

All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan



POSITION STATEMENT FOR BIOSIMILAR MEDICINES

AWMSG does not normally appraise biosimilar medicines.

Existing health technology assessment (HTA) advice for the 'reference' medicine, published by AWMSG or The National Institute for Health and Care Excellence, will automatically apply for biosimilar medicines licensed for the same indication and in the same population as the 'reference' medicine. In the absence of advice for the 'reference' product, the biosimilar medicine is not endorsed for use within NHS Wales.

The marketing authorisation holder of the 'reference' or biosimilar medicine is encouraged to engage with AWMSG where there is negative HTA advice or in the absence of advice. Please refer to the AWMSG Process for Industry Engagement for further information.

AWMSG reserves the right to request a submission for appraisal of any biological medicine, when directed by the AWMSG Steering Committee.