary organisation)

Other NHS organisations, provider organisations and professional bodies

Common themes amongst this group include concerns around the evidence used and that some cohorts may not want or be able to afford to pay for these treatments over the counter. Other themes mentioned include the need to consider the impact on vulnerable groups and quality of life overall. There are concerns around the possibility of unintended consequences as a result of the changes, e.g. greater pressure on healthcare professionals.

Some comments also mention the requirement to take into consideration the impact on those with long-term conditions and those with self-limiting ailments, as well as the need for clearer guidance around the proposal.

Industry

Industry bodies comment that more than cost to the NHS should be considered when making these decisions and the effectiveness of treatments should be evaluated by

speaking to those who use them. Other points raised include: the possible impacts on healthcare professionals as a result of the changes; concerns some may not be able to pay for these treatments; and the belief that there should be a greater emphasis on self-care and patient empowerment.

Most commonly mentioned over the counter products that should be prioritised for early review	
Treatment	**No. of mentions**
Paracetamol	280
Homeopathy	225
Ibuprofen	110
Herbal treatments	89
Cough mixtures/medicines	79
Antihistamines	75
Cold remedies	57
Ready-made gluten free items	49
Analgesia products	47
Vitamins	46
Skin Emollients	42
Sun cream/sun tan lotions	38
All over the counter medicines	36
Painkillers	34
Aspirin	33
NSAID gels/creams	32
Gastric anti-acid products	32
Moisturisers/treatments for dry skin	30
Hay fever treatments	29
Base	*1,345*

6 Feedback on our proposals to update guidance

This section presents respondents' views and opinions on the proposed process for identification of items for possible addition or removal from the guidance.

Consultation respondents were asked to provide feedback on how they thought guidance should be updated and revised in the future. Respondents were asked how they felt about the proposed process for identification of items for possible addition to the guidance or possible removal from the guidance.

Almost all respondents to the consultation commented (5,353). There was an almost equal split between those who agreed with the proposed process for identification (32% and those who disagreed (37%). Only 15% neither agreed nor disagreed and 16% were unsure.

Patients

Patients are concerned about the impact that the removal of treatments will have on some patients. They say that the effectiveness of treatments should be gauged by speaking to those who use them. Some are concerned about what evidence was used when informing the proposal, whilst others suggest negotiating the current pricing from sole provider of this treatment to the UK because the treatments is cheaper in Europe. Patients also feel that the proposal goes against a patient's freedom to choose their treatment.

Members of the public and family

This group raises the same points as the patients. They also say that proposals should be based on cost, efficacy and whether the alternatives are of equal benefit and cost effectiveness.

CCGs

CCGs agree that the proposal makes better use of limited NHS resources but suggest further amendments. They suggest that there should be a review and treatment change where necessary if the treatment has new or safer alternatives.

"Vast amounts of money are being used from the NHS pot by people who are prescribed these less appropriate treatments. CCGs at the moment have work in place to reduce this cost, but to remove the option would ensure that CCGs could move their work in medicines management forward, whilst using the NHS purse appropriately."

Clinicians

Clinicians raise similar points to the patients. They express concerns over evidence consulted, and that the proposals go against a patient's freedom to choose their treatment. They suggest further amendments to the proposal, better use of limited NHS resources and consideration of the effectiveness of treatments by speaking to those using them.

"It depends how it actually works in practice. It needs to have detailed feedback from patients and clinicians and this should be actively sought rather than waiting for interested parties to contact the CCG."

"There is no point in wasting money on items that have been shown not to work. It takes funds away from useful treatments. It gives useless therapies a veneer of respectability."

Patient representative organisations, voluntary organisations and charities

This cohort raises concerns around the evidence consulted to inform the proposal, and the impact on a patient's freedom to choose their treatment. Further amendments are suggested.

Professional representative bodies and other healthcare organisations

These groups mention the same points raised by the other stakeholder groups. They also state that a more robust system for adding and removing treatments with equal representation from all stakeholders is needed.

"The process does not seem robust! Instead it seems deliberately otherwise, to take acceptance of a very robust process carried out for non-contentious items to then carry out a 'light' version without good consultation on more contentious medicines."
(Professional Representative Body)

Industry

Respondents from the industry are concerned about the evidence consulted when informing the proposal, but they agree that the proposal makes better use of limited NHS resources. They add that a robust system is needed for adding and removing treatments and that this should have equal representation from all stakeholders.

7 Annex

The breakdown of responses to the closed questions for each of the products is presented in this annex. The first data row shows the percentages presented in the charts in the product sections. The subsequent rows show how the different respondent types answered these questions (note – some respondents did not specify a type and are therefore included under 'all responses' but not within the subcategories below)

Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** has been calculated as a proportion of those who 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and 'unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Co-proxamol

Respondents were asked the extent to which they agree with three new guidance proposals for Co-proxamol. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Co-proxamol for any new patient		Q2. To support prescribers in deprescribing Co-proxamol in all patients		Q3. That in exceptional circumstances if there is a clinical need for Co-proxamol to be prescribed in primary care this should be undertaken in cooperation arrangement with a multidisciplinary team and/or other healthcare professional	
	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**85%**	**1234**	**85%**	**1213**	**74%**	**1226**
All responses	71%	1,488	70%	1,480	61%	1,494
CCG	98%	120	95%	118	43%	118
Other healthcare organisation	98%	43	88%	43	67%	43
Clinician	90%	353	85%	352	64%	354
Other	87%	70	80%	69	61%	72
Professional representative body	74%	23	68%	22	55%	22
Industry	67%	3	67%	3	67%	3
Members of the public	66%	319	67%	318	59%	318
Patient representative / voluntary / charity organisation	53%	64	62%	65	64%	73
Patient	52%	485	53%	483	491	63%

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Dosulepin

Respondents were asked the extent to which they agree with three new guidance proposals for Dosulepin. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Dosulepin for any new patient		Q2. To support prescribers in deprescribing Dosulepin in all patients		Q3. That if, in exceptional circumstances, if there is a clinical need for Dosulepin to be prescribed in primary care, this should be undertaken in cooperation arrangement with a multidisciplinary team and/or other healthcare professional	
	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**84%**	**302**	**75%**	**289**	**72%**	**280**
All respondent responses	80%	316	69%	315	64%	315
CCG	99%	89	90%	88	68%	88
Clinician	74%	103	63%	103	63%	104
Other	84%	25	64%	25	64%	25
Professional representative body	100%	7	86%	7	29%	7
Industry	0%	1	0%	1	0%	1
Members of the public	76%	29	69%	29	62%	29
Patient representative / voluntary / charity organisation	75%	4	25%	4	25%	4
Patient	53%	43	42%	43	71%	42
Other healthcare organisation	93%	14	71%	1	57%	14

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Prolonged-release Doxazosin

Respondents were asked the extent to which they agree with three new guidance proposals for Prolonged-release Doxazosin. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Prolonged-release Doxazosin for any new patient		Q2. To support prescribers in deprescribing Prolonged-release Doxazosin in all patients		Q3. That in exceptional circumstances if there is a clinical need for Prolonged-release Doxazosin to be prescribed in primary care this should be undertaken in cooperation arrangement with a multidisciplinary team and/or other healthcare professional	
	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**87%**	**254**	**83%**	**255**	**59%**	**245**
All respondent responses	80%	277	77%	276	53%	273
CCG	95%	87	93%	86	51%	85
Clinician	83%	86	81%	86	56%	84
Other	100%	9	82%	17	53%	17
Professional representative body	78%	9	78%	9	33%	9
Industry	0%	1	0%	1	0%	1
Members of the public	61%	23	57%	23	57%	23
Patient representative / voluntary / charity organisation	50%	4	50%	4	75%	4
Patient	53%	40	45%	40	48%	40

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Immediate-release Fentanyl

Respondents were asked the extent to which they agree with three new guidance proposals for Immediate-release Fentanyl. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Immediate-release Fentanyl for any new patient		Q2. To support prescribers in deprescribing Immediate-release Fentanyl in all patients		Q3. That in exceptional circumstances if there is a clinical need for Immediate-release Fentanyl to be prescribed in primary care this should be undertaken in cooperation arrangement with a multidisciplinary team and/or other healthcare professional	
	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**65%**	**387**	**59%**	**375**	**76%**	**380**
All responses	60%	425	52%	425	68%	422
CCG	86%	90	80%	89	76%	88
Other healthcare organisation	75%	16	69%	16	75%	16
Clinician	67%	147	53%	148	76%	148
Other	55%	22	41%	22	55%	22
Professional representative body	50%	10	50%	10	67%	79
Industry	11%	9	11%	9	22%	9
Members of the public	35%	60	33%	60	50%	60
Patient representative / voluntary / charity organisation	43%	7	29%	7	71%	7
Patient	35%	62	37%	62	67%	61

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Glucosamine and Chondroitin

Respondents were asked the extent to which they agree with two new guidance proposals for Glucosamine and Chondroitin. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Glucosamine and Chondroitin for any new patient		Q2. To support prescribers in deprescribing Glucosamine and Chondroitin in all patients	
	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**73%**	**457**	**72%**	**458**
All respondent responses	71%	471	70%	473
CCG	98%	92	95%	91
Other healthcare organisation	92%	13	85%	13
Clinician	88%	112	81%	112
Other	87%	23	83%	24
Professional representative body	69%	13	69%	13
Industry	-	0	-	0
Members of the public	56%	85	58%	85
Patient representative / voluntary / charity organisation	57%	7	57%	8
Patient	41%	125	46%	127

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Herbal Treatments

Respondents were asked the extent to which they agree with three new guidance proposals for Herbal Treatments. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Herbal Treatments for any new patient		Q2. To support prescribers in deprescribing Herbal Treatments in all patients	
	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**46%**	**1349**	**52%**	**1321**
All responses	45%	1,367	51%	1,364
CCG	98%	92	93%	91
Clinician	66%	176	65%	175
Other	62%	53	58%	53
Professional representative body	44%	16	50%	16
Industry	33%	6	33%	6
Members of the public	48%	439	53%	438
Patient representative / voluntary / charity organisation	32%	25	40%	25
Patient	24%	536	36%	536

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Homeopathy

Respondents were asked the extent to which they agree with three new guidance proposals for Homeopathy. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Homeopathy for any new patient		Q2. To support prescribers in deprescribing Homeopathy in all patients	
	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**46%**	**2402**	**52%**	**2361**
All responses	46%	2,421	50%	2,412
CCG	94%	90	93%	89
Clinician	56%	312	54%	312
Other	46%	100	49%	97
Professional representative body	50%	18	56%	18
Other healthcare organisation	53%	30	60%	30
Industry	60%	5	80%	5
Members of the public	55%	946	57%	946
Patient representative / voluntary / charity organisation	50%	18	36%	33
Patient	27%	875	37%	872

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Lidocaine Plasters

Respondents were asked the extent to which they agree with three new guidance proposals for Lidocaine Plasters. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Lidocaine Plasters for any new patient		Q2. To support prescribers in deprescribing Lidocaine Plasters in all patients		Q3. That in exceptional circumstances if there is a clinical need for Lidocaine Plasters to be prescribed in primary care this should be undertaken in cooperation arrangement with a multidisciplinary team and/or other healthcare professional	
	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**59%**	**484**	**58%**	**472**	**71%**	**464**
All responses	54%	527	52%	526	62%	526
CCG	86%	95	82%	94	61%	94
Clinician	54%	217	47%	216	66%	217
Other	79%	28	57%	28	61%	28
Professional representative body	60%	10	60%	10	50%	10
Industry	50%	2	50%	2	0%	2
Members of the public	46%	41	56%	41	54%	41
Patient representative / voluntary / charity organisation	29%	7	29%	7	71%	7
Patient	21%	113	31%	114	61%	113

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Liothyronine

Respondents were asked the extent to which they agree with three new guidance proposals for Liothyronine. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Liothyronine for any new patient		Q2. To support prescribers in deprescribing Liothyronine in all patients		Q3. That in exceptional circumstances if there is a clinical need for Liothyronine to be prescribed in primary care this should be undertaken in cooperation arrangement with a multidisciplinary team and/or other healthcare professional	
	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**16%**	**1646**	**28%**	**1640**	**51%**	**1420**
All responses	16%	1,691	27%	1,687	43%	1,687
CCG	94%	95	90%	94	61%	94
Clinician	7%	117	69%	117	66%	116
Other healthcare organisation	100%	11	82%	11	64%	11
Other	63%	24	50%	24	57%	23
Professional representative body	73%	11	70%	10	64%	11
Industry	40%	5	0%	5	60%	5
Members of the public	9%	227	19%	226	39%	228
Patient representative / voluntary / charity organisation	42%	12	42%	12	58%	12
Patient	3%	1,184	18%	1,183	39%	1,182

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Lutein and Antioxidants

Respondents were asked the extent to which they agree with two new guidance proposals for Lutein and Antioxidants. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Lutein and Antioxidants for any new patient.		Q2. To support prescribers in deprescribing Lutein and Antioxidants in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.	
	No. agreeing with proposal	No. answering question	No. agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**74%**	**319**	**73%**	**318**
All respondent responses	71%	332	70%	332
CCG	97%	91	94%	90
Clinician	90%	79	85%	79
Other	70%	20	60%	20
Professional representative body	50%	12	42%	12
Industry	0%	1	0%	1
Members of the public	55%	40	54%	41
Patient representative / voluntary / charity organisation	38%	8	38%	8
Patient	30%	69	42%	69
Other healthcare organisation	100%	9	89%	9

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Omega-3 fatty acid compounds

Respondents were asked the extent to which they agree with two new guidance proposals for Omega-3 fatty acid compounds. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Omega-3 fatty acid compounds for any new patient		Q2. To support prescribers in deprescribing Omega-3 fatty acid compounds in all patients	
	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**69%**	**421**	**72%**	**418**
All responses	67%	433	68%	438
CCG	97%	86	90%	87
Other healthcare organisation	92%	12	83%	12
Clinician	85%	86	84%	87
Other	70%	23	63%	24
Professional representative body	67%	9	67%	9
Industry	100%	1	100%	1
Members of the public	52%	93	56%	93
Patient representative / voluntary / charity organisation	67%	6	67%	6
Patient	41%	115	50%	117

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Oxycodone and Naloxone Combination Product

Respondents were asked the extent to which they agree with three new guidance proposals for Oxycodone and Naloxone Combination Product. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Oxycodone and Naloxone Combination Product for any new patient		Q2. To support prescribers in deprescribing Oxycodone and Naloxone Combination Product in all patients		Q3. That in exceptional circumstances if there is a clinical need for Oxycodone and Naloxone Combination Product to be prescribed in primary care this should be undertaken in cooperation arrangement with a multidisciplinary team and/or other healthcare professional	
	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**85%**	**279**	**86%**	**270**	**72%**	**260**
All respondent responses	81%	294	79%	292	64%	291
CCG	98%	87	97%	86	59%	86
Clinician	84%	102	78%	100	76%	99
Other	81%	16	69%	16	50%	16
Professional representative body	75%	8	88%	8	63%	8
Industry	N/A	N/A	N/A	N/A	N/A	N/A
Members of the public	71%	24	71%	24	67%	24
Patient representative / voluntary / charity organisation	25%	4	50%	4	25%	4
Patient	49%	41	59%	41	54%	41

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Paracetamol and Tramadol Combination Product

Respondents were asked the extent to which they agree with two new guidance proposals for Paracetamol and Tramadol Combination Product. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Paracetamol and Tramadol Combination Product for any new patient		Q2. To support prescribers in deprescribing Paracetamol and Tramadol Combination Product in all patients	
	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**77%**	**426**	**77%**	**421**
All respondent responses	73%	447	73%	448
CCG	98%	86	97%	86
Clinician	87%	103	82%	103
Other	86%	21	81%	21
Professional representative body	78%	9	78%	9
Industry	50%	2	50%	2
Members of the public	67%	60	67%	61
Patient representative / voluntary / charity organisation	82%	11	73%	11
Patient	45%	139	51%	139

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Perindopril Arginine

Respondents were asked the extent to which they agree with three new guidance proposals for Perindopril Arginine. They were to advise CCGs:

Respondent type	Q1. That prescribers in primary care **should not** initiate Perindopril Arginine for any new patient		Q2. To support prescribers in deprescribing Perindopril Arginine in all patients	
	No. agreeing with proposal	No. answering question	No. agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**92%**	**237**	**90%**	**231**
All respondent responses	88%	246	85%	244
CCG	97%	86	95%	84
Clinician	92%	65	88%	65
Other	94%	17	88%	17
Professional representative body	88%	8	88%	8
Industry	0%	1	0%	1
Members of the public	75%	24	67%	24
Patient representative / voluntary / charity organisation	100%	2	100%	2
Patient	63%	32	63%	32

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Rubefacients

Respondents were asked the extent to which they agree with two new guidance proposals for Rubefacients. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Rubefacients for any new patient		Q2. To support prescribers in deprescribing Rubefacients in all patients	
	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**76%**	**288**	**78%**	**285**
All respondent responses	76%	306	73%	305
CCG	92%	86	91%	85
Other healthcare organisation	85%	13	92%	13
Clinician	60%	99	61%	99
Other	64%	22	73%	22
Professional representative body	75%	8	50%	8
Industry	50%	2	50%	2
Members of the public	82%	34	82%	34
Patient representative / voluntary / charity organisation	100%	2	100%	2
Patient	46%	39	54%	39

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Once Daily Tadalafil

Respondents were asked the extent to which they agree with two new guidance proposals for Once Daily Tadalafil. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Once Daily Tadalafil for any new patient		Q2. To support prescribers in deprescribing Once Daily Tadalafil in all patients	
	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**87%**	**269**	**84%**	**261**
All respondent responses	83%	283	77%	282
CCG	94%	87	92%	86
Clinician	80%	89	72%	89
Other	95%	19	89%	19
Professional representative body	63%	8	63%	8
Industry	50%	2	50%	2
Members of the public	79%	28	64%	28
Patient representative / voluntary / charity organisation	100%	2	50%	2
Patient	57%	35	60%	35

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Travel Vaccines

Respondents were asked the extent to which they agree with three new guidance proposals for Travel Vaccines. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Travel Vaccines for any new patient	
	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**61%**	**732**
All respondent responses	54%	815
CCG	88%	92
Other healthcare organisation	63%	19
Clinician	67%	161
Other	77%	35
Professional representative body	50%	18
Industry	14%	7
Members of the public	45%	189
Patient representative / voluntary / charity organisation	27%	26
Patient	43%	264

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Trimipramine

Respondents were asked the extent to which they agree with three new guidance proposals for Trimipramine. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Trimipramine for any new patient		Q2. To support prescribers in deprescribing Trimipramine in all patients		Q3. That in exceptional circumstances if there is a clinical need for Trimipramine to be prescribed in primary care this should be undertaken in cooperation arrangement with a multidisciplinary team and/or other healthcare professional	
	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**93%**	**241**	**87%**	**234**	**73%**	**222**
All respondent responses	87%	258	80%	256	64%	255
CCG	97%	87	94%	86	64%	86
Clinician	94%	68	88%	68	75%	67
Other	100%	20	73%	11	58%	19
Professional representative body	100%	7	67%	3	57%	7
Industry	0%	1	0%	1	0%	1
Members of the public	68%	25	63%	24	52%	25
Patient representative / voluntary / charity organisation	67%	3	67%	3	67%	7
Patient	60%	35	51%	35	54%	35

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Over the Counter medicines

Extent participants agree with the proposed criteria to assess items for potential restriction

Respondent type	Q1. Do you agree with our proposed criteria to assess items for potential restriction?	
	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**65%**	**3532**
All responses	44%	5,248
CCG	93%	129
Other healthcare organisation	71%	65
Clinician	66%	731
Other	61%	171
Professional representative body	39%	49
Industry	18%	28
Members of the public	50%	1,412
Patient representative / voluntary / charity organisation	56%	118
Patient	29%	2,518

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Specialist Pharmacy Service

Annex B

NHS

Clinical evidence for Versatis® (lidocaine 5%) medicated plasters for Post-herpetic Neuralgia

Brief: Lidocaine plasters are included in the NHS England document published in July 2017: Items which should not routinely be prescribed in primary care: a consultation on guidance for CCGs. This item is classified as being of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns. This evidence review has been prepared in response to concerns raised by the manufacturer Grünental Ltd regarding inclusion of lidocaine plasters in the NHS England document. This review aims to focus on the literature available on the licensed indication.

Summary of clinical evidence

- Versatis® (lidocaine 5%) plasters are licensed for the treatment of neuropathic pain associated with previous herpes zoster infection in adults (SPC) which is also referred to as Post Herpetic Neuralgia (PHN). They are not licenced for any other indication.
- Lidocaine plasters are not included as a treatment option in the NICE Clinical Guideline on neuropathic pain (CG173) and neither are they included in the 'treatments that should not be used' category. The full NICE guideline considered the evidence for topical lidocaine and only one small placebo cross-over study (n=28) for postsurgical incisional pain was reviewed, which showed no difference in effect of lidocaine patches compared to placebo on pain reduction. No studies for PHN were included in the review as the exclusion criteria included RCTs with enriched enrolment. Overall, it was concluded there was an absence of necessary effectiveness evidence.
- Other bodies such as the SMC, PresQIPP and the Special Interest Group on Neuropathic Pain conclude that the effectiveness of lidocaine plasters is limited and of low quality, and the clinical effectiveness remains unclear. Nevertheless, these bodies have approved their use in patients who are intolerant of first-line systemic therapies for post-herpetic neuralgia or where these therapies have been ineffective.
- Several systematic evidence reviews have been conducted on the use of topical lidocaine (any formulation) for PHN, including a Cochrane review and one published in the Lancet Neurology. Their conclusions are broadly similar and note that there is limited evidence from good quality Randomised Controlled Trials (RCT's) to support the use of topical lidocaine. These reviews also suggest lidocaine plasters as a treatment option in select group of patients (i.e. second line).
- A number of small open-label studies suggest that lidocaine plasters are effective for pain relief, but they did not meet the criteria for inclusion in the NICE and Cochrane review as only higher quality studies of a randomised, double-blind design were considered.
- The NICE Guideline Development Group have made a research recommendation to further investigate the use of topical lidocaine plasters for localised peripheral pain as they could be a potential alternative treatment for people who do not wish to, or are unable to, take oral pain medications. There are several on-going clinical trials, as mentioned in the Cochrane review, which may help answer questions around clinical efficacy in a variety of pain indications. Although some of the studies have been completed the results have not been published; Grünental Ltd Medical Information were not able to provide further information in the timescale required for this review.
- Overall, the evidence base for lidocaine plasters is limited and robust evidence for the use in PHN does not exist. However, there may be a place for use in patients with PHN who are intolerant of first-line systemic and topical therapies or where these therapies have been ineffective.

Place in national guidance

The NICE Clinical Guideline (CG173) on neuropathic pain recommends amitriptyline, duloxetine, gabapentin or pregabalin as initial treatment options for neuropathic pain. For people who wish to avoid, or are unable to take oral medication, topical capsaicin cream 0.075% is recommended as a treatment option. Lidocaine patches are not included as treatment option in the Clinical Guideline on neuropathic pain and neither is it included in the 'treatments that should not be used' category. These guidelines were published in 2013 and a NICE review in September 2017, concluded that they found no new evidence that affects the recommendations in the guideline.

It is worth noting that in the full version of the NICE CG 173, the evidence for topical lidocaine was considered under a specific review protocol which included randomised controlled trials (RCTs) and which excluded, for example, RCTs with enriched enrolment or single-blind placebo run-in period. The full review protocol is available as appendix D (https://www.nice.org.uk/guidance/cg173/evidence/appendix-d-pdf-191621343). Only one small placebo cross-over study (n=28) for lidocaine patches was included, which showed no effect on pain reduction post-surgery in patients with cancer. No studies for PHN were identified for inclusion in the review. Overall, it was concluded that there was an absence of necessary effectiveness evidence, and furthermore a health economic analysis could not conducted. The Guideline Development Group felt that a research recommendation should be made to further investigate the use of this treatment for localised peripheral pain because it could be a potential alternative treatment for people who do not wish to, or are unable to, take oral pain medications.

The Scottish Medicines Consortium (2008) accepted lidocaine 5% medicated plaster (Versatis®) for restricted use within NHS Scotland for the treatment of neuropathic pain associated with previous herpes zoster infection (PHN). They state, due to the limited comparative data available for lidocaine plasters, the comparative clinical effectiveness remains unclear. As such, it is restricted for use in patients who are intolerant of first-line systemic therapies for PHN or where these therapies have been ineffective.

Similarly, PrescQIPP considered the evidence in November 2013 and concluded that the effectiveness of lidocaine plasters is weak and limited. They recommend that prescribing of lidocaine plasters should be restricted to patients diagnosed with PHN, in whom alternative treatments have proved ineffective or where such treatments are contra-indicated, and that patients being prescribed the lidocaine plasters for unlicensed indications should be reviewed and have their therapy discontinued.

Licensing studies

The licence for Versatis® was based on two small studies including a 14 day placebo-controlled cross-over study (n=32) and an open-label study (n=265) in which patients who had previously responded to lidocaine patches were entered into the placebo-controlled randomised part of the trial (Galer 1999; Binder 2009). Both these studies were criticised by the Medicines and Healthcare Products Regulatory Agency [MHRA] for using “enriched populations” i.e. patients were only included if they had previously responded to lidocaine. The MHRA also noted that the manufacturer was not able to define prospectively which patients would respond to the plasters and it is not clear how many patients with derive benefit.

Systematic reviews

Several systematic evidence reviews have been conducted on the use of topical lidocaine for neuropathic pain. This includes a Cochrane systematic review published in July 2014. The review included double-blind RCTs of at least two weeks' duration comparing any formulation of topical lidocaine with placebo or another active treatment in chronic neuropathic pain. No evidence from good quality RCTs was found to support the use of topical lidocaine to treat neuropathic pain; all of the studies included were at high risk of bias because of small size or incomplete outcome assessment, or both. They acknowledge, however, that individual studies indicated that it was effective for relief of pain and clinical experience also supports efficacy in some patients. Limited information from single studies, mainly in PHN, indicates that lidocaine 5% plaster may be effective in treating neuropathic pain in a small number of patients, and is well tolerated, at least in the short term. They state several large ongoing studies, of adequate duration, with clinically useful outcomes should provide more robust conclusions about both efficacy and harm.

A more recent systematic review published in the Lancet Neurology was the basis of a revised Special Interest Group on Neuropathic Pain (NeuPSIG) recommendation. The systematic review only identified two enriched-enrolment studies in PHN due to an inclusion criteria of randomised, double-blind, placebo-controlled studies. A weak recommendation was assigned to lidocaine patches for neuropathic pain and as such these recommendations have been adopted by the NeuPSIG guidelines: lidocaine patches 5% are recommended as a second line of treatment due to low quality of evidence (Finnerup).

Other studies

In addition, to the RCTs considered in the Cochrane review (Galer 1999, Binder 2009, Galer 2002, Rowbotham 1996), the clinical evidence base for lidocaine plasters for PHN include a number of open-label studies. In one open-label non-inferiority RCT of 4 weeks duration (n=96, PHN; n=204, diabetic peripheral neuropathy), more patients with PHN responded to lidocaine 5% plasters than to pregabalin (62.2% vs. 46.5%, p value not given for the PHN group (Baron 2009a). However, this is a non-inferiority study so superiority of lidocaine cannot be extrapolated and the open-label

design as well as the short duration and small size are limitations to the findings. Similar limitations such as open-label design, short duration (2-8 weeks) and lack of control apply to the other studies investigating lidocaine plasters in PHN (Baron 2009b, Katz 2002, Rehm 2010, White 2003). The longest duration of the open-label studies is 12 months and 4 years over which the long-term efficacy and safety was evaluated (Hans 2009, Sabatowski). In the 12 month study, newly recruited patients (n=97) had a mean average pain intensity of 5.9±1.4 at baseline, which decreased to 3.9± at week 12 and remained stable 3.9±2.3 until the end of the 12 month period.

It is worth noting all these studies were published before recommendations were made by NICE, PrescQIPP and Cochrane. Although, individually these studies indicate that lidocaine plasters are effective for pain relief, they did not meet the criteria for inclusion in the NICE and Cochrane review as only higher quality studies of a randomised, double-blind design were considered.

We have also conducted an independent literature search (2013-2017) and were not able to identify any significant new evidence to the above to support the use of lidocaine plasters for the licensed indication. Additional studies identified included small open-label or retrospective observational studies (Binder 2016, Fogliardi 2013).

Written by London Medicines Information, contact: lwnh-tr.medinfo@nhs.net. October 2017.

Search Strategy

NICE www.nice.org.uk
Scottish medicines Consortium www.scottishmedicines.org.uk
PresQIPP www.prescqipp.info
NHS Evidence via www.evidence.nhs.uk
Cochrane Library via www.thecochranelibrary.com
Medicines and Healthcare Products Regulatory Agency www.mhra.gov.uk
Medline - ("NEURALGIA, POSTHERPETIC"/ AND LIDOCAINE/) [DT 2013-2017]
EMBASE - (LIDOCAINE/ AND ("NEUROPATHIC PAIN"/ AND "POSTHERPETIC NEURALGIA"/)) [DT 2013-2017]
Personal communication: Grünental Ltd Medical Information

References

Summary of Product Characteristics. Versatis 5% Medicated Plaster. Grünental Ltd. Revision of text: November 2014. www.emc.medicines.org.uk

NICE. Clinical Guideline 173. Neuropathic pain in adults: pharmacological management in non-specialist settings. 20 November 2013. https://www.nice.org.uk/guidance/cg173/resources/neuropathic-pain-in-adults-pharmacological-management-in-nonspecialist-settings-pdf-35109750554053

NICE . Neuropathic pain in adults: pharmacological management in non-specialist settings Clinical guideline [CG173]. Published date: November 2013 Last updated: February 2017. https://www.nice.org.uk/guidance/cg173/evidence/full-guideline-pdf-191621341

Scottish Medicines Consortium. Lidocaine 5% medicated plaster (Versatis). July 2008. https://www.scottishmedicines.org.uk/SMC_Advice/Advice/lidocaine_5__plaster__Versatis____334-06_/lidocaine_5__medicated_plaster__Versatis_

PrescQIPP. Lidocaine plasters. Bulletin 51. November 2013, v2. Accessed from https://www.prescqipp.info/-lidocaine-plasters/category/54-lidocaine-plasters

Binder A, Bruxelle J, Rogers P et al. Topical 5% lidocaine (lignocaine) medicated plaster treatment for post-herpetic neuralgia: results of a double-blind, placebo-controlled, multinational efficacy and safety trial. Clinical Drug Investigation 2009;29(6):393–408.

Galer BS, Rowbotham MC, Perander J et al. Topical lidocaine patch relieves postherpetic neuralgia more effectively than a vehicle topical patch: results of an enriched enrollment study. Pain 1999;80(3):533–8.

Medicines and Healthcare Products Regulatory Agency. Versatis (lidocaine) 5% medicated plaster. Public Assessment Report. Approved 9.4.2015. Accessed from http://www.mhra.gov.uk/home/groups/par/documents/websiteresources/con2032998.pdf

Derry S, Wiffen PJ, Moore RA, Quinlan J. Topical lidocaine for neuropathic pain in adults. Cochrane Database of Systematic Reviews 2014, Issue 7. Art. No.: CD010958. DOI: 10.1002/14651858.CD010958.pub2. http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD010958.pub2/pdf

Finnerup N, Attal N, Haroutounian S Pharmacotherapy for neuropathic pain in adults: a systematic review and meta-analysis. Lancet Neurol 2015; 162–73.

International Association for the Study of Pain. Treating Herpes Zoster and Postherpetic Neuralgia. May 2015. http://iasp.files.cms-plus.com/Content/ContentFolders/Publications2/PainClinicalUpdates/Archives/pcu_vol23_no4_may2015.pdf

Galer BS, Jensen MP, Ma T et al. The lidocaine patch 5% effectively treats all neuropathic pain qualities: results of a randomized, double-blind, vehicle-controlled, 3-week efficacy study with use of the neuropathic pain scale. Clinical Journal of Pain 2002;18(5): 297–301.

Rowbotham MC, Davies PS, Verkempinck C et al. Lidocaine patch: double-blind controlled study of a new treatment method for post-herpetic neuralgia. Pain 1996; 65(1):39–44.

Baron R, Mayoral V, Leijon G et al. 5% lidocaine medicated plaster versus pregabalin in post-herpetic neuralgia and diabetic polyneuropathy: an open-label, non-inferiority two-stage RCT study. Current Medical Research and Opinion 2009;25(7):1663-76 [Baron-a]

Baron R, Mayoral V, Leijon G et al. Efficacy and safety of combination therapy with 5% lidocaine medicated plaster and pregabalin in post-herpetic neuralgia and diabetic polyneuropathy. Current Medical Research and Opinion 2009; 25 (7) 1677-1687 [Baron-b]

Katz NP, Gammaitoni A , Davis MW et al. Lidocaine Patch 5% reduces pain intensity and interference with quality of life in patients with postherpetic neuralgia: An Effectiveness Trial. Pain Medicine 2002; 3(4): 324

Rehm S, Binder A, Baron R. Post-herpetic neuralgia: 5% lidocaine medicated plaster, pregabalin, or a combination of both? A randomized, open, clinical effectiveness study. Current Medical Research & Opinion Vol. 26, No. 7, 2010, 1607–1619

White WT, Patel N, Drass M. Lidocaine patch 5% with systemic analgesics such as gabapentin: a rational polypharmacy approach for the treatment of chronic pain. Pain Medicine 2003; 4 (4): 321-330.
Hans G, Sabatowski R, Binder A et al. Efficacy and tolerability of a 5% lidocaine medicated plaster for the topical treatment of post-herpetic neuralgia: results of a long term study. Current Medical Research and opinions 2009; 25 (5): 1295-1305.
Sabatowski R, Hans G, Tacken I. Safety and efficacy outcomes of long-term treatment up to 4 years with 5% lidocaine medicated plaster in patients with post-herpetic neuralgia. Current Medical Research & Opinion 2012; 28 (8): 1-10.
Binder A, Rogers P; Hans G et al. Impact of topical 5% lidocaine-medicated plasters on sleep and quality of life in patients with postherpetic neuralgia. Source Pain management 2016; 6 (3): 229-239.
Fogliardi, A; Brunori, C. Experience with 5% lidocaine medicated plaster in the treatment of localized neuropathic pain. Minerva Medica 2013; 104 (6): 631-637.

Clinical evidence for homeopathy

Brief

Homeopathic remedies are included in the NHS England document published in July 2017: Items which should not routinely be prescribed in primary care: a consultation on guidance for CCGs. These items are classified as being of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns. This evidence review has been prepared in response to concerns raised by the British Homeopathic Association (BHA) regarding inclusion of homeopathic remedies in the NHS England document. This review aims to focus on the literature available and will assess the quality of this literature.

Summary of clinical evidence

- The principles on which homeopathy is based are very different to conventional medical beliefs. Two theories central to homeopathy are;
    - Like cures like: A substance, that could in conventional doses cause an undesirable effect, is used, in very dilute amounts, to treat that symptom.
    - The more dilute a preparation is the more potent it is. Homeopathic remedies are prepared by repeated dilutions of a base substance. The dilution process is known as potentisation, implying that each subsequent dilution and succussion increases the potency of the preparation.
- In 2015, the Australian National Health and Medical Research Council (NHMRC) conducted a systematic evidence review summarising the evidence from systematic reviews regarding the effectiveness of homeopathy as a treatment for any clinical condition in humans. The review included 57 systematic reviews for a total of 68 clinical conditions.
- The Australian NHMRC concluded overall that there was no condition for which there was a high level of confidence (LOC) in the body of evidence. One condition was associated with a moderate LOC (post-operative ileus). The remainder were associated with a moderate-low, low or very low LOC. They concluded that the available evidence is not compelling and fails to demonstrate that homeopathy is an effective treatment for any of the reported clinical conditions in humans.
- A literature search for systematic reviews published subsequent to the Australian search has identified a further 8 reviews. Seven of these have been scored using the AMSTAR tool for assessing methodological quality of systematic reviews and summarised below. One could not be obtained within the timeframe.
- The BHA, in their submission to NHS England, included a summary of clinical evidence. We identified three review papers that were not considered by the Australian review; the remaining papers within the BHA submission were either included in the Australian review or had been rejected by the review process as being of insufficient quality or the wrong type of evidence.

Place in national/ International guidance

- We have not identified any NICE guidance which recommends the use of homeopathy for any clinical condition. NICE specifically recommend against the use of homeopathy for the treatment of otitis media with effusion, induction of labour or treatment of lower urinary tract symptoms (LUTS) in men.
- The Australian NHMRC concluded that homeopathy should not be used to treat health conditions that are chronic, serious, or could become serious. People who choose homeopathy may put their health at risk if they reject or delay treatments for which there is good evidence for safety and effectiveness. People who are considering whether to use homeopathy should first get advice from a registered health practitioner. Those who use homeopathy should tell their health practitioner and should keep taking any prescribed treatments.
- The UK Science and Technology Committee report into homeopathy in 2010 concluded that the systematic reviews and meta-analyses conclusively demonstrate that homeopathic products perform no better than placebos. They recommended that by providing homeopathy on the NHS and allowing MHRA licensing of products, the Government runs the risk of endorsing homeopathy as an efficacious system of medicine. To maintain patient trust, choice and safety, the Government should not endorse the use of placebo treatments, including homeopathy. Their overall recommendation was that homeopathy should not be funded on the NHS and the MHRA should stop licensing homeopathic products.
- The government response noted that there remains some controversy, since there are peer-reviewed reports that suggest there may be limited evidence of efficacy of homeopathy in certain circumstances. They reasserted the government position on the use of homeopathy within the NHS was that the local NHS and clinicians, rather than Whitehall, are best placed to make decisions on what treatment is appropriate for their patients - including complementary or alternative treatments such as homeopathy - and provide accordingly for those treatments. They further noted that in order for the public to make informed choices, it is vitally important that the scientific evidence base for homeopathy is clearly explained and available.

- In the US, the Federal Trade Commission (FTC) issued a policy statement in 2016 to the effect that the FTC will hold efficacy and safety claims for OTC homeopathic drugs to the same standard as other products making similar claims. That is, companies must have competent and reliable scientific evidence for health-related claims, including claims that a product can treat specific conditions.

Systematic reviews

Process:

1. The Australian NHMRC review was considered a robust, comprehensive systematic review of the evidence published around homeopathy up to January 2013.
2. A comprehensive literature search was therefore undertaken to identify any further systematic reviews published subsequent to the NHMRC document (see appendix for search strategy). We concentrated on literature published from 2013 to date. Eight systematic reviews were identified, of which one could not be accessed within the available time frame. We have not considered lower-quality evidence- for example case studies or surveys.
3. For completeness, we also reviewed the BHA submission, concentrating on their summary of clinical trial data. Any systematic reviews cited in the BHA submission that were not considered by the NHMRC document were also sourced and reviewed. Two systematic reviews and one review of three trials were identified.
4. In total, 10 systematic reviews were identified (of which 9 were appraised and summarised below), in addition to the NHMRC review.
5. We used the AMSTAR tool for scoring methodological quality of systematic reviews. This scores a systematic review on a scale 0-11. We considered a score of 8-11 as a high quality systematic review; 4-7 moderate quality and 0-3 a low quality systematic review.

Systematic reviews published subsequent to NHMRC document:

Summary: A summary of the main findings from each of the systematic reviews or meta-analysis published subsequent to the NHMRC document are included below; whilst the systematic reviews conducted appear to be of moderate to good quality when scored using the AMSTAR tool, the quality of the trials included within most of the reviews are variable thus this new data does not change the conclusion of the NHMRC review conducted in 2015

Mathie et al 2014
A systematic review and meta-analysis of trials of individualised homeopathic treatments. In individualised homeopathy, the homeopath matches all the person's symptoms to a single homeopathic medicine, rather than treating the person for a particular health condition using one or more homeopathic medicines. Individualised homeopathy typically involves a long interview between the practitioner and the patient. The review included 32 eligible trials covering 24 different medical conditions and patient numbers completing the trials ranging from 3 to 199. Twenty-two trials were included in a meta-analysis. From this the odds ratio in favour of individualised homeopathy was 1.53 (95%CI 1.22 to 1.91). However the authors found that 29 of the 32 trials had unclear or high risk of bias and concluded that the finding should be interpreted with caution.
The systematic review was considered high quality (AMSTAR score 9/11).

Boehm et al 2014
A systematic review and meta-analysis of homeopathy in the treatment of fibromyalgia. The authors identified 6 controlled trials suitable for inclusion in the meta-analysis. Patient numbers ranged from 20-62. The homeopathic treatments used differed between the trials. Meta-analysis found in favour of homeopathy for three measures – tender point count, pain intensity and fatigue. Measures for sensory or affective pain or depression showed no difference to placebo. Overall quality of trial reporting and methodology in the included trials was considered low.
The systematic review was considered moderate quality (AMSTAR score 7/11).

Mathie et al 2015
A Cochrane review of homeopathic Oscillococcinum® for the prevention or treatment of influenza and influenza-like illness (ILI). This was an update of a previous Cochrane systematic review; this update limited the search to trials of the branded product. Oscillococcinum® is made from a serial dilution of a solution of wild duck heart and liver extract, which may be reservoirs and vectors of influenza vaccine. The authors found that the overall standard of trial reporting was poor. The authors concluded that there is insufficient good evidence to enable robust conclusions to be made about Oscillococcinum® in the prevention or treatment of influenza and ILI. There was no evidence of efficacy in the prevention of influenza or ILI. They did not rule out the possibility that Oscillococcinum®

could have a clinically useful treatment effect but, given the low quality of the eligible studies, the evidence is not compelling. There was no evidence of clinically important harms due to Oscillococcinum®.
The systematic review was considered high quality (AMSTAR score 10/11).

Stub et al 2016
This meta-analysis concentrates on the reporting of adverse effects and homeopathy aggravation in clinical trials. Homeopathy aggravations are thought to be the temporary appearance of new symptoms, or a temporary intensification of existing symptoms, following a dose of a homeopathic remedy. The meta-analysis conducted was of high quality as rated utilising the AMSTAR tool (8/11). Adverse effects data from 39 RCTs were included in the meta-analysis with a total of 5902 subjects. The conclusions from the meta-analysis note that the proportion of patients experiencing adverse effects to be similar for patients randomized to homeopathic treatment compared to patients randomized to control such as placebo and conventional medicine. They also note that for the concept of 'homeopathic aggravations' the evidence was not strong enough to provide support for the existence of aggravations.

Mathie et al 2017
This systematic review and meta-analysis included RCTs of non-individualised homeopathy for any medical condition, and aimed to test the null hypothesis that non-individualised homeopathy is not distinguishable from placebo. The review was of high quality (AMSTAR score 9/11). Included trials (n=75, 54 of which could be included in the meta-analysis) were found to have high heterogeneity, and there was evidence of publication bias towards trials favouring homeopathy. Meta-analysis of all 54 trials found a small effect size in favour of homeopathy (standardised mean difference [SMD] -0.33, 95% CI -0.44 to -0.21, p<0.001).
An additional analysis was performed, taking into account the risk of bias of each individual trial, as assessed using the Cochrane risk-of-bias appraisal tool. Trials with a high (n=28) or uncertain risk of bias (n=23) retained a small effect size in favour of homeopathy (high risk of bias, SMD -0.38, 95% CI -0.50 to -0.26, p<0.001; uncertain risk of bias, SMD -0.31, 95% CI -0.51 to -0.11, p=0.002). The trials with the lowest risk of bias (n=3) found no significant effect size (SMD = -0.18, 95% CI -0.46 to 0.09, p=0.165). No significant difference was found between these three effect estimates (p=0.417). The authors concluded that the evidence did not support rejection of the null hypothesis.

Shaddel et al 2014
A systematic review of trials of homeopathy in people with intellectual disabilities included trials which enrolled patients with attention deficit hyperactivity disorder (ADHD), autism, dyslexia, and speech and social development in people with cerebral palsy.
The review was of moderate quality (AMSTAR score 5/11). Included trials (n=12) were of variable quality with Jadad scores ranging to 1 to 5 (on a possible scale of 0 to 5). No meta-analysis was performed and no trial results were presented; trial outcomes were simply presented as +, - , or ±.
There were eight trials in people with ADHD, including five which were of good quality. Three of these (total sample size 187 patients, average 24 weeks follow-up) found in favour of homeopathy while two (sample size 63, average follow-up 11 weeks) found against. Two good quality trials found no significant clinical effect of homeopathic treatment in patients with speech difficulties. All other trials were of low quality. The authors concluded that evidence is conflicting on the evidence for homeopathy for treatment of ADHD, and that there is no evidence to support the use of homeopathy for autism or speech difficulties.

Saha et al 2013
This review and meta-analysis included prospective, double-blind, randomised trials of individualised homeopathy in patients with headache and migraine. The review was of moderate quality (AMSTAR score 6/11). Included trials (n=4) had Jadad scores which ranged from 3 to 5 and were found to have significant heterogeneity. There was evidence of significant publication bias in favour of trials with significant results and positive effects. Meta-analysis found no significant difference between homeopathy and placebo (risk ratio 1.58, 95% CI 0.8 to 3.1, p=0.187). Adjustment for publication bias reduced the risk ratio to 0.98 (95% CI 0.5 to 1.9). Only one of the four included trials found a significant benefit of homeopathy compared to; this trial also had the poorest quality of the four.
The authors concluded that, due to the quality and quantity of the literature, there is no clear evidence that homeopathy is superior to placebo for treatment of headache and migraine.

Reviews cited by the BHA but not considered by the NHMRC

Summary: The reviews cited by the BHA but not considered by the NHMRC review are summarised below, however all three were scored as being of low quality using the AMSTAR tool for assessing systematic reviews.

Bellavite P et al 2006
A systematic review of homeopathy for common upper respiratory tract infections and otorhinolaryngologic conditions. Twenty-four studies were included covering eleven clinical conditions. A narrative summary of each study was provided. No attempt was made in the paper to provide a summarised overview of the evidence. Nine trials compared homeopathy against placebo, eight against conventional therapy and seven were uncontrolled. No statistical data were reported thus it is not possible to verify the statistical significance of the results.
The systematic review was considered low quality (AMSTAD score 2/11).

Bergemann 2011
A systematic review assessing homeopathy for upper respiratory tract infections and allergic conditions. Twenty nine studies were identified as suitable for inclusion covering 11 clinical conditions. A total of 5062 patients were included with study size ranging from 1 to 1479. Sixteen studies were placebo controlled; in the remainder homeopathy was compared against conventional management or no control. Of the sixteen placebo-controlled studies, the author concluded that eight showed results in favour of homeopathy, however details are limited and most trials appear to have significant methodological limitations. No statistical details were provided.
The systematic review was considered low quality (AMSTAD score 2/11).

Other reviews
The BHA submission included a paper summarising the results of three randomised, placebo-controlled, double blind trials of homeopathic arnica therapy in patients receiving knee surgery. A total of 343 patients having arthroscopy, artificial knee joint implantation or cruciate ligament reconstruction. No difference was seen between arnica and placebo in percentage change in knee circumference (the primary measure) in patients having arthroscopy or artificial knee joint implantation. Patients having cruciate ligament reconstruction receiving arnica showed statistically significantly less percentage increase in knee circumference than placebo. Secondary outcome measures (including pain on days 1 and 2, number of punctures and total drainage of fluid), showed no statistically significant difference between arnica and placebo for any indication other than a borderline statistically significantly less pain with arnica in patients having cruciate ligament reconstruction. There were no statistically significant differences in adverse events between arnica and placebo.

References

UKMi Medicines Q&A Considerations when addressing questions about potential for adverse effects and drug interactions with homeopathic remedies 27 June 2017 (Available from www.sps.nhs.uk Accessed 3/11/2017)

Australian Government National Health and Medical Research Council NHMRC Statement on Homeopathy and NHMRC Information Paper - Evidence on the effectiveness of homeopathy for treating health conditions (Available from https://www.nhmrc.gov.au/guidelines-publications/cam02 , accessed 1/11/2017)

Government Response to the Science and Technology Committee report 'Evidence Check 2: Homeopathy' July 2010 (Available from https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216053/dh_117811.pdf , accessed 3/1/2017)

Federal Trade Commission Enforcement Policy Statement on Marketing Claims for Over-the-Counter Homeopathic Drugs December 2016 (Available from https://www.ftc.gov/policy/federal-register-notices/federal-trade-commission-enforcement-policy-statement-marketing accessed 3/11/2017)

Mathie RT, Lloyd SM, Legg LA et al. Randomised placebo-controlled trials of individualised homeopathic treatment: systematic review and meta-analysis Systematic Reviews 2014, 3:142

Boehm K, Raak C, Cramer H et al Homeopathy in the treatment of fibromyalgia—A comprehensive literature-review and meta-analysis Complementary Therapies in Medicine (2014) 22, 731—742

Mathie RT, Frye J, Fisher P. Homeopathic Oscillococcinum® for preventing and treating influenza and influenza-like illness. *Cochrane Database of Systematic Reviews* 2015, Issue 1. Art. No.: CD001957. DOI: 10.1002/14651858.CD001957.pub6.

Stub T, Musial F, Kristoffersen A et al Adverse effects of homeopathy, what do we know? A systematic review and meta-analysis of randomized controlled trials Complementary Therapies in Medicine 26 (2016) 146–163

Mathie RT, Ramparsad N, Legg LA, Clausen J, Moss S, Davidson JR, Messow CM, McConnachie A. Randomised, double-blind, placebo-controlled trials of non-individualised homeopathic treatment: systematic review and meta-analysis. Syst Rev. 2017 Mar 24;6(1):63. doi: 10.1186/s13643-017-0445-3.

Shaddel F, Ghazirad M, Bryant M. What is the best available evidence for using homeopathy in patients with intellectual disabilities? Iran J Pediatr. 2014 Aug;24(4):339-44.

Saha S, Koley M. Homeopathic treatment of headaches & migraine: a meta-analysis of the randomized controlled trials. Asian Journal of Pharmaceutical and Clinical Research. 2013 Aug; 6(suppl 3):194-199

Bellavite P, Ortolani R, Pontarollo F, et al. Immunology and homeopathy. 4. Clinical studies – Part 1. Evidence-based Complementary and Alternative Medicine: eCAM, 2006; 3: 293–301.

Bergemann SM, Bornhöft, Bloch D, et al, Clinical Studies on the Effectiveness of Homeopathy for URTI/A (Upper Respiratory Tract Infections and Allergic Reactions). In Bornhöft G, Matthiessen PF (eds), Homeopathy in Healthcare – Effectiveness, Appropriateness, Safety, Costs. Springer, Berlin 2011.

Brinkhaus B, Wilkens JM, Lüdtke R, et al. Homeopathic arnica therapy in patients receiving knee surgery: Results of three randomized double-blind trials. Complementary Therapies in Medicine, 2006; 14: 237–246

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October 2017.

Appendix: search strategy

Database: EMBASE.

1	"NETWORK META-ANALYSIS"/	482
2	"META ANALYSIS"/	136068
3	"SYSTEMATIC REVIEW"/	153257
4	("meta analysis").ti,ab	132872
5	("systematic review").ti,ab	123143
6	("pooled analysis").ti,ab	10380
7	REVIEW/	2276720
8	(review).ti,ab	1585192
9	(systemat* OR pool*).ti,ab	635821
10	(1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9)	3666855
11	HOMEOPATHY/	8926
12	(homeopath*).ti,ab	5859
13	(homoeopath*).ti,ab	969
14	(11 OR 12 OR 13)	10616
15	(10 AND 14)	2122
16	15 [DT FROM 2013] [English language]	395

ANNEX D

NHS Clinical Commissioners
The independent collective voice of clinical commissioning groups

NHS England

Items which should not routinely be prescribed in primary care: Guidance for CCGs

[GATEWAY APPROVAL NUMBER TO BE ADDED]

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the recommendations set out in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

CONTENTS

1 Background

1.1 Who is this guidance for?

This guidance is addressed to CCGs to support them to fulfil their duties around appropriate use of their resources. We expect CCGs to take the proposed guidance into account in formulating local polices, and for prescribers to reflect local policies in their prescribing practice. The guidance does not remove the clinical discretion of the prescriber in accordance with their professional duties.

This guidance is issued as general guidance under s14Z10 and S2 of the NHS Act 2006 and is addressed to CCGs to support them to fulfil their duties around appropriate use of prescribing resources. The objective of this guidance is to support CCGs in their decision-making, to address unwarranted variation, and to provide clear national advice to make local prescribing practices more effective.

1.2 Why have we developed this guidance?

Last year 1.1 billion prescription items[1] were dispensed in primary care at a cost of £9.2billion[2]. This growing cost coupled with finite resources means it is important that the NHS achieves the greatest value from the money that it spends. We know that across England there is significant variation in what is being prescribed and to whom. Some patients are receiving medicines which have been proven to be relatively ineffective or in some cases potentially harmful, and/or for which there are other more effective, safer and/or cheaper alternatives; there are also products which are no longer appropriate to be prescribed on the NHS.

NHS England has partnered with NHS Clinical Commissioners to support Clinical Commissioning Groups (CCGs) in ensuring that they can use their prescribing resources effectively and deliver best patient outcomes from the medicines that their local population uses. CCGs asked for a nationally co-ordinated approach to the creation of commissioning guidance, developed with and by CCGs. The aim was a more equitable basis on which CCGs can take an individual and local implementation decisions. CCGs will still need to take individual decisions on implementation locally, ensuring they take into account their legal duties to advance equality and have regard to reducing health inequalities.

1.3 How have the recommendations in this guidance been developed?

In response to calls from GPs and Clinical Commissioning Groups (CCGs) who were having to take individual decisions about their local formularies, NHS Clinical Commissioners (NHSCC), the national representative organisation for CCGs, surveyed their members during February and March 2017 to assess views as to

[1] An item is anything which can be prescribed on an NHS prescription. More information on what is prescribed on an NHS prescription is available in the Drug Tariff.
[2] NHS Digital Prescription Cost Analysis 2016

whether a range of medicines and other products should be routinely available for prescription on the NHS.

NHS Clinical Commissioners asked NHS England to work with them to produce commissioning guidance to support their member organisations in taking decisions about prescribing of these products in primary care.

Together, NHS England and NHSCC established a clinical working group, chaired by representatives of these two organisations, with membership including GPs and pharmacists, CCGs, Royal College of General Practitioners, National Institute for Health and Care Excellence (NICE), Department of Health, the Royal Pharmaceutical Society and others (full membership listed at appendix A). This clinical working group was tasked with identifying which products should no longer be routinely prescribed in primary care.

Work focused on developing guidelines for an initial list of eighteen products which fall into one or more of the following categories:

- Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns;
- Products which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation; or
- Products which are clinically effective but, due to the nature of the product, are deemed a low priority for NHS funding.

The group assigned one or more of the following recommendations to products considered:

- Advise CCGs that prescribers in primary care should not initiate {item} for any new patient;
- Advise CCGs to support prescribers in deprescribing {item} in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change;
- Advise CCGs that if, in exceptional[3] circumstances, there is a clinical need for the item to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional;
- Advise CCGs that all prescribing should be carried out by a specialist; and/or
- Advise CCGs that this item should not be routinely prescribed in primary care but may be prescribed in named circumstances such as {item}.

In reaching its recommendations for the 18 products listed in this guidance document, the group considered recommendations from NICE, where relevant, in

[3] In this context, “exceptional circumstances” should be interpreted as: Where the prescribing clinician considers no other medicine or intervention is clinically appropriate and available for the individual

order to support CCGs in implementing NICE guidance across the country; in particular it identified items which NICE consider to be "Do not do's[4]".

Where NICE guidance was not available the group considered evidence from a range of sources, for example; the Medicines and Healthcare products Regulatory Agency (MHRA), the British National Formulary, the Specialist Pharmacist Service and PrescQIPP Community Interest Company (CIC) evidence reviews.

The group reviewed each product against the following criteria:

- **Legal Status** i.e. is it prescription only, or is it available over the counter in pharmacies and/or any retail outlet?
- **Indication** i.e. what condition is it used to treat?
- **Background** i.e. a general narrative on the drug including. pack size, tablet size, whether administered orally etc.
- **Patent Protection** i.e. is the drug still subject to a patent?
- **Efficacy** i.e. is it clinically effective?
- **Safety** i.e. is the drug safe?
- **Alternative treatments and exceptionality for individuals** i.e. do alternatives exist and if so, who would they be used for?
- **Equalities and Health Inequalities** i.e. are there groups of people who would be disproportionately affected?
- **Financial implications, comprising:**
    - **Commissioning/funding pathway** i.e. how does the NHS pay for the drug?
    - **Medicine Cost** i.e. how much does the drug cost per item?
    - **Healthcare Resource Utilisation** i.e. what NHS resources would be required to implement a change?
    - **Annual Spend** i.e. what is the annual spend of the NHS on this item?
- **Unintended consequences**

The group's recommendations on the 18 items within this guidance were publicly consulted on for a period of 3 months, from 21st July – 21st October 2017. During the consultation we heard from members of the public, patients and their representative groups, NHS staff, various Royal Colleges and the pharmaceutical industry, amongst others. Section 1.4 details the main findings from the consultation and the changes that have been made as a result of what we have heard. A more detailed report on the consultation can be found in *Items which should not routinely be prescribed in primary care: consultation report of findings* published alongside this guidance. The final recommendations set out in this guidance document reflect the outcome of the consultation. The potential equality impact of these recommendations has also been considered and is outlined in the Equality and Health Inequalities Impact Assessment document published alongside this guidance.

1.4 How have the recommendations in this guidance been developed following the results of the consultation?

We listened to what our stakeholders told us through the consultation and refined our draft guidance in light of the responses, discussion through webinars and the

[4] Practices NICE recommend should be discontinued completely or should not be used routinely

engagement exercises, as well as recommendations from the joint clinical working group which considered the feedback in detail.

Whilst overall the final guidance remains largely unchanged from the draft guidance published in July 2017, there have been some important refinements and clarifications made in respect of a number of products. Details of each product are as follows:

Co-proxamol – We received a significant number of responses during the consultation around co-proxamol and the safety of continuing to prescribe this treatment emerged as the main theme. As a result of what we heard, the joint clinical working group recommended that we keep our original recommendations.

Dosulepin – As a result of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for dosulepin.

Prolonged-release Doxazosin - As a result of what we heard the joint clinical working group did not feel it necessary to amend the proposed recommendations on deprescribing for prolonged-release doxazosin; however the group felt that there would not be cases of exceptionality that would warrant referral to a multidisciplinary team so removed that recommendation.

Immediate release Fentanyl – During the consultation we heard from patients, healthcare professionals and others that it is important that immediate-release fentanyl is available for use in palliative care. The joint clinical working group therefore decided that the three original proposed recommendations should remain but that a defined exemption and clarification should be provided for use as outlined in NICE guidance for palliative care.

Glucosamine and Chondroitin - As a result of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for glucosamine and chondroitin.

Herbal Treatments - As a result of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for Herbal treatments.

Homeopathy – During the consultation we heard a range of views both agreeing and disagreeing with our proposals on homeopathy. Due to the volume of evidence submitted a further review of the evidence was commissioned from the Specialist Pharmacy Service (SPS) by NHS England. The SPS review found that there was no clear or robust evidence base to support the use of homeopathy in the NHS and therefore, also taking into account responses received from medical and scientific bodies, the joint clinical working group did not feel it necessary to amend the proposed recommendations for homeopathy.

Lidocaine Plasters - During the consultation we heard from patients, healthcare professionals and others that there may be some specialist uses for this item which may be outside the terms of its license. We also received further submissions of evidence and a review of this evidence was commissioned from the Specialist Pharmacy Service (SPS) by NHS England. The joint clinical working group

considered the consultation feedback and the SPS evidence review and decided that the three recommendations should remain, but that a defined exemption and clarification should be provided for the use of lidocaine plasters in Post Herpetic Neuralgia (PHN) only, for which it is licensed in adults and for which there is some evidence of efficacy.

Liothyronine - We received a significant number of responses during the consultation around liothyronine. The main recurring theme – particularly from patients and organisational bodies - is that liothyronine is an effective treatment which is invaluable to patient wellbeing, quality of life and condition management. We also heard that a small proportion of patients treated with levothyroxine continue to suffer with symptoms despite adequate biochemical correction. The joint clinical working group considered the consultation feedback and therefore decided that liothyronine should still be prescribed for a small cohort of patients. The joint clinical working group changed the recommendations so that initiation of prescribing of liothyronine in appropriate patients should be initiated by a consultant endocrinologist in the NHS, and that deprescribing in 'all' patients is not appropriate as there are recognised exceptions.

Lutein and Antioxidants – As a result of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for lutein and antioxidants.

Omega-3 Fatty Acid Compounds - As a result of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for omega-3 fatty acid compounds.

Oxycodone and Naloxone combination product - As a result of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for oxycodone and naloxone combination product.

Paracetamol and Tramadol combination product - As a result of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for paracetamol and tramadol Combination Product.

Perindopril Arginine - As a result of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for perindopril arginine.

Rubefacients (excluding topical NSAIDs) - As a result of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for rubefacients (excluding topical NSAIDs).

Once daily Tadalafil - As a result of what we heard the joint clinical working group did not feel it necessary to amend the proposed recommendations for once daily tadalafil.

Vaccines administered exclusively for the purposes of travel - As a result of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for vaccines administered *exclusively for the purposes of*

travel. However we did hear that confusion persists around travel vaccines and we have amended the wording of our guidance to reduce confusion.

Trimipramine - As a result of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for deprescribing trimipramine however the group felt that there would not be cases of exceptionality that would warrant referral to a multidisciplinary team so removed that recommendation.

Whilst not a part of our consultation, the Department of Health recently consulted on the availability of Gluten free foods in primary care. The Department of Health will make recommendations in due course and we have removed references to Gluten free foods from this commissioning guidance.

2 How will this guidance be updated and reviewed?

To ensure that the NHS continues to allocate its resources effectively, the joint clinical working group will review the guidance at least annually (or more frequently if required) to identify potential items to be retained, retired or added to the current guidance. There will be three stages:

Item identification
Organisations represented on the joint clinical working group will, taking into account previous feedback, identify items from the wide range of items that can be prescribed on NHS prescription in primary care in the categories defined in section 1.3.

Item prioritisation
The joint clinical working group will prioritise items based on the following criteria:

- Safety Issue
- Evidence of efficacy
- Degree of variation in prescribing
- Cost to the NHS
- Clinician or patient feedback

In order to seek initial views from interested parties, a draft list of items will be made available online through the NHS England website for a four week period, when comments will be sought. Organisations detailed in Appendix 1 and others where appropriate may be sent an invitation to comment. Feedback will then be collated and published on the NHS England website.

Item selection for inclusion or removal from the guidance
The joint clinical working group will consider the feedback and produce a final list of recommendations for consideration by NHS England and NHS Clinical Commissioners to update the proposed commissioning guidance for items which should not be routinely prescribed in primary care. It is envisaged that we will now consult formally on these recommendations as has been done for the products included in this guidance.

3 Definitions

Annual Spend: Unless otherwise indicated this is the total value from NHS Prescription Services at the NHS Business Services Authority. Prescriptions written by General Medical Practitioners and non-medical prescribers (nurses, pharmacists etc.) in England represent the vast majority of prescriptions included. Prescriptions written by dentists and hospital doctors are also included provided that they were dispensed in the community. Also included are prescriptions written in Wales, Scotland, Northern Ireland and the Isle of Man but dispensed in England. Prescriptions written in England but dispensed outside England are not included. The figure quoted is the net ingredient cost which refers to the cost of the drug before discounts and does not include any dispensing costs or fees. It does not include any adjustment for income obtained where a prescription charge is paid at the time the prescription is dispensed or where the patient has purchased a prepayment certificate.

BNF: British National Formulary provides healthcare professionals with authoritative and practical information on the selection and clinical use of medicines.

Exceptional Circumstances: In the context of this guidance, “exceptional circumstances” should be interpreted as: Where the prescribing clinician considers no other medicine or intervention is clinically appropriate and available for the individual

Item: An item is anything which can be prescribed on an NHS prescription. More information on what is prescribed on an NHS prescription is available in the Drug Tariff.

New patient: This refers to any patient newly initiated on an item listed in the guidance.

NICE: The National Institute for Health and Care Excellence. They provide the NHS with clinical guidance on how to improve healthcare.

MHRA: Medicines and Healthcare products Regulatory Agency. They regulate medicines, medical devices and blood components for transfusion in the UK.

NHS Clinical Commissioners: NHSCC are the independent membership organisation for CCGs, providing their collective voice, facilitating shared learning and delivering networking opportunities for CCG members.

PHE: Public Health England. They protect and improve the nation's health and wellbeing, and reduce health inequalities.

PrescQIPP CIC (Community Interest Company): PrescQIPP are an NHS funded not-for-profit organisation that supports quality, optimised prescribing for patients. They produce evidence-based resources and tools for primary care commissioners, and provide a platform to share innovation across the NHS.

4 Recommendations

Our final recommendations by product are listed below.

4.1 Co-proxamol

Recommendation	• Advise CCGs that prescribers in primary care should not initiate co-proxamol for any new patient. • Advise CCGs to support prescribers in deprescribing co-proxamol in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
Annual Spend	£9,002,824 (NHS Digital)
Background and Rationale	Co-proxamol was a pain-killer which was previously licensed in the UK until being fully withdrawn from the market in 2007 due to safety concerns. All use in the UK is now on an unlicensed basis. Since 1985 advice aimed at the reduction of co-proxamol toxicity and fatal overdose has been provided, but this was not effective and resulted in withdrawal of co-proxamol by the MHRA. Since the withdrawal, further safety concerns have been raised which have resulted in co-proxamol being withdrawn in other countries. Due to the significant safety concerns, the joint clinical working group considered co-proxamol suitable for inclusion in this guidance.
Further Resources and Guidance for CCGs	MHRA Drug Safety Update: November 2007, January 2011 PrescQIPP CIC Drugs to Review for Optimised Prescribing - Co-proxamol insert weblink for patient leaflets

4.2 Dosulepin

Recommendation	• Advise CCGs that prescribers in primary care should not initiate dosulepin for any new patient. • Advise CCGs to support prescribers in deprescribing dosulepin in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change. • Advise CCGs that if, in exceptional circumstances, there is a clinical need for dosulepin to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
Annual Spend	£2,651,544 (NHS Digital)
Background and Rationale	Dosulepin, formerly known as dothiepin, is a tricyclic antidepressant. NICE CG90: Depression in Adults has a "do not do" recommendation: "*Do not switch to, or start, dosulepin because evidence supporting its tolerability relative to other antidepressants is outweighed by the increased cardiac risk and toxicity in overdose.*" Due to the significant safety concerns advised by NICE, the joint clinical working group considered dosulepin suitable for inclusion in this guidance.
Further Resources and Guidance for CCGs	NICE CG90: Depression in Adults PrescQIPP CIC Drugs to Review for Optimised Prescribing - Dosulepin insert weblink for patient leaflets

4.3 Prolonged-release Doxazosin (also known as Doxazosin Modified Release

Recommendation	• Advise CCGs that prescribers in primary care should not initiate prolonged-release doxazosin for any new patient. • Advise CCGs to support prescribers in deprescribing Prolonged-release doxazosin in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation.
Annual Spend	£7,769,931 (NHS Digital)
Background and Rationale	Doxazosin is an alpha-adrenoceptor blocking drug that can be used to treat hypertension and benign prostatic hyperplasia. There are two oral forms of the medication (immediate release and prolonged-release) and both are taken once daily. Prolonged-release Doxazosin is approximately six times the cost of doxazosin immediate release (NHS Drug Tariff). NICE CG127 Hypertension in adults: diagnosis and management recognises that doxazosin should be used in treatment but does not identify benefits of prolonged-release above immediate release. NICE CG97 Lower urinary tract symptoms in men: management recommends Doxazosin as an option in men with moderate to severe lower urinary tract symptoms. It does not identify benefits of Prolonged-release above immediate release. Due to the significant extra cost of prolonged-release doxazosin and the availability of once daily immediate release doxazosin, the joint clinical working group considered prolonged-release doxazosin suitable for inclusion in this guidance.
Further Resources and Guidance for CCGs	NICE CG127 Hypertension in adults: diagnosis and management NICE CG97 Lower urinary tract symptoms in men PrescQIPP CIC Drugs to Review for Optimised Prescribing - Prolonged Release Doxazosin BNF - Doxazosin

	insert weblink for patient leaflets

4.4 Immediate Release Fentanyl

Recommendation	• Advise CCGs that prescribers in primary care should not initiate immediate release fentanyl for any new patient. • Advise CCGs to support prescribers in deprescribing immediate release fentanyl in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change. • Advise CCGs that if, in exceptional circumstances, there is a clinical need for immediate release fentanyl to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional.
Exceptions and further recommendations	**These recommendations do not apply to patients undergoing palliative care treatment** and where the recommendation to use immediate release fentanyl in line with NICE guidance (see below), has been made by a multi-disciplinary team and/or other healthcare professional with a recognised specialism in palliative care.
Category	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation.
Annual Spend	£10, 952,130 (NHS Digital)
Background and Rationale	Fentanyl is a strong opioid analgesic. It is available as an immediate release substance in various dosage forms; tablets, lozenges, films and nasal spray. Immediate release fentanyl is licensed for the treatment of breakthrough pain in adults with cancer who are already receiving at least 60mg oral morphine daily or equivalent. NICE CG140 Opioids in Palliative Care states *Do not offer fast-acting fentanyl as first-line rescue medication.* This recommendation does not apply to longer sustained release versions of fentanyl which come in patch form. Due to the recommendations from NICE and immediate release fentanyl being only licensed for use in cancer, the joint clinical working group considered immediate release fentanyl was suitable for inclusion in this guidance with specific exceptions for people receiving palliative care reflecting NICE and the terms of the product licence.
Further	Opioids Aware: A resource for patients and healthcare

Resources and Guidance for CCGs	professionals to support prescribing of opioid medicines for pain PrescQIPP CIC Drugs to Review for Optimised Prescribing - Immediate Release Fentanyl Faye's story: good practice when prescribing opioids for chronic pain insert weblink for patient leaflets

4.5 Glucosamine and Chondroitin

Recommendation	• Advise CCGs that prescribers in primary care should not initiate Glucosamine and Chondroitin for any new patient. • Advise CCGs to support prescribers in deprescribing glucosamine and chondroitin in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Items of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
Annual Spend	£444,535 (NHS Digital)
Background and Rationale	Glucosamine and Chondroitin are nutraceuticals which used to improve pain associated with osteoarthritis. The BNF states the following about glucosamine, *The mechanism of action is not understood and there is limited evidence to show it is effective.* NICE CG177: Osteoarthritis care and management has the following "do not do" recommendation: *Do not offer glucosamine or chondroitin products for the management of osteoarthritis* Due to the recommendation from NICE and due to the lack of evidence as advised by the BNF, the joint clinical working group considered glucosamine and chondroitin suitable for inclusion in this guidance
Further Resources and Guidance for CCGs and prescribers	BNF NICE CG177: Osteoarthritis care and management PrescQIPP CIC Drugs to Review for Optimised Prescribing - Glucosamine

	insert weblink for patient leaflets

4.6 Herbal Treatments

Recommendation	• Advise CCGs that prescribers in primary care should not initiate herbal items for any new patient • Advise CCGs to support prescribers in deprescribing herbal items in all patients and where appropriate, ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
Annual Spend	£100,009 (Source: NHS Business Services Authority)
Background and Rationale	Under a Traditional Herbal Registration there is no requirement to prove scientifically that a product works, the registration is based on longstanding use of the product as a traditional medicine. Due to the lack of scientific evidence required to register these products with the MHRA, the joint clinical working group felt that they were suitable for inclusion in this guidance.
Further Resources and Guidance for CCGs and prescribers	GOV.UK Traditional herbal medicines: registration form and guidance GOV.UK Herbal medicines granted a traditional herbal registration (THR) insert weblink for patient leaflets

4.7 Homeopathy

Recommendation	• Advise CCGs that prescribers in primary care should not initiate homeopathic items for any new patient • Advise CCGs to support prescribers in deprescribing homeopathic items in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
Annual Spend	£92,412 (NHS Digital)
Background and Rationale	Homeopathy seeks to treat patients with highly diluted substances that are administered orally. During the consultation we received a range of submissions pertaining to homeopathy and it was deemed necessary to have a further, up to date review of the evidence which was conducted by the Specialist Pharmacy Service. The review found that there was no clear or robust evidence to support the use of homeopathy on the NHS.
Further Resources and Guidance for CCGs and prescribers	SPS Review link GOV.UK Register a homeopathic medicine or remedy insert weblink for patient leaflets

4.8 Lidocaine Plasters

Recommendation	• Advise CCGs that prescribers in primary care should not initiate lidocaine plasters for any new patient (apart from exceptions below) • Advise CCGs to support prescribers in deprescribing lidocaine plasters in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change. • Advise CCGs that if, in exceptional circumstances, there is a clinical need for lidocaine plasters to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional.
Exceptions and further recommendations	These recommendations do not apply to patients who have been treated in line with NICE CG173 *Neuropathic pain in adults: pharmacological management in non-specialist settings* but are still experiencing neuropathic pain associated with previous herpes zoster infection (post-herpetic neuralgia).
Category	Item of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns
Annual Spend	£19,295,030 (NHS Digital)
Background and Rationale	Lidocaine plasters can be applied for pain relief and are licensed for symptomatic relief of neuropathic pain associated with previous herpes zoster infection (post-herpetic neuralgia, PHN) in adults. NICE CG173 Neuropathic pain in adults: pharmacological management in non-specialist settings does not recommend lidocaine plasters for treating neuropathic pain. The joint clinical working group also considered a PrescQIPP CIC review, and during the consultation more evidence was provided and an up to date evidence summary was deemed necessary and prepared by the Specialist Pharmacy Service to inform the joint clinical working group's recommendations. Based on this review and non-inclusion, the lidocaine plasters are included with defined exceptions.
Further Resources and Guidance for CCGs and prescribers	NICE Clinical Knowledge Summaries - Post-herpetic neuralgia insert weblink for patient leaflets insert link to SPS review

4.9 Liothyronine (including Armour Thyroid and liothyronine combination products)

Recommendation	• Advise CCGs that prescribers in primary care should not initiate liothyronine for any new patient • Advise CCGs that individuals currently prescribed liothyronine should be reviewed by a consultant NHS endocrinologist with consideration given to switching to levothyroxine where clinically appropriate. • Advise CCGs that a local decision, involving the Area Prescribing Committee (or equivalent) informed by National guidance (e.g. from NICE or the Regional Medicines Optimisation Committee), should be made regarding arrangements for on-going prescribing of liothyronine. This should be for individuals who, in exceptional circumstances, have an on-going need for liothyronine as confirmed by a consultant NHS endocrinologist.
Exceptions and further recommendations	The British Thyroid Association (BTA) advise that a small proportion of patients treated with levothyroxine continue to suffer with symptoms despite adequate biochemical correction. In these circumstances, where levothyroxine has failed and in line with BTA guidance, endocrinologists providing NHS services may recommend liothyronine for individual patients after a carefully audited trial of at least 3 months duration of liothyronine. Liothyronine is used for patients with thyroid cancer, in preparation for radioiodine ablation, iodine scanning, or stimulated thyroglobulin test. In these situations it is appropriate for patients to obtain their prescriptions from the centre undertaking the treatment and not be routinely obtained from primary care prescribers.
Category	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation.
Annual Spend	£34,802,312 (NHS Digital) In addition £1,000,049 is spent on Liothyronine + Levothyroxine combination products e.g. armour thyroid
Background and Rationale	Liothyronine (sometimes known as T3) is used to treat hypothyroidism. It has a similar action to levothyroxine but is more rapidly metabolised and has a more rapid effect. It is sometimes used in combination with levothyroxine in products. The price (NHS Drug Tariff) of liothyronine has risen significantly

	and there is limited evidence for efficacy above Levothyroxine. The British Thyroid Association, in their 2015 position statement, state "*There is no convincing evidence to support routine use of thyroid extracts, L-T3 monotherapy, compounded thyroid hormones, iodine containing preparations, dietary supplementation and over the counter preparations in the management of hypothyroidism".* Due to the significant costs associated with liothyronine and the limited evidence to support its routine prescribing in preference to levothyroxine, the joint clinical working group considered liothyronine suitable for inclusion in this guidance. However during the consultation we heard and received evidence about a cohort of patients who require liothyronine and the clinical working group felt it necessary to include some exceptions based on guidance from the British Thyroid Association.
Further Resources and Guidance for CCGs and prescribers	British Thyroid Association Guidelines UKMI Medicines Q&A - What is the rationale for using a combination of levothyroxine and liothyronine (such as Armour® Thyroid) to treat hypothyroidism? insert weblink for patient leaflets

4.10 Lutein and Antioxidants

Recommendation	• Advise CCGs that prescribers in primary care should not initiate lutein and antioxidants for any new patient • Advise CCGs to support prescribers in deprescribing lutein and antioxidants in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Items of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
Annual Spend	£1,500,000 (NHS Digital)
Background and Rationale	Lutein and antioxidants (e.g. vitamin A, C E and zinc) are supplements which are sometimes recommended for Age Related Macular Degeneration. A variety of supplements are available to purchase in health food stores and other outlets where they are promoted to assist with "eye health". Two Cochrane Reviews have been conducted on this topic **Antioxidant vitamin and mineral supplements for preventing age-related macular degeneration** http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD000253.pub3/full The authors conclude *"There is accumulating evidence that taking vitamin E or beta-carotene supplements will not prevent or delay the onset of AMD. There is no evidence with respect to other antioxidant supplements, such as vitamin C, lutein and zeaxanthin, or any of the commonly marketed multivitamin combinations".* **Antioxidant vitamin and mineral supplements for slowing the progression of age-related macular degeneration** http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD000254.pub3/full The authors conclude *"People with AMD may experience delay in progression of the disease with antioxidant vitamin and mineral supplementation. This finding is drawn from one large trial conducted in a relatively well-nourished American population. The generalisability of these findings to other populations is not known."* PrescQIPP CIC has issued a bulletin which did not find evidence to support prescribing of lutein and antioxidants routinely on the NHS. NICE have published draft consultation guidance on Age-Related Macular Degeneration and proposed that the effectiveness and cost-effectiveness of the use of lutein and

	antioxidants is currently a research recommendation.
Further Resources and Guidance for CCGs and prescribers	PrescQIPP CIC Drugs to Review for Optimised Prescribing - Lutein and Antioxidants NICE - Macular Degeneration insert weblink for patient leaflets

4.11 Omega-3 Fatty Acid Compounds

Recommendation	• Advise CCGs that prescribers in primary care should not initiate omega-3 Fatty Acids for any new patient. • Advise CCGs to support prescribers in deprescribing omega-3 Fatty acids in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Item of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns
Annual Spend	£6,317,927 per annum (NHS Digital)
Background and Rationale	Omega-3 fatty acid compounds are essential fatty acids which can be obtained from the diet. They are licensed for adjunct to diet and statin in type IIb or III hypertriglyceridemia; adjunct to diet in type IV hypertriglyceridemia; adjunct in secondary prevention in those who have had a myocardial infarction in the preceding 3 months. NICE have reviewed the evidence and advised they are not suitable for prescribing by making “Do not do” recommendations Do not offer or advise people to use omega-3 fatty acid capsules or omega-3 fatty acid supplemented foods to prevent another myocardial infarction. If people choose to take omega-3 fatty acid capsules or eat omega-3 fatty acid supplemented foods, be aware that there is no evidence of harm. Do not offer omega-3 fatty acid compounds for the prevention of cardiovascular disease to any of the following: people who are being treated for primary prevention, people who are being treated for secondary prevention, people with chronic kidney disease, people with type 1 diabetes, people with type 2 diabetes. Do not offer the combination of a bile acid sequestrant (anion exchange resin), fibrate, nicotinic acid or omega-3 fatty acid

	compound with a statin for the primary or secondary prevention of CVD. Do not offer omega-3 fatty acids to adults with non-alcoholic fatty liver disease because there is not enough evidence to recommend their use. Initiation of omega-3-acid ethyl esters supplements is not routinely recommended for patients who have had a myocardial infarction (MI) more than 3 months earlier. Do not use omega-3 fatty acids to manage sleep problems in children and young people with autism. People with familial hypercholesterolemia (FH) should not routinely be recommended to take omega-3 fatty acid supplements. Do not offer omega-3 or omega-6 fatty acid compounds to treat multiple sclerosis (MS). Explain that there is no evidence that they affect relapse frequency or progression of MS. The joint clinical working group agreed with NICE recommendations and considered omega-3 fatty acid compounds suitable for inclusion in this guidance.
Further Resources and Guidance for CCGs and prescribers	NICE - Omega-3 PrescQIPP CIC Drugs to Review for Optimised Prescribing - Omega 3 Fatty Acids insert weblink for patient leaflets

4.12 Oxycodone and Naloxone Combination Product

Recommendation	• Advise CCGs that prescribers in primary care should not initiate oxycodone and naloxone combination product for any new patient. • Advise CCGs to support prescribers in deprescribing oxycodone and naloxone combination product in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change. • Advise CCGs that if, in exceptional circumstances, there is a clinical need for oxycodone and naloxone combination product to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation.
Annual Spend	£5,062,928 (NHS Digital)
Background and Rationale	Oxycodone and naloxone combination product is used to treat severe pain and can also be used second line in restless legs syndrome. The opioid antagonist naloxone is added to counteract opioid-induced constipation by blocking the action of oxycodone at opioid receptors locally in the gut. PrescQIPP CIC have issued a bulletin and did not identify a benefit of oxycodone and naloxone in a single product over other analgesia (with laxatives if necessary). Due to the significant cost of the oxycodone and naloxone combination product and the unclear role of the combination product in therapy compared with individual products, the joint clinical working group considered oxycodone and naloxone suitable for inclusion in this guidance.
Further Resources and Guidance for CCGs and prescribers	Opioids Aware: A resource for patients and healthcare professionals to support prescribing of opioid medicines for pain Faye's story: good practice when prescribing opioids for chronic pain PrescQIPP CIC Drugs to Review for Optimised Prescribing - Oxycodocne and Naloxone Combination Product insert weblink for patient leaflets

4.13 Paracetamol and Tramadol Combination Product

Recommendation	• Advise CCGs that prescribers in primary care should not initiate paracetamol and tramadol combination product for any new patient. • Advise CCGs to support prescribers in deprescribing paracetamol and tramadol combination product in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation.
Annual Spend	£1,980,000 (NHS Digital)
Background and Rationale	Paracetamol and tramadol combination products are more expensive than the products with the individual components (Drug Tariff). PrescQIPP CIC also issued a bulletin which did not identify any significant advantages over individual products, however it does recognise that some people may prefer to take one product instead of two. There are also different strengths of tramadol (37.5mg) and paracetamol (325mg) in the combination product compared to commonly available individual preparations of tramadol (50mg) and paracetamol (500mg), although the PrescQIPP CIC review found no evidence that combination product is more effective or safer than the individual preparations. Due to the significant extra cost of a combination product, the joint clinical working group considered paracetamol and tramadol combination products suitable for inclusion in this guidance.
Further Resources and Guidance for CCGs and prescribers	PrescQIPP CIC Drugs to Review for Optimised Prescribing - Paracetamol and Tramadol Combination Product insert weblink for patient leaflets

4.14 Perindopril Arginine

Recommendation	• Advise CCGs that prescribers in primary care should not initiate perindopril arginine for any new patient. • Advise CCGs to support prescribers in deprescribing perindopril arginine in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation.
Annual Spend	£529,403 (NHS Digital)
Background and Rationale	Perindopril is an ACE inhibitor used in heart failure, hypertension, diabetic nephropathy and prophylaxis of cardiovascular events. The perindopril arginine salt version was developed as it is more stable in extremes of climate than the perindopril erbumine salt, which results in a longer shelf-life. perindopril arginine is significantly more expensive than perindopril erbumine and a PrescQIPP CIC review of the topic found there was no clinical advantage of the arginine salt. NICE CG127: Hypertension in adults: diagnosis and management recommends that prescribing costs are minimised. Due to the significant extra costs with the arginine salt and the availability of the erbumine salt, the joint clinical working group considered perindopril arginine suitable for inclusion in this guidance.
Further Resources and Guidance for CCGs and prescribers	NICE CG127: Hypertension in adults: diagnosis and management PrescQIPP CIC Drugs to Review for Optimised Prescribing - Perindopril Arginine insert weblink for patient leaflets

4.15 Rubefacients (excluding topical NSAIDs[5])

Recommendation	• Advise CCGs that prescribers in primary care should not initiate rubefacients (excluding topical NSAIDs) for any new patient. • Advise CCGs to support prescribers in deprescribing rubefacients (excluding topical NSAIDs) in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
Annual Spend	£4,301,527 (source: NHS BSA)
Background and Rationale	Rubefacients are topical preparations that cause irritation and reddening of the skin due to increased blood flow. They are believed to relieve pain in various musculoskeletal conditions and are available on prescription and in over-the-counter remedies. They may contain nicotinate compounds, salicylate compounds, essential oils and camphor. The BNF states *"The evidence available does not support the use of topical rubefacients in acute or chronic musculoskeletal pain."* NICE have issued the following "Do not do" recommendation: Do not offer rubefacients for treating osteoarthritis. Due to limited evidence and NICE recommendations the joint clinical working group considered rubefacients (excluding topical NSAIDS) suitable for inclusion in this guidance.
Further Resources and Guidance for CCGs and prescribers	PrescQIPP CIC Drugs to Review for Optimised Prescribing - Rubefacients NICE CG177 Osteoarthritis: care and management BNF: Soft-tissue disorders insert weblink for patient leaflets

[5] This does not relate to topical non-steroidal anti-inflammatory drug (NSAID) items such as Ibuprofen and Diclofenac.

4.16 Once Daily Tadalafil

Recommendation	• Advise CCGs that prescribers in primary care should not initiate once daily tadalafil for any new patient • Advise CCGs to support prescribers in deprescribing once daily tadalafil in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Products which are clinically effective but where more cost-effective products are available this includes products that have been subject to excessive price inflation.
Annual Spend	£11,474,221 (NHS Digital)
Background and Rationale	Tadalafil is a phosphodiesterase-5-inhibitor and is available in strengths of 2.5mg, 5mg, 10mg and 20mg used to treat erectile dysfunction. In addition 2.5mg and 5mg can be used to treat benign prostatic hyperplasia. Only 2.5mg and 5mg should be used once daily. 10mg and 20mg[6] are used in a "when required fashion". Tadalafil can be prescribed for erectile dysfunction in circumstances as set out in part XVIIIB of the Drug Tariff. Benign Prostatic Hyperplasia: NICE terminated their technology appraisal (TA273) due to receiving no evidence from the manufacturer. In NICE CG97: Lower Urinary Tract Symptoms in Men NICE state that there is not enough evidence to recommend phosphodiesterase inhibitors in routine clinical practice. Erectile Dysfunction: PrescQIPP CIC have reviewed the evidence for Tadalfil and although tadalafil is effective in treating erectile dysfunction, there is not enough evidence to routinely recommend once daily preparations in preference to "when required" preparations particularly as when required preparations are now available as a generic. Due to recommendations from NICE and that alternative tadalafil preparations are available, the joint clinical working group felt once daily tadalafil was suitable for inclusion in this guidance.
Further Resources and Guidance for CCGs and prescribers	NICE CG97: Lower Urinary Tract Symptoms in Men NICE Clinical knowledge Summaries - Erectile Dysfunction PrescQIPP CIC Drugs to Review for Optimised Prescribing - Once Daily Tadalafil

[6] *There is also a 20mg once daily preparation, branded *Adcirca*, which is used to treat pulmonary hypertension. This recommendation does not apply to this product, however it should only be prescribed by specialist centres and not routinely prescribed in primary care.

	insert weblink for patient leaflets

4.17 Travel Vaccines (vaccines administered exclusively for the purposes of travel)

Recommendation	• Advise CCGs that prescribers in primary care should not initiate the stated vaccines exclusively for the purposes of travel for any new patient **N.B This is a restatement of existing regulations and no changes have been made as a result of this guidance.**
Exceptions and further recommendations	The vaccines in this proposal are listed below and they may continue to be administered for purposes other than travel, if clinically appropriate. NHS England and NHS Clinical Commissioners recognise that vaccination for the purposes of travel on the NHS can be confusing for prescribers and the public. The working group has recommended that Public Health England and Department of Health, working collaboratively with NHS England and NHS Clinical Commissioners, conduct a review of travel vaccination and publish the findings in Spring 2018.
Category	Items which are clinically effective but due to the nature of the product, are deemed a low priority for NHS funding.
Annual Spend	£4,540,351 (NHS Digital) Only some of this total will be administered for the purposes of travel.
Background and Rationale	To note the following vaccines may still be administered on the NHS exclusively for the purposes of travel, if clinically appropriate, pending any future review: • Cholera • Diptheria/Tetanus/Polio • Hepatitis A • Typhoid This guidance covers the following vaccinations which should not be prescribed on the NHS exclusively for the purposes of travel: • Hepatitis B • Japanese Encephalitis • Meningitis ACWY • Yellow Fever • Tick-borne encephalitis • Rabies

	• BCG These vaccines may continue to be administered on the NHS for other purpose for example where teenagers and first-time university students are offered Meningitis ACWY vaccination as part of a national immunisation programme.
Further Resources and Guidance for CCGs and prescribers	The Green Book Travel Health Pro (NaTHNaC) PrescQIPP CIC Drugs to Review for Optimised Prescribing - Travel Guidance insert weblink for patient leaflets from PrescQIPP

4.18 Trimipramine

Recommendation	• Advise CCGs that prescribers in primary care should not initiate trimipramine for any new patient. • Advise CCGs to support prescribers in deprescribing trimpramine in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation.
Annual Spend	£19,835,783 (NHS Digital)
Background and Rationale	Trimipramine is a tricyclic antidepressant (TCA) however the price of trimipramine is significantly more expensive than other antidepressants. NICE CG90: Depression in Adults recommends selective serotonin reuptake inhibitor (SSRI) antidepressants first line if medicines are indicated as they have a more favourable risk:benefit ratio compared to TCA. However if a TCA is required there are more cost-effective TCAs than trimipramine available. Due to the significant cost associated with trimipramine and the availability of alternative treatments, the joint clinical working group considered trimipramine suitable for inclusion in this guidance.
Further Resources and	NICE CG90: Depression in Adults

Guidance for CCGs and prescribers	NICE Clinical Knowledge Summaries – Depression insert weblink for patient leaflets

Appendix 1

Membership of the Joint Clinical Working group

Graham Jackson (Co-chair)	NHSCC Co-chair and Clinical Chair Aylesbury CCG	NHS Clinical Commissioners & Aylesbury Vale CCG
Bruce Warner (Co-chair)	Deputy Chief Pharmaceutical Officer	NHS England
Arvind Madan	Director of Primary Care and Deputy Medical Director	NHS England
Julie Wood	Chief Executive	NHS Clinical Commissioners
David Webb	Regional Pharmacist	NHS England
David Geddes	Director of Primary Care Commissioning	NHS England
Paul Chrisp	Programme Director, Medicines and Technologies Programme	NICE
Claire Potter	Medicines and Pharmacy	Department of Health
Carol Roberts	Chief Executive	PrescQIPP CIC
Margaret Dockey	Information Services Manager	NHS Business Services Authority
Manir Hussain	Local professional Network Chair & Assoc Director Medicines Optimisation	NHS England & North Staffs/Stoke on Trent CCGs
Duncan Jenkins	Pharmaceutical Public Health	Dudley Public Health/CCG
Kate Arnold	Head of Medicines and Primary Care Development	Solihull CCG
Paul Gouldstone	Head of Medicines Management	Enfield CCG
Steve Pike	Clinical Lead Medicines Management	Coastal West Sussex CCG
David Paynton	National Clinical Lead for Commissioning	Royal College of GPs
Robbie Turner	Director for England	Royal Pharmaceutical Society
Lauren Hughes	Director, Clinical Policy and Operations	NHS England

Stakeholder Organisations

Association of the British Pharmaceutical Industry (ABPI)	NHS Clinical Commissioners
Aylesbury Vale CCG	NHS England
British Generic Manufacturers Association	NHS Improvement
British Medical Association (General Practitioners Committee)	NICE
Care Quality Commission	Patients Association
Department of Health	Pharmaceutical Services Negotiating Committee (PSNC)
Enfield CCG	PrescQIPP
General Medical Council	Public Health England
Healthwatch England	Royal Pharmaceutical Society
National Voices	

ANNEX E

NHS England

Equality and Health Inequalities – Full Analysis - Items which should not be routinely prescribed in primary care

Update Nov 2017

Document Title: Equalities and Health Inequalities Full Analysis - Items which should not be routinely prescribed in primary care

Version number: V1

First published: July 2017

To be read in conjunction with the Equalities and Health Inequalities Analysis Guidance, Equality and Health Inequalities Unit, NHS England, July 2016

Classification: OFFICIAL-SENSITIVE: COMMERCIAL

This information can be made available in alternative formats, such as easy read or large print, and may be available in alternative languages, upon request. Please contact NHS England on england.medicines@nhs.net

PART A: General Information

1. Title of project, programme or work:
Items which should not be routinely prescribed in primary care

2. What are the intended outcomes?
Production of commissioning guidance, in partnership with NHS Clinical Commissioners, to advise CCGs on items which should not be routinely prescribed in primary care.

Recommendations will categorise items as one of the following;

- Items of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
- Items which are clinically effective but where more cost-effective products are available, this includes products that have been subject to excessive price inflation.
- Items which are clinically effective but due to the nature of the product, are deemed a low priority for NHS funding.

3. Who will be affected by this project, programme or work?

- Staff – primarily primary care prescribers who prescribe items in the finalised guidance. Other staff groups (for example community pharmacy staff, secondary care) will also be impacted and will have a role to support patients in changes to their therapies.
- Patients – who receive the prescription for items listed in the guidance.
- Partner organisations (for example NICE, MHRA). We are using recommendations from partner organisations and they will have a role to play in implementation.

4. Which groups protected by the Equality Act 2010 and/ or groups that face health inequalities are very likely to be affected by this work?

Proposals for CCG commissioning guidance

The 18 defined items within the review could potentially be prescribed to anyone in the population requiring them to treat a medical condition, therefore covering all characteristics. This is the case for all items included, apart from once daily tadalafil which would only be prescribed to men.

The profile of people who are currently being prescribed each item can only be interrogated accurately for age and sex as national prescribing data (Source: NHS Business Services Authority) is only available for these two characteristics.

Overall this prescribing data for 2016 indicates that on average, more females (61.3%) are prescribed the defined list of medicines than males (38.7%). 85% of liothyronine prescriptions in 2016 were for women which corresponds with national prevalence for hypothyroidism. Prescribing data for the hypertension drugs see a more equal male/female spilt and omega 3 prescribing in 2016 was more common in men (~ 70%). See 5.8 for more details.

Looking at the age profiles of patients prescribed medications in 2016 (see 5.1) on average, for adults, the prevalence of these medicines increases with age. This pattern is seen in both females and males with no significant differences in prevalence between age groups by gender. In most

cases, the proportion of prescriptions for children is very small at around one or two percent, except for herbal (19.3%), and homeopathic medicines (14.7%). The majority of medications were prescribed most frequently to adults aged 45 and over. Three of the medications were prescribed most frequently to over 65 year olds (glucosamine and chondroitin, co-proxamol, and lutein and antioxidants).

A literature review was also undertaken to explore research evidence including prevalence of patient characteristics for disease areas rather than individual medications such as chronic pain, hypertension and depression. The aim of this was to explore if there were indications that particular groups may be affected by the proposals in a more general sense. It should be noted that a caveat to this is that it provides some indication of the general population, although does not provide accurate information about the actual medicines in the review and if these generalisations about particular disease areas would apply to the particular cohorts being prescribed the medications in the review.
It is important to note that not doing this work also has an impact on all characteristics. **Some of the drugs in the review are shown to be unsafe, ineffective or have a more cost effective alternative. Without review and implementation by CCGs, inequalities to the wider population are likely due to unnecessary variation in prescribing and use of NHS funding on medications which are shown to be of low value. Money used on these products may displace funding on more evidence based and cost effective treatments. Not undertaking this work could result in inequality for the wider population by not making most effective use of the NHS prescribing budget and NHS budgets more generally.**

Consultation results

A 3 month consultation was undertaken from July – October 2017. This consultation provided an opportunity for views to be provided on the proposals for the 18 medicines and on the principle of restricting over the counter items. A full equality and health inequalities impact assessment will be undertaken for the policy development on over the counter (OTC) items. Appendix C includes an overview of key themes from the consultation for the 18 medicines. Key themes and results have also been reflected throughout the remainder of this document. The analysis undertaken as part of this equality and health inequalities impact assessment will be taken account of when considering the content of the final CCG guidance. It should be noted that the themes highlighted in appendix C should be considered within the wider context of the consultation results and report (see Items that should not be routinely prescribed in primary care consultation report, November 2017).

PART B: Equalities Groups and Health Inequalities Groups

5. Impact of this work for the equality groups listed below.

Focusing on each equality group listed below (sections 5.1. to 5.9), please answer the following questions:

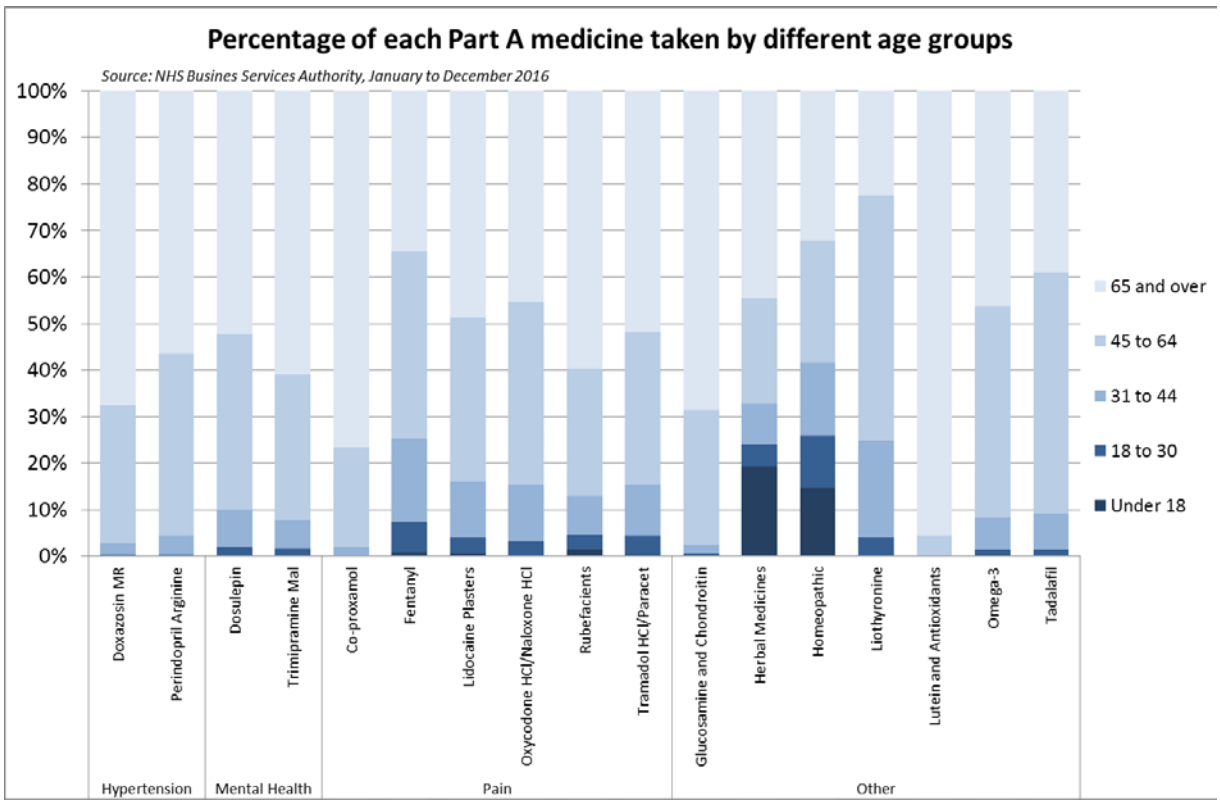
a) Does the equality group face discrimination in this work area?
b) Could the work tackle this discrimination and/or advance equality or good relations?
c) Could the work assist or undermine compliance with the Public Sector Equality Duty (PSED)?
d) Does any action need to be taken to address any important adverse impact? If yes, what action should be taken?
e) If you cannot answer these questions what action will be taken and when?

5.1. Age

Does the equality group face discrimination in this work area?
As people get older they are more likely to be taking prescribed medications, however there is no evidence to suggest that this prescribing is due to discrimination and is more likely due to increasing prevalence of various diseases related to increasing age.

Supporting Reference:
http://content.digital.nhs.uk/catalogue/PUB16076/HSE2013-Ch5-pres-meds.pdf

Figure 1. NHS BSA prescribing data 2016 by age (see appendix B for source data)



Could the work tackle this discrimination and/or advance equality or good relations?
Looking at the age profiles of patients prescribed the defined medications in 2016 on average, for adults, the prevalence of these medicines increases with age. This pattern is seen in both females and males with no significant differences in prevalence between age groups by gender. In most cases, the proportion of prescriptions for children is very small at around one or two percent, except for herbal (19.3%), and homeopathic medicines (14.7%). The majority of medications were prescribed most frequently to adults aged 45 and over. Three of the medications were prescribed in 70% of cases to over 65 year olds (glucosamine and chondroitin, co-proxamol, and lutein and antioxidants).

During the consultation, responses were monitored to ascertain if there are any unintended consequences on this protected characteristic, see appendix C for results. The demographic analysis of the patients who responded to the online consultation showed that the patients from the older age groups, particularly disagreed with the proposals for herbal treatments and homeopathy. Age was also reported as a protected characteristic likely to be disproportionately affected by this

work by 56% of those responding to the question 'Do you feel there any groups, protected by the Equality Act 2010, likely to be disproportionately affected by this work?'

Could the work assist or undermine compliance with the Public Sector Equality Duty (PSED)?
As people of increasing age take prescribed medicines, overall older people will receive more medicines from the category 'Items of low clinical effectiveness', where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns. This guidance, if adopted by CCGs, should prompt review of treatments meaning more people of an increasing age will receive reviews to optimise their treatment. It could assist in potentially reducing harm caused by certain medicines of which older people are more likely to receive.

Does any action need to be taken to address any important adverse impact? If yes, what action should be taken?
CCGs will be required to assess the impact on their population with regard to the particular demographics of the population they serve.

5.2. Disability

Does the equality group face discrimination in this work area?
There is no routinely collected data on prescribing and disability so we cannot definitively assess fully at a national level. Studies have identified that people with disability are more likely to suffer from chronic pain however it is unknown if this is applicable to the population taking the medications within the review.

During the consultation, responses were monitored to ascertain if there are any unintended consequences on this protected characteristic, see appendix C for results. The demographic analysis of the patients who responded to the online consultation showed that the patients who reported having a disability particularly disagreed with the proposals for herbal treatments, homeopathy, immediate release fentanyl, lidocaine plasters, liothyronine, paracetamol and tramadol and travel vaccines. Disability was also reported as a protected characteristic likely to be disproportionately affected by this work by 63% of those responding to the question 'Do you feel there any groups, protected by the Equality Act 2010, likely to be disproportionately affected by this work?' which was the highest reported protected characteristic for this question. A number of themes also emerged relating to disability including a concern that the proposal could adversely affect those who require considerable care (for example people with disabilities).

Could the work tackle this discrimination and/or advance equality or good relations?
This guidance, if adopted by CCGs, should prompt review of treatments meaning more people with a disability will receive reviews to optimise their treatment. It could assist in potentially reducing harm caused by certain medicines.

Could the work assist or undermine compliance with the Public Sector Equality Duty (PSED)?
There is the potential that it could assist in reducing harm caused by certain medicines if a person with a disability is more likely to receive them.

Does any action need to be taken to address any important adverse impact? If yes, what action should be taken?
Taking into account the consultation results and based on the clinical evidence, the CCG guidance has been updated to include a number of exceptions that take account of potential inequality e.g.

immediate release fentanyl for cancer and palliative care patients and liothyronine for patients with hypothyroidism, who, in exceptional circumstances, have an on-going need for liothyronine as confirmed by a consultant NHS endocrinologist.

CCGs will be required to assess the impact on their population with regard to the particular demographics of the population they serve.

5.3. Gender reassignment

Does the equality group face discrimination in this work area?
There is no routinely collected data on prescribing and gender reassignment so we cannot definitively assess, at a national level, how many people will be affected. None of the items included in the proposed guidance are used for the purposes of gender reassignment.

During the consultation, responses were monitored to ascertain if there were likely unintended consequences on the protected characteristic. There were no results from the consultation that indicated this.

Could the work tackle this discrimination and/or advance equality or good relations?
Unsure as we cannot accurately assess impact in the national population.

Could the work assist or undermine compliance with the Public Sector Equality Duty (PSED)?
Unsure as we cannot accurately assess impact in the national population.

Does any action need to be taken to address any important adverse impact? If yes, what action should be taken?
CCGs will also be required to assess the impact of their population with regard to the particular demographics of the population they serve.

5.4. Marriage and civil partnership

Does the equality group face discrimination in this work area?
There is no routinely collected data on prescribing and marriage/civil partnership so we cannot definitively assess, at a national level, how many people in a marriage/civil partnership will be affected. No link between prescribing and marriage/civil partnership has been identified.

During the consultation, responses were monitored to ascertain if there were likely unintended consequences on the protected characteristic. There were no results from the consultation that indicated this.

Could the work tackle this discrimination and/or advance equality or good relations?
Unsure as we cannot accurately assess impact in the national population.

Could the work assist or undermine compliance with the Public Sector Equality Duty (PSED)?
Unsure as we cannot accurately assess impact in the national population.

Does any action need to be taken to address any important adverse impact? If yes, what action should be taken?
CCGs will also be required to assess the impact of their population with regard to the particular

demographics of the population they serve.

5.5. Pregnancy and maternity

Does the equality group face discrimination in this work area?
There is no routinely collected data on prescribing and pregnancy/maternity so we cannot definitively assess, at a national level, how many people in a pregnancy/maternity partnership will be affected.

None of the items proposed in the guidance are used for conditions that are closely related to pregnancy or maternity. We assume that prescribers will use medications Summary of Product Characteristics to inform treatment if any of these medicines are going to be used in pregnancy to ensure a shared decision is reached.

During the consultation, responses were monitored to ascertain if there were likely unintended consequences on the protected characteristic. There were no results from the consultation that indicated this.

Could the work tackle this discrimination and/or advance equality or good relations?
Unsure as we cannot accurately assess impact in the national population.

Could the work assist or undermine compliance with the Public Sector Equality Duty (PSED)?
Unsure as we cannot accurately assess impact in the national population.

Does any action need to be taken to address any important adverse impact? If yes, what action should be taken?
CCGs will also be required to assess the impact of their population with regard to the particular demographics of the population they serve.

5.6. Race

Does the equality group face discrimination in this work area?
There is no routinely collected data on prescribing and race so we cannot definitively assess, at a national level, how many people will be affected.

During the consultation, responses were monitored to ascertain if there were likely unintended consequences on the protected characteristic. There were no results from the consultation that indicated this.

Could the work tackle this discrimination and/or advance equality or good relations?
Unsure as we cannot accurately assess impact in the national population.

Could the work assist or undermine compliance with the Public Sector Equality Duty (PSED)?
Unsure as we cannot accurately assess impact in the national population.

Does any action need to be taken to address any important adverse impact? If yes, what action should be taken?
CCGs will also be required to assess the impact of their population with regard to the particular

demographics of the population they serve.

5.7. Religion or belief

Does the equality group face discrimination in this work area?
There is no routinely collected data on prescribing and religious beliefs so we cannot definitively assess, at a national level, how many people will be affected. We have not identified any religious beliefs that would make you more or less likely to receive the items included in the guidance.

During the consultation, responses were monitored to ascertain if there were likely unintended consequences on the protected characteristic. There were no results from the consultation that indicated this.

Could the work tackle this discrimination and/or advance equality or good relations?
Unsure as we cannot accurately assess impact in the national population.

Could the work assist or undermine compliance with the Public Sector Equality Duty (PSED)?
Unsure as we cannot accurately assess impact in the national population.

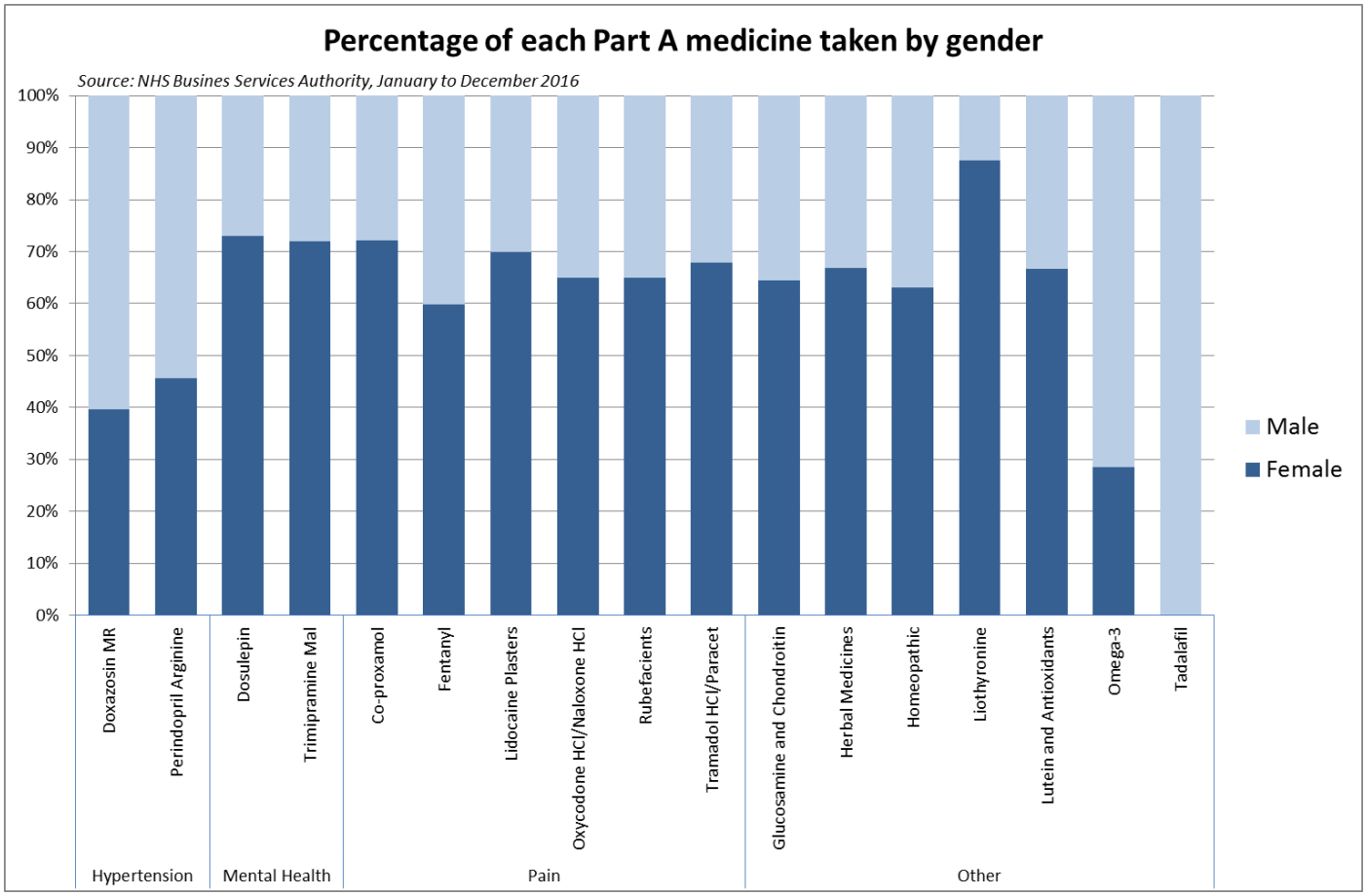
Does any action need to be taken to address any important adverse impact? If yes, what action should be taken?
CCGs will also be required to assess the impact of their population with regard to the particular demographics of the population they serve

5.8. Sex or gender

Does the equality group face discrimination in this work area?
43% of men and 50% of women take at least one prescribed medicine. This proportion is higher among young women than young men but increased with age more sharply in men than women. 22% of men and 24% of women report that they take at least three prescribed medicines and although this proportion increased with age it does not vary by sex.

Source
http://content.digital.nhs.uk/catalogue/PUB16076/HSE2013-Ch5-pres-meds.pdf

Figure 2. NHS BSA prescribing data 2016 by gender (see appendix B for source data)



One item on the list, once daily tadalafil, is used exclusively by men. It falls into the category Items which are clinically effective but where more cost-effective products are available, this includes products that have been subject to excessive price inflation. An alternative tadalafil product (i.e. tadalafil “when required”) will be available as well as alternative treatments.

During the consultation, responses were monitored to ascertain if there are any unintended consequences on this protected characteristic (see appendix C). The demographic analysis of the patients who responded to the online consultation showed that the female patients particularly disagreed with the proposals for liothyronine, herbal treatments and homeopathy. Gender was also reported as a protected characteristic likely to be disproportionately affected by this work by 31% of those responding to the question ‘Do you feel there any groups, protected by the Equality Act 2010, likely to be disproportionately affected by this work?’. A key theme reported for liothyronine was that the removal of this drug would adversely affect many people, mainly women who are more prone to hypothyroidism.

Could the work tackle this discrimination and/or advance equality or good relations?
Overall this prescribing data for 2016 indicates that on average, more females (60%) are prescribed these medicines than males (40%). This indicates that reviews and potential deprescribing may be most commonly required in women for the majority of medications, particularly the pain and depression medications where over 60% of those prescribed these medicines in 2016 were women. 85% of liothyronine prescriptions in 2016 were for women which corresponds with national prevalence for hypothyroidism (Appendix A). Prescribing data for the

hypertension drugs see a more equal male/female spilt and omega 3 prescribing in 2016 was more common in men (~ 70%). This guidance, if adopted by CCGs, should prompt review of treatments meaning more people will receive reviews to optimise their treatment from the groups above.

Could the work assist or undermine compliance with the Public Sector Equality Duty (PSED)?
There is the potential that it could assist in potentially reducing harm caused by certain medicines which particular genders are more likely to receive.

Does any action need to be taken to address any important adverse impact? If yes, what action should be taken?
Taking into account the consultation results and based on the clinical evidence, the CCG guidance has been updated to include a number of exceptions for liothyronine.

CCGs will also be required to assess the impact of their population with regard to the particular demographics of the population they serve.

5.9. Sexual orientation

Does the equality group face discrimination in this work area?
There is no routinely collected data on prescribing and sexual orientation so we cannot definitively assess, at a national level, how many people will be affected. There is no established link between prescribing of items proposed in this guidance and sexual orientation.

During the consultation, responses were monitored to ascertain if there were likely unintended consequences on the protected characteristic. There were no results from the consultation that indicated this.

Could the work tackle this discrimination and/or advance equality or good relations?
Unsure as we cannot accurately assess impact in the national population.

Could the work assist or undermine compliance with the Public Sector Equality Duty (PSED)?
Unsure as we cannot accurately assess impact in the national population.

Does any action need to be taken to address any important adverse impact? If yes, what action should be taken?
CCGs will also be required to assess the impact of their population with regard to the particular demographics of the population they serve.

6. Implications of our work for the health inclusion groups listed below.
Focusing on the work described in sections 1 and 2, in relation to each health inclusion group listed below (Sections 6.1. To 6.12), and any others relevant to your work[1], please answer the following questions:

[1] Our guidance document explains the meaning of these terms if you are not familiar with the language.

f) Does the health inclusion group experience inequalities in access to healthcare?
g) Does the health inclusion group experience inequalities in health outcomes?
h) Could the work be used to tackle any identified inequalities in access to healthcare or health outcomes?
i) Could the work assist or undermine compliance with the duties to reduce health inequalities?
j) Does any action need to be taken to address any important adverse impact? If yes, what action should be taken?
k) As some of the health inclusion groups overlap with equalities groups you may prefer to also respond to these questions about a health inclusion group when responding to 5.1 to 5.9. That is fine; please just say below if that is what you have done.
l) If you cannot answer these questions what action will be taken and when?

6.1. Alcohol and / or drug misusers

None of the medicines in the review are specifically used in the treatment of addiction. There is no data available on the prevalence of alcohol of drug users who are currently prescribed the medications in the review. There was no indication from the consultation results that the proposals would result in this health inclusion group experiencing inequalities in access to healthcare or health outcomes.

6.2. Asylum seekers and /or refugees

There is no data available on the prevalence of asylum seekers and/or refugees who are currently prescribed the medications in the review. There was no indication from the consultation results that the proposals would result in this health inclusion group experiencing inequalities in access to healthcare or health outcomes.

6.3. Carers

There is no data available on the prevalence of carers who are currently prescribed the medications in the review. There was no indication from the consultation results that the proposals would result in this health inclusion group experiencing inequalities in access to healthcare or health outcomes.

6.4. Ex-service personnel / veterans

There is no data available on the prevalence of ex-service personnel / veterans who are currently prescribed the medications in the review. There was no indication from the consultation results that the proposals would result in this health inclusion group experiencing inequalities in access to healthcare or health outcomes.

6.5. Those who have experienced Female Genital Mutilation (FGM)

There is no data available on the prevalence of those who have experienced Female Genital Mutilation (FGM) who are currently prescribed the medications in the review. There was no indication from the consultation results that the proposals would result in this health inclusion group experiencing inequalities in access to healthcare or health outcomes.

6.6. Gypsies, Roma and travellers

There is no data available on the prevalence of Gypsies, Roma and travellers who are currently prescribed the medications in the review.

The consultation received a response from the Friends and Families of Travellers highlighting that gypsy and traveller communities face the worse health, education and life outcomes of any group

within UK. They recommended implementing a system where doctors will only prescribe these medicines to people that really can't afford to pay for it as well as an awareness campaign aimed at this community. As this statement refers to medicines that are available OTC it is applicable to the items from the list of 18 that are also available OTC.

6.7. Homeless people and rough sleepers

There is no data available on the prevalence of homeless people and rough sleepers who are currently prescribed the medications in the review. There was no indication from the consultation results that the proposals would result in this health inclusion group experiencing inequalities in access to healthcare or health outcomes.

6.8. Those who have experienced human trafficking or modern slavery

There is no data available on the prevalence of those who have experienced human trafficking or modern slavery who are currently prescribed the medications in the review. There was no indication from the consultation results that the proposals would result in this health inclusion group experiencing inequalities in access to healthcare or health outcomes.

6.9. Those living with mental health issues

Two medicines that are being proposed in the guidance, dosulepin and trimipramine, are used for the treatment of mental health conditions. There are significant safety concerns with dosulepin, so by optimising people's treatment for mental health it may improve outcomes and reduce the chance of a person with mental health issues experiencing a negative safety impact from their prescribed medicines. Trimpramine is not a recognised first line treatment for mental health issues so by having a review of treatment it may identify more appropriate treatment options.

The ONS releases an annual report on the numbers of people who died in the previous year from poisoning which includes suicides. There is good evidence (World Health Organisation) that reducing access to means (including toxic medications) can reduce deaths from suicides. From the items being proposed in the guidance; co-proxamol, fentanyl and dosulepin are all analysed individually in the report showing deaths. Deaths related to trimipramine, tramadol and paracetamol combination, oxycodone and naloxone could be included but due to the way the data is presented it is not possible to definitively identify. Reducing prescribing of these medicines can potentially contribute in reducing access to means and therefore deaths from suicides.

There was no indication from the consultation results that the proposals would result in this health inclusion group experiencing inequalities in access to healthcare or health outcomes.

6.10.Sex workers

There is no data available on the prevalence of sex workers who are currently prescribed the medications in the review. There was no indication from the consultation results that the proposals would result in this health inclusion group experiencing inequalities in access to healthcare or health outcomes.

6.11.Trans people or other members of the non-binary community

There is no data available on trans people or other members of the non-binary community who are currently prescribed the medications in the review. There was no indication from the consultation results that the proposals would result in this health inclusion group experiencing inequalities in access to healthcare or health outcomes.

6.12.The overlapping impact on different groups who face health inequalities

There is no data available on different groups who face health inequalities who are currently prescribed the medications in the review.

There was no indication from the consultation results that the proposals would result in this health inclusion group experiencing inequalities in access to healthcare or health outcomes.

7. Other groups that face health inequalities that we have identified.

Have you have identified other groups that face inequalities in access to healthcare?

Does the group experience inequalities in access to healthcare and/or inequalities in health outcomes?
n/a as above.

Short explanatory notes - other groups that face health exclusion.
As we research and gather more data, we learn more about which groups are facing health inequalities. If your work has identified more groups that face important health inequalities please answer questions 7 and 8. Please circle as appropriate.

If you have not identified additional groups, that face health inequalities, just say not applicable or N/A in the box below.

Yes Complete section 8	**No** Go to section 9	N/A

N/A

8. Other groups that face health inequalities that we have identified.

PART C: Promoting integrated services and working with partners

Short explanatory notes: Integrated services and reducing health inequalities.

Our detailed guidance explains the duties in relation to integrated services and reducing health inequalities. Please answer the questions listed below.

9. Opportunities to reduce health inequalities through integrated services.

Does the work offer opportunities to encourage integrated services that could reduce health inequalities? If yes please also answer 10.

Yes Go to section 10	**No** Go to section 11	Do not know

No

10. How can this work increase integrated services and reduce health inequalities?

Please explain below, in a few short sentences, how the work will encourage more integrated services that reduce health inequalities and which partners we will be working with.

PART D: Engagement and involvement

11. Engagement and involvement activities already undertaken.

How were stakeholders, who could comment on equalities and health inequalities engaged, or involved with this work? For example in gathering evidence, commenting on evidence, commenting on proposals or in other ways? And what were the key outputs?

NHS England established a working group in partnership with NHS Clinical Commissioners with membership from their own organisations plus partner organisations. On June 13 a stakeholder session with wider partners and patient groups was invited to contribute their views on the proposals. The attendance at this meeting included representatives of;

- National Voices
- Healthwatch
- Patient Association
- British Medical Association – General Practice Council
- Royal Pharmaceutical Society
- British Generic Manufactures Association (BGMA)
- Association British Pharmaceutical Industry (ABPI)
- PrescQIPP

Comments and suggestions were received on how to consult and reach further group

affected by the proposals.

A 3 month consultation was undertaken from July – October 2017. This consultation provided an opportunity for views to be provided on the proposals for the 18 medicines. As part of this consultation 5544 online responses and almost 200 written responses were received. A programme of engagement was also undertaken including webinars and engagement events with key stakeholder groups e.g. patients, professionals, CCGs, parliamentarians.

12. Which stakeholders and equalities and health inclusion groups were involved?

NHS England, NHS Clinical Commissioners, Royal Pharmaceutical Society, NICE, Department of Health, PrescQIPP, NHS Business Services Authority, Royal College of GPs, Academy of Medical Royal Colleges, National Voices, Patients Association, Healthwatch England.

The consultation had involvement of a number of stakeholders and equalities and health inclusion groups (see Items that should not be routinely prescribed in primary care consultation report, November 2017).

13. Key information from the engagement and involvement activities undertaken.

Were key issues, concerns or questions expressed by stakeholders and if so what were these and how were they addressed? Were stakeholders broadly supportive of this work?

Stakeholders are broadly supportive of the work on the proposals for the initial list of 18 items and concerns relating the equalities and health inequalities raised by stakeholders are reflected in appendix C and throughout this review.

14. Stakeholders were not broadly supportive but we need to go ahead.

If stakeholders were not broadly supportive of the work but you are recommending progressing with the work anyway, why are you making this recommendation?

For some of the 18 items there are groups that are not broadly supportive of the specific recommendations. Further details can be found in appendix C and the ‘Items that should not be routinely prescribed in primary care consultation report (Nov 2017).

15. Further engagement and involvement activities planned.

Are further engagement and involvement activities planned? If so what is planned, when and why?

Publication of the final CCG guidance on the 30 November, alongside the results from the

consultation.

PART E: Monitoring and Evaluation

16. In relation to equalities and reducing health inequalities, please summarise the most important monitoring and evaluation activities undertaken in relation to this work

Analysis, reporting and consideration of the prescribing data and consultation responses.

17. Please identify the main data sets and sources that you have drawn on in relation to this work. Which key reports or data sets have you drawn on?

NHS Business Services Authority (BSA) prescribing data, Jan – Dec 2016.

http://content.digital.nhs.uk/catalogue/PUB16076/HSE2013-Ch5-pres-meds.pdf
http://content.digital.nhs.uk/catalogue/PUB23631/pres-cost-anal-eng-2016-rep.pdf

Please see appendix A for further evidence and literature references and sources.

Items that should not be routinely be prescribed in primary care consultation report (Nov 2017)

18. Important equalities or health inequalities data gaps or gaps in relation to evaluation.

In relation to this work have you identified any:

- important equalities or health inequalities data gaps or
- gaps in relation to monitoring and evaluation?

Yes	No

There is currently no nationally collected data for 7 or the 9 characteristics and additional health improvement groups for the individual medications in this review.

19. Planned action to address important equalities or health inequalities data gaps or gaps in relation to evaluation.

If you have identified important gaps and you have identified action to be taken, what action are you planning to take, when and why?

This is something that individual CCGs may have more insight on when looking at their local population data and will be encouraged to consider this as part of local consultation and impact assessment.

PART F: Summary analysis and recommended action		
20. Contributing to the first PSED equality aim. Can this work contribute to eliminating discrimination, harassment or victimisation?		
Yes	**No**	Do not know
If yes please explain how, in a few short sentences		
N/A		
21. Contributing to the second PSED equality aim. Can this policy or piece of work contribute to advancing equality of opportunity? Please circle as appropriate.		
Yes	No	Do not know
Currently patients could be receiving medications that are unsafe, ineffective or where there is a more cost effective alternative available. By setting a national direction on a set of defined medications this project encourages CCGs to implement policy that encourages review of patients taking these medications to ensure that their treatment is optimised. This enables patients to have access to the most effective medications to achieve the best outcomes. If more cost effective options are utilised this frees up funding for other care and treatment to optimise wider population benefit and outcomes.		
22. Contributing to the third PSED equality aim. Can this policy or piece of work contribute to fostering good relations between groups? Please circle as appropriate.		
Yes	No	Do not know
The Low Value Medicines working group includes representatives from NHSCC, CCG medicines optimisation teams, NICE etc. We are also working with other stakeholders as described in question 12. The common aim to ensure that the CCG guidance developed supports CCGs in effective medicines optimisation for the population they serve. Fostering of good relationships will also be enhanced through engagement with a number of other stakeholders including charities and patient groups. The consultation also provided an opportunity for organisations, health professionals, patients and the public to be considered in the development of the CCG guidance.		

23. Contributing to reducing inequalities in access to health services.

Can this policy or piece of work contribute to reducing inequalities in access to health services?

Yes	No	Do not know

Currently patients could be receiving medications that are unsafe, ineffective or where there is a more cost effective alternative available. By setting a national direction on a set of defined medications this project encourages CCGs to implement policy that encourages review of patients taking these medications to ensure that their treatment is optimised. This enables patients to have access to the most effective medications to achieve the best outcomes. If more cost effective options are utilised this frees up funding for other care and treatment to optimise wider population benefit and outcomes.

Patients currently taking the medication will benefit. If CCGs implement the guidance once finalised, all patients being prescribed the included medications should be considered for medication review aiming to optimise their treatment and outcomes. There are also wider population gains than those who may benefit from the more efficient use of the money currently spent on low value medicines.

CCGs will need to consider this national impact assessment and the report form the national consultation when undertaking their own consultation and impact assessment as part of local implementation. This will help ensure that specific groups locally are not impacted adversely.

24. Contributing to reducing inequalities in health outcomes.

Can this work contribute to reducing inequalities in health outcomes?

Yes	No	Do not know

See section 23.

25. Contributing to the PSED and reducing health inequalities.

How will the policy or piece of work contribute to the achieving the PSED and reducing health inequalities in access and outcomes? Please describe below in a few short sentences.

As section 23

26. Agreed or recommended actions.

What actions are proposed to address any key concerns identified in this Equality and Health Inequalities Analysis (EHIA) and / or to ensure that the work contributes to the reducing unlawful discrimination / acts, advancing equality of opportunity, fostering

good relations and / or reducing health inequalities? Is there a need to review the EHI analysis at a later stage?				
Action	Public Sector Equality Duty	Health Inequality	By when	By whom
Ensure that CCGs are encouraged to consider their local demographic and prescribing data available to ensure that local implementation decisions are effective and in line with legislation.	Yes	Yes	Post national consultation	CCGs
Support implementation with resources referenced in the guidance to support prescribers with deprescribing and offer of alternative medication where appropriate.	Yes	Yes	Post consultation	Project team LVM working group

Appendix A

Equalities and Health Inequalities Evidence Search

Pain (Co-proxamol, Lidocaine Plasters, Rubefacients, Fentanyl Immediate Release, Paracetamol & Tramadol, Oxycodone & Naloxone)

The following evidence does indicate that the prevalence of chronic pain increases with age was higher among females, and in people with disability, low income and low educational level. The evidence also suggests that females may be more likely to report pain and that there are lots of other influencing factors which would affect the epidemiology of different types of chronic pain. The draft recommendations for all of the pain medications ensure that patients would be offered a suitable alternative. Where required this would involve an MDT of other health professionals. There are no recommendations that result in patients being disadvantaged by offering no pain relief or an alternative that was not agreed collaboratively by the patient and clinician.

For the recommendations that reflect NICE guidance an equality impact assessment has been undertaken as part of the development of this guideline as follows:

- NICE CG173 Neuropathic pain in adults: pharmacological management in non-specialist settings (includes Lidocaine plasters)
- NICE CG177 Osteoarthritis (includes do not do for rubefacients)
- NICE CG140 Opioids in Palliative Care (includes fentanyl immediate release)

Prevalence of chronic pain in the UK: a systematic review and meta-analysis of population studies (Fayaz, 2016)
The prevalence of chronic pain, derived from 7 studies, ranged from 35.0% to 51.3% (pooled estimate 43.5%, 95% CIs 38.4% to 48.6%). The prevalence of moderate-severely disabling chronic pain (Von Korff grades III/IV), based on 4 studies, ranged from 10.4% to 14.3%. 12 studies stratified chronic pain prevalence by age group, demonstrating a trend towards increasing prevalence with increasing age from 14.3% in 18–25 years old, to 62% in the over 75 age group, although the prevalence of chronic pain in young people (18–39 years old) may be as high as 30%. Reported prevalence estimates were summarised for chronic widespread pain (pooled estimate 14.2%, 95% CI 12.3% to 16.1%; 5 studies), chronic neuropathic pain (8.2% to 8.9%; 2 studies) and fibromyalgia (5.4%; 1 study). Chronic pain was more common in female than male participants, across all measured phenotypes.

National pain audit (2013)
The prevalence of chronic pain is estimated at 8-60% of the population, depending on the definition. Severe pain is estimated at 11% for adults and 8% for children. Older age, female sex, poor housing and type of employment (for example heavy manual work) are significant predictors of chronic pain in the community.

The epidemiology of chronic pain in the community (1999, Elliott et al)
A survey in Scotland (n = 3605) identified age, sex, housing tenure, and employment status as significant predictors of the presence of chronic pain in the community.

https://www.ncbi.nlm.nih.gov/pubmed/11166468
Chronic pain in Australia: a prevalence study (Blyth et al, 2001)
This study reports chronic pain prevalence in a randomly selected sample of the

adult Australian population. Data were collected by Computer-Assisted Telephone Interview (CATI) (n = 17,543) Having chronic pain was significantly associated with older age, female gender, lower levels of completed education, and not having private health insurance; it was also strongly associated with receiving a disability benefit (adjusted OR=3.89, P<0.001) or unemployment benefit (adjusted OR=1.99, P<0.001); being unemployed for health reasons (adjusted OR=6.41, P<0.001); having poor self-rated health (adjusted OR=7.24, P<0.001); and high levels of psychological distress (adjusted OR=3.16, P<0.001).

http://ovidsp.uk.ovid.com/sp-3.25.0a/ovidweb.cgi?&S=HBIEPDNJPPHFFLLOFNGKOHEGHGHAAA00&Abstract=S.sh.91%7c99%7c1

Chronic pain: One year prevalence and associated characteristics, the HUNT pain study (Elsevier, 2013)

The total prevalence of chronic pain was 36% (95% CI 34-38) among women and 25% (95% CI 22-26) among men. The prevalence increased with age, was higher among people with high BMI, and in people with low income and low educational level.

http://ovidsp.uk.ovid.com/sp-3.25.0a/ovidweb.cgi?&S=HBIEPDNJPPHFFLLOFNGKOHEGHGHAAA00&Complete+Reference=S.sh.91%7c405%7c1

The prevalence of chronic pain in united states adults: Results of an internet-based survey (Johannas, 2010)

A cross-sectional, Internet-based survey was conducted in a nationally representative sample of United States (US) adults to estimate the point prevalence of chronic pain and to describe sociodemographic correlates and characteristics of chronic pain (n = 27,035). The weighted point-prevalence of chronic pain (defined as chronic, recurrent, or long-lasting pain lasting for at least 6 months) was 30.7% (95% CI, 29.8-31.7). Prevalence was higher for females (34.3%) than males (26.7%) and increased with age. Multiple logistic regression analysis identified low household income and unemployment as significant socioeconomic correlates of chronic pain. Chronic pain is prevalent among US adults and is related to indicators of poorer socioeconomic status

Gender considerations in the epidemiology of chronic pain (LeResche, 1999)

Indicates age and sex differences for different types of chronic pain conditions. Some indication that women may be more likely to report chronic pain, although this may not be a true indication of cases in the population.

Omega-3

NICE have undertaken an equality impact assessment for each of their guidelines where the 'do not do' recommendations originate from these are referenced as follows. The recommendations for Omega- 3 are reflecting the NICE recommendations.

MI secondary prevention
https://www.nice.org.uk/guidance/cg172/documents/mi-secondary-prevention-update-equality-impact-assessment-form2

Cardiovascular disease: risk assessment and reduction, including lipid modification
https://www.nice.org.uk/guidance/cg181/documents/lipid-modification-update-equality-impact-assessment-form-scoping2

Familial hypercholesterolaemia: identification and management
https://www.google.co.uk/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwjJ0eybkM_UAhUFKVAKHTogBLMQFgglMAA&url=https%3A%2F%2Fwww.nice.org.uk%2Fguidance%2Fgid-cgwave0825%2Fdocuments%2Fequality-impact-assessment&usg=AFQjCNEaNBGaVw2HH8wQ60MkqRVqm7Fg3Q

Non-alcoholic fatty liver disease (NAFLD): assessment and management
https://www.nice.org.uk/guidance/ng49/documents/equality-impact-assessment-2
https://www.nice.org.uk/guidance/ng49/documents/equality-impact-assessment-3

Autism spectrum disorder in under 19s: support and management
https://www.nice.org.uk/guidance/cg170/documents/autism-management-of-autism-in-children-and-young-people-guideline-eia2

Multiple sclerosis in adults: management
https://www.nice.org.uk/guidance/cg186/documents/multiple-sclerosis-2014-equality-impact-assessment-scoping2

Mental Health (Dosulepin, Trimpramine)

The following evidence does indicate that common mental health disorders are more prevalent with some of the protected characteristics (see below for details). The draft recommendations for the above medications ensure that patients would be offered a suitable alternative. Where required this would involve an MDT of other health professionals. There are no recommendations that result in patients being disadvantaged by offering no alternative or one that was not agreed collaboratively by the patient and clinician.

The recommendations reflect NICE guidance on depression in adults and an equality impact assessment has been undertaken as part of the development of this guideline.

https://www.nice.org.uk/guidance/gid-cgwave0725/documents/equality-impact-assessment-2

https://www.nice.org.uk/guidance/gid-cgwave0725/documents/equality-impact-assessment-3

McManus S, Bebbington P, Jenkins R, Brugha T. (eds.) (2016). Mental health and wellbeing in England: Adult psychiatric morbidity survey 2014**. Leeds: NHS digital.**

One in three adults aged 16-74 (37 per cent) with conditions such as anxiety or depression, surveyed in England, were accessing mental health treatment, in 2014. This figure has increased from one in four (24 per cent) since the last survey was carried out in 2007. Overall, around one in six adults (17 per cent) surveyed in England met the criteria for a common mental disorder (CMD) in 2014.

Women were more likely than men to have reported CMD symptoms. One in five women (19 per cent) had reported CMD symptoms, compared with one in eight men (12 per cent). Women were also more likely than men to report severe symptoms of CMD - 10 per cent of women surveyed reported severe symptoms compared to 6 per cent of men.

Age
CMD symptoms were associated with age. Overall, working-age people were around twice as likely to have symptoms of CMD as those aged 65 and over. Between 16 and 64, the proportion with CMD symptoms remained around 17%–18%. But among those aged 65 and over the rate was much lower
(10.2% of 65 to 74 year olds and 8.1% of those aged 75 and over). A similar pattern was observed for severe symptoms of CMD.

Ethnic group
In men, prevalence of CMD did not vary significantly by ethnic group, whereas it did in women. Using age-standardised figures, non-British White women were less likely than White British women to have a CMD (15.6%, compared with 20.9% respectively), while CMDs were more common in Black and Black British women

(29.3%). Perhaps because of small sample sizes, differences between ethnic groups in rates of specific disorders were not statistically significant. However, depression appeared to be more prevalent among Black women.

Disability
Overall, just over a quarter of adults (27.7%) reported having at least one of the five chronic physical conditions considered in this chapter diagnosed, and present in the last 12 months. High blood pressure was the most common, followed by asthma, diabetes, and cancer.

Other
Adults aged between 16 and 59 who lived alone were significantly more likely to have CMD than people who lived with others. Employed adults were less likely to have a CMD than those who were economically inactive or unemployed. Two-thirds of adults aged 16 to 64 in receipt of Employment and Support Allowance (ESA, a disability-related out-of-work benefit) had a CMD (66.1%), compared with one in six adults not in receipt of this benefit (16.9%). More than four in five women in receipt of ESA had a CMD (81.0%), compared with one in five (21.1%) of those not in receipt.

CMDs were more prevalent in certain groups of the population. These included Black women, adults under the age of 60 living alone, women living in large households, adults who were not in employment or who were in receipt of benefits and those who smoked cigarettes.

Common Mental Health Disorders data (PHE fingertips data, 2014/2015)

Indicator	Period	England
Estimated prevalence of common mental health disorders: % of population aged 16-74	2014/15	15.6*
Depression recorded prevalence (QOF): % of practice register aged 18+	2015/16	8.3
Depression recorded incidence (QOF): % of practice register aged 18+	2015/16	1.4
Long-term mental health problems (GP Patient Survey): % of respondents (aged 18+)	2015/16	5.2
Depression and anxiety prevalence (GP Patient Survey): % of respondents aged 18+	2015/16	12.7

*estimated

Liothyronine

The following evidence does indicate hypothyroidism is more prevalent with some of the protected characteristics (see below for details). The draft recommendations for liothyronine ensure that patients would be offered a suitable alternative. Where required this would involve an MDT of other health professionals. There are no recommendations that result in patients being disadvantaged by offering no alternative or one that was not agreed collaboratively by the patient and clinician.

QOF prevalence for hypothyroidism (2013/2014) – 3.3%

Vanderpump MPJ. Braverman LE, Utiger RD. The epidemiology of thyroid diseases, Werner and Ingbar's The Thyroid: A Fundamental and Clinical Text , 2005, 9th edn, Philadelphia, JB Lippincott-Raven (pg. 398-496)

In iodine-replete communities, the prevalence of spontaneous hypothyroidism is between 1 and 2%, and it is more common in older women and 10 times more common in women than in men. Studies in Northern Europe, Japan and the USA have found the prevalence to range between 0.6 and 12 per 1000 women and between 1.3 and 4.0 per 1000 in men investigated. The prevalence is higher in surveys of the elderly in the community. Overt hypothyroidism was found in 7% of 558 subjects aged between 85 and 89 years in Leiden, Netherlands. A lower prevalence is seen in areas of iodine deficiency.

Flynn RV, MacDonald TM, Morris AD, et al. The thyroid epidemiology, audit and research study; thyroid dysfunction in the general population, J Clin Endocrinol Metab , 2004, vol. 89 (pg. 3879-84)

Data from the large population study in Tayside, UK has demonstrated that the standardized incidence of primary hypothyroidism varied between 3.90 and 4.89 per 1000 women per year between 1993 and 2001. The incidence of hypothyroidism in men significantly increased from 0.65 to 1.01 per 1000 per year (P = 0.0017). The mean age at diagnosis of primary hypothyroidism decreased in women from 1994 to 2001.

Hypertension (Doxazosin, Perindopril)
The following evidence does indicate hypertension is more prevalent with some of the protected characteristics (see below for details). The draft recommendations these drugs ensure that patients would be offered a suitable alternative. Where required this would involve an MDT of other health professionals. There are no recommendations that result in patients being disadvantaged by offering no alternative or one that was not agreed collaboratively by the patient and clinician

Knott C, Mindell J. Health Survey for England - 2011: Chapter 3, Hypertension. Leeds, UK: Health and Social Care Information Centre, 2012.

Age/sex
The relationship between age and the prevalence of hypertension
differed between the sexes the prevalence of survey-defined hypertension was significantly higher in men than women across each age group apart from those aged 65 and over.

Deprivation
Mirroring the trends found with equivalised household income, the age-standardised prevalence of hypertension was highest among those living in areas of high deprivation. Prevalence rose from 26% of men and 23% of women in the least deprived quintile to 34% of men and 30% of women in the most deprived quintile.

2015/2016 QOF recorded prevalence for hypertension
The highest prevalence rates are for **Hypertension (13.8 per cent)**, Obesity (9.5 per cent) and Depression (8.3 per cent).

Hypertension (7.9 million), Obesity (4.3 million) and Depression (3.8 million) are the conditions reporting the highest register numbers.

National CVD Intelligence network (2014)
Estimated expected prevalence per total population = 23.6% (includes undiagnosed estimates)
NICE Equality Impact assessment for Hypertension CG34

NICE Equality Impact assessment for hypertension in pregnancy CG107

Appendix B

Patients prescribed Part A medicines, by gender

Prescriptions dispensed Jan - Dec 2016 *Source: NHS Business Services Authority*

	Number of patients			Percentage of patients		
	Female	**Male**	**Total**	**Female**	**Male**	**Total**
Hypertension	**53,939**	**79,726**	**133,665**	**40.4%**	**59.6%**	**100.0%**
Doxazosin MR	45,811	70,020	115,831	39.5%	60.5%	100.0%
Perindopril Arginine	8,128	9,706	17,834	45.6%	54.4%	100.0%
Mental Health	**93,183**	**34,458**	**127,641**	**73.0%**	**27.0%**	**100.0%**
Dosulepin	87,525	32,262	119,787	73.1%	26.9%	100.0%
Trimipramine Mal	5,658	2,196	7,854	72.0%	28.0%	100.0%
Pain	**388,707**	**203,092**	**591,799**	**65.7%**	**34.3%**	**100.0%**
Co-proxamol	5,591	2,153	7,744	72.2%	27.8%	100.0%
Fentanyl	3,834	2,571	6,405	59.9%	40.1%	100.0%
Lidocaine Plasters	50,396	21,767	72,163	69.8%	30.2%	100.0%
Oxycodone HCl/Naloxone HCl	7,612	4,112	11,724	64.9%	35.1%	100.0%
Rubefacients	302,161	163,411	465,572	64.9%	35.1%	100.0%
Tramadol HCl/Paracet	19,113	9,078	28,191	67.8%	32.2%	100.0%
Other	**29,013**	**59,175**	**88,188**	**32.9%**	**67.1%**	**100.0%**
Glucosamine and Chondroitin	1,273	703	1,976	64.4%	35.6%	100.0%
Herbal Medicines	2,021	1,002	3,023	66.9%	33.1%	100.0%
Homeopathic	1,541	899	2,440	63.2%	36.8%	100.0%
Liothyronine	11,432	1,628	13,060	87.5%	12.5%	100.0%
Lutein and Antioxidants	4,661	2,337	6,998	66.6%	33.4%	100.0%
Omega-3	8,042	20,118	28,160	28.6%	71.4%	100.0%
Tadalafil	43	32,488	32,531	0.1%	99.9%	100.0%
Grand Total	**564,842**	**376,451**	**941,293**	**60.0%**	**40.0%**	**100.0%**

Notes: Data for three patients omitted as no gender data available. Includes only prescriptions dispensed in the community

Patients prescribed Part A medicines, by age

Source: NHS

Prescriptions dispensed Jan - Dec 2016

	Number of patients						Percentage of patients				
	Under 18	**18 to 30**	**31 to 44**	**45 to 64**	**65 and over**	**Total**	**Under 18**	**18 to 30**	**31 to 44**	**45 to 64**	**65 and over**
Hypertension	**8**	**377**	**3,763**	**41,132**	**88,385**	**133,665**	**0.0%**	**0.3%**	**2.8%**	**30.8%**	**66.1%**
Doxazosin MR	4	322	3,049	34,144	78,312	115,831	0.0%	0.3%	2.6%	29.5%	67.6%
Perindopril Arginine	4	55	714	6,988	10,073	17,834	0.0%	0.3%	4.0%	39.2%	56.5%
Mental Health	**68**	**2,547**	**10,142**	**47,554**	**67,330**	**127,641**	**0.1%**	**2.0%**	**7.9%**	**37.3%**	**52.7%**
Dosulepin	55	2,427	9,657	45,102	62,546	119,787	0.0%	2.0%	8.1%	37.7%	52.2%
Trimipramine Mal	13	120	485	2,452	4,784	7,854	0.2%	1.5%	6.2%	31.2%	60.9%
Pain	**7,966**	**18,849**	**52,722**	**170,877**	**341,388**	**591,802**	**1.3%**	**3.2%**	**8.9%**	**28.9%**	**57.7%**
Co-proxamol		11	144	1,658	5,931	7,744	0.0%	0.1%	1.9%	21.4%	76.6%
Fentanyl	52	422	1,141	2,581	2,209	6,405	0.8%	6.6%	17.8%	40.3%	34.5%
Lidocaine Plasters	450	2,523	8,634	25,522	35,034	72,163	0.6%	3.5%	12.0%	35.4%	48.5%
Oxycodone HCl/Naloxone HCl	8	365	1,418	4,620	5,313	11,724	0.1%	3.1%	12.1%	39.4%	45.3%
Rubefacients	7,369	14,356	38,316	127,268	278,266	465,575	1.6%	3.1%	8.2%	27.3%	59.8%
Tramadol HCl/Paracet	87	1,172	3,069	9,228	14,635	28,191	0.3%	4.2%	10.9%	32.7%	51.9%
Other	**976**	**1,454**	**5,893**	**25,871**	**25,834**	**60,028**	**1.6%**	**2.4%**	**9.8%**	**43.1%**	**43.0%**
Glucosamine and Chondroitin	2	12	34	571	1,357	1,976	0.1%	0.6%	1.7%	28.9%	68.7%
Herbal Medicines	584	145	261	689	1,344	3,023	19.3%	4.8%	8.6%	22.8%	44.5%
Homeopathic	359	273	386	635	787	2,440	14.7%	11.2%	15.8%	26.0%	32.3%

Liothyronine	28	511	2,705	6,872	2,944	13,060	0.2%	3.9%	20.7%	52.6%	22.5%
Lutein and Antioxidants			6	301	6,691	6,998	0.0%	0.0%	0.1%	4.3%	95.6%
Omega-3	73	346	1,924	12,803	13,014	28,160	0.3%	1.2%	6.8%	45.5%	46.2%
Tadalafil	3	513	2,501	16,803	12,711	32,531	0.0%	1.6%	7.7%	51.7%	39.1%
Grand Total	**9,091**	**23,573**	**74,444**	**298,237**	**535,951**	**941,296**	**1.0%**	**2.5%**	**7.9%**	**31.7%**	**56.9%**

Notes: Data for three patients omitted as no gender data available. Includes only prescriptions dispensed in the community

Appendix C

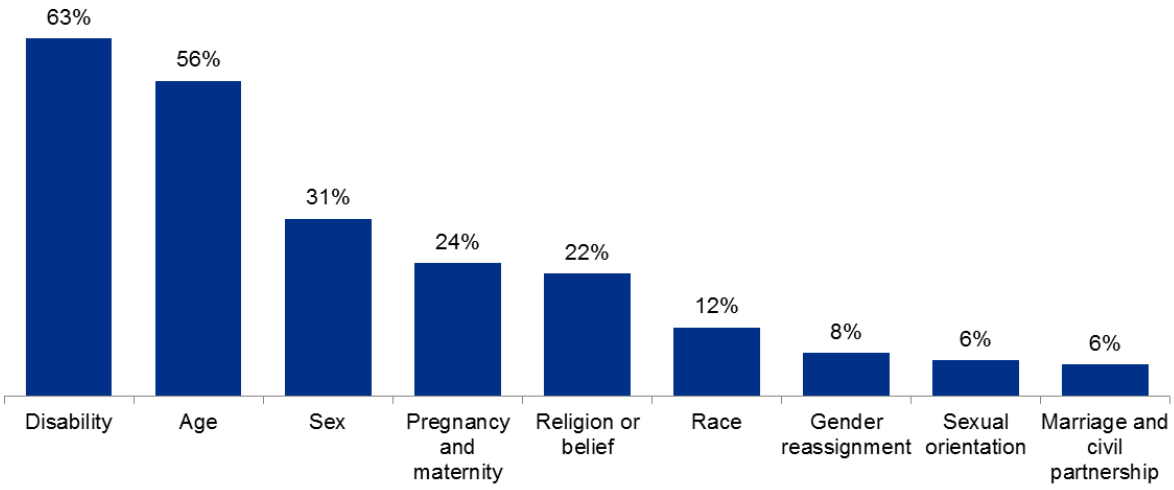
As part of the online consultation survey there were two questions that focused on the impact of the work on equalities and health inequalities as follows. Key results for these questions are also reported.

1. **Do you feel there any groups, protected by the Equality Act 2010, likely to be disproportionately affected by this work?**

Table 1 – Responses to consultation question 'Do you feel there any groups, protected by the Equality Act 2010, likely to be disproportionately affected by this work?' (n = 5541)

Response	Percentage
Yes	45%
No	33%
Prefer not to say	22%

Figure 1 – Responses to consultation question 'Which groups do you think will be effected' (n = 2230)



It should be noted that this questions related to the entirety of the project (i.e. 18 medicines review and the OTC item element) and so we cannot say with certainty which medicines figure 1 refers to. Although respondents were asked to provide further information on why they thought this might be the case, and the following relevant themes likely to relate to the 18 medicines emerged (other themes relating to OTC are picked up in the equalities and health inequalities impact assessment for this part of the project).

- The need for further communication/ assistance for BME communities and those with poor English.
- That the removal of liothyronine will adversely affect many people, mainly women who are more prone to hypothyroidism.
- That the proposal for herbal medicines would impact Chinese Community and users of herbal medication.

- That travel vaccines would have a greater uptake amongst BME groups who require vaccines when travelling to country of origin.
- This proposal adversely affects those who require considerable care (e.g. disabled, elderly).
- Proposal will make it harder for some to access treatment (e.g. elderly, disabled).
- Adversely affects those who cannot communicate their reliance on NHS-provided treatments, due to disability/age/computer literacy.

Themes that could relate to the 18 items that are also available OTC

- Adverse effects on living/impact ability to earn/ provide for family.
- Concerns some cohorts may not want to pay/be able to afford them (e.g. elderly, chronic illness) if they don't pay for them currently.

2. Do you feel there is any further evidence we should consider in our proposals on the potential impact on health inequalities experience by certain groups e.g. people on low incomes; people from BME communities?

Table 2 – Responses to consultation question 'Do you feel there is any further evidence we should consider in our proposals on the potential impact on health inequalities experience by certain groups' (n = 5407)

Response	Percentage
Yes	48%
No	29%
Unsure	23%

The relevant key themes reported from the further information for this question include:

- Consider the impact on patients with learning difficulties who won't understand the restrictions being placed on their medication.
- Consider effect on vulnerable groups and those who don't have the capacity to make their own decisions, those in care settings.
- Consider the implications on hypothyroid patients following the removal of treatments which have limited alternatives.
- Consider the quality of life for hypothyroid patients following removal of a key treatment.
- Concerns some medications may be less available/affordable in some areas (e.g. postcode lottery, rural area)*

*Applicable to some of the 18 medicines that are available OTC.

Some organisations, associations and societies responded to the consultation raising concerns about some form of discrimination for some or all of the groups mentioned in the Equality Act 2010. They were the Patients Association, National Association of Patient Participation (NAPP), Friends, Families and Travellers (FFT), Age UK, UK Health Prevention Forum, Leukaemia Care, Humanists UK, Thyroid UK, Royal Pharmaceutical Society, Royal Pharmaceutical Society, Pharmaceutical Services Negotiating Committee, Middlesex Pharmaceutical Group of Local Pharmaceutical

Committees, Dorset LPC, British Medical Association, National Pharmacy Association, Bayer, Pfizer UK, Dermal Laboratories Ltd, Company Chemists Association (CCA) and Association of the British Pharmaceutical Industry.

NICE did not feel that any groups, protected by the Equality Act 2010, were likely to be disproportionately affected by this work; nor does it feel that there is any further evidence NHS England should consider in their proposals on the potential impact on health inequalities experienced by certain groups.

The consultation also provided an opportunity for responders to say if they agreed or disagreed with the proposals for each of the 18 medicines and to provide further information. The following medicine specific themes relating to equalities and health inequalities were reported:

Doxazosin
- Consider impact on vulnerable groups.

Glucosamine and Chondroitin*
- Consider the impact on those on low income/ lower socioeconomic background and their ability to purchase the medication they, or their families need.

Homeopathy & herbal treatments*
- Consider the impact on those on low income/ lower socioeconomic background and their ability to purchase the medication they, or their families need.

IR Fentanyl
- Consider the effect on patients if this treatment is removed/limited (cancer, palliative care and patients with chronic pain specifically mentioned).

Lidocaine plasters
- May be implications for patients having to travel to hospital to collect their prescription.
- Restricting primary care prescribing of lidocaine plasters will significantly disadvantage pain and palliative care patients

Liothyronine
- Disproportionately impact low income households.
- The impact will be biased on age impacting patients who rely on pensions or young children who require parental income support.
- Withdrawal will breach obligations to patients with protected characteristics.
- That the removal of liothyronine will adversely affect many people, mainly women who are more prone to Hypothyroidism.

Lutein & antioxidants*
- Consider the impact on those on low income/ lower socioeconomic background and their ability to purchase the medication they, or their families need.

Omega-3 fatty Acid Compounds*
- Consider the impact on those on low income/lower socioeconomic background and their ability to purchase the medication they, or their families need

Travel Vaccines

- Consider impact on vulnerable groups (e.g. low income, high risk groups, BME, elderly)

*Available OTC

Although these themes relate to equalities and health inequalities, they should be considered in the context of the wider themes for the item (see consultation report, Nov 2017).

The demographic data from the consultation responses (based on the 9 protected characteristics) was also analysed for each of the proposals to see if there were any significant patterns of those who agreed/disagreed for each of the 18 items. The results showed that in general the only patient group to particularly disagree with proposals were, those patients considering themselves to have a disability. For certain medicines where females or older age groups were predominant users of the medicines, these groups were also identified to particularly disagree with the proposals.

Analysis by protected characteristic was performed for respondents identifying themselves as a patient. Patient groups were identified as particularly disagreeing with the proposal if the number of patients disagreeing was greater than those agreeing. Results were only included if total number either agreeing or disagreeing was greater than 50 (51 or over). If results were similar between groups of the same characteristic and in line with the overall response then result was not judged to be significant e.g. where patients in most age groups disagreed with the proposal.

Herbal treatments

Patients from older age groups, female patients and those considering themselves to have a disability particularly disagreed with the proposals:

Herbal Treatments

		Age groups				
Proposal	**Response**	**50-59**	**60-69**	**70-79**	**Females**	**Disability**
Advise CCGs that prescribers in primary care should not initiate herbal items for any new patient.	Agree	27	22	6	66	54
	Disagree	104	109	41	282	62
	Neither agree or disagree	0	1	0	3	2
	Unsure	0	0	0	4	4
	Percent disagree	**79%**	**83%**	**87%**	**79%**	**51%**
Advise CCGs to support prescribers in deprescribing herbal items in all patients and where appropriate, ensure the availability of relevant services to facilitate this change.	Agree	47	29	14	112	60
	Disagree	80	98	31	228	110
	Neither agree or disagree	1	2	1	4	0
	Unsure	2	3	1	10	3
	Percent disagree	**62%**	**74%**	**66%**	**64%**	**64%**

Homeopathic items

Patients from older age groups, female patients and those considering themselves to have a disability particularly disagreed with the proposals.

Homeopathic items

		Age groups					
Proposal	**Response**	**40-49**	**50-59**	**60-69**	**70-79**	**Female**	**Disability**
Advise CCGs that prescribers in primary care should not initiate homeopathic items for any new patient.	Agree	54	54	37	10	100	60
	Disagree	104	155	174	68	445	110
	Neither agree or disagree	0	0	1	1	0	0
	Unsure	2	1	1	0	4	3
	Percent disagree	**65%**	**74%**	**82%**	**86%**	**81%**	**64%**
Advise CCGs to support prescribers in deprescribing homeopathic items in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.	Agree	72	87	54	14	175	79
	Disagree	83	119	156	61	367	85
	Neither agree or disagree	3	3	2	3	5	6
	Unsure	2	1	0	0	2	2
	Percent disagree	**52%**	**57%**	**74%**	**78%**	**67%**	**49%**

IR Fentanyl

Patients considering themselves to have a disability particularly disagreed with the proposals. Whilst the total number responding was less than 50 the results are nonetheless included here as the number of people with a disability made up a significant proportion of all those responding to the questions for this medicine.

IR Fentanyl

Patients considering themselves to have a disability

Response	Advise CCGs that prescribers in primary care should not initiate Immediate Release Fentanyl for any new patient.	Advise CCGs to support prescribers in deprescribing Immediate Release Fentanyl in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
Agree	6	9
Disagree	20	19
Neither agree or disagree	4	2
Unsure	0	0
Percent disgaree	**67%**	**63%**

Lidocaine plasters

Patients considering themselves to have a disability particularly disagreed with the proposals.

Lidocaine Plasters

Patients considering themselves to have a disability

Response	Advise CCGs that prescribers in primary care should not initiate Lidocaine plasters for any new patient.	Advise CCGs to support prescribers in deprescribing lidocaine plasters in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
Agree	7	17
Disagree	57	50
Neither agree or disagree	5	1
Unsure	2	3
Percent disgaree	80%	70%

Liothyronine

Female patients and those considering themselves to have a disability particularly disagreed with the proposals.

Liothyronine

Proposal	Response	Female	Disability
Advise CCGs that prescribers in primary care should not initiate Liothyronine for any new patient.	Agree	20	11
	Disagree	1025	385
	Neither agree or disagree	17	8
	Unsure	8	2
	Percent disagree	**96%**	**95%**
Advise CCGs to support prescribers in deprescribing Liothyronine in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.	Agree	201	79
	Disagree	843	318
	Neither agree or disagree	16	5
	Unsure	9	3
	Percent disagree	**79%**	**79%**

Omega-3 Fatty Acids

Female patients particularly disagreed with the proposal to not initiate medicine for new patients

Omega-3 Fatty Acids

Female patients

	Advise CCGs that prescribers in primary care should not initiate Omega-3 Fatty Acids for any new patient.	**Advise CCGs to support prescribers in deprescribing Omega-3 Fatty acids in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.**
Agree	28	35
Disagree	40	33
Neither agree or disagree	2	3
Unsure	1	1
Percent disagree	56%	46%

Paracetamol and Tramadol

Patients considering themselves to have a disability particularly disagreed with the proposal to advise CCGs not to initiate combination product for new patients

Paracetamol and Tramadol
Patients considering themselves to have a disability

	Advise CCGs that prescribers in primary care should not initiate Paracetamol and Tramadol combination product for any new patient.
Agree	28
Disagree	46
Neither agree or disagree	3
Unsure	3
Percent disagree	58%

Travel vaccines

Patients considering themselves to have a disability particularly disagreed with the proposal

Travel vaccines

Patients considering themselves to have a disability

	Advise CCGs that prescribers in primary care should not initiate the stated travel vaccines for any new patient.
Agree	27
Disagree	59
Neither agree or disagree	1
Unsure	2
Percent disagree	66%

Annex F

Indicative conditions or items for which prescribing could be restricted:

1. Probiotics
2. Vitamins and minerals
3. Acute Sore Throat
4. Cold Sores
5. Conjunctivitis
6. Coughs and colds and nasal congestion
7. Cradle Cap (Seborrhoeic dermatitis – infants)
8. Haemorrhoids
9. Infant Colic
10. Contact Dermatitis
11. Dandruff
12. Diarrhoea
13. Dry Eyes/Sore (tired) Eyes
14. Earwax
15. Excessive sweating (Hyperhidrosis)
16. Indigestion and Heartburn
17. Insect bites and stings
18. Malaria prevention
19. Mild Acne
20. Mild Dry Skin/Sunburn
21. Mild to Moderate Hay fever/Allergic Rhinitis
22. Mild Migraine
23. Minor burns and scalds
24. Minor conditions associated with pain, discomfort and/fever. (eg aches and sprains, headache, period pain, back pain)
25. Mouth ulcers
26. Nappy Rash
27. Oral Thrush
28. Prevention of dental caries
29. Ringworm/Athletes foot
30. Scabies/ Head Lice
31. Simple Constipation
32. Teething/Mild toothache
33. Threadworms
34. Travel Sickness
35. Vaginal Thrush
36. Warts and Verrucae