

**British Association of Dermatologists
Therapy & Guidelines sub-committee
Biologics Register steering sub-committee**

Comments on the public consultation “NICE approach to biosimilar medicines”

The British Association of Dermatologists would like to thank NICE for the opportunity to comment on this consultation. We principally agree with the approach laid out in the consultation document to the managed introduction of biosimilar medicines.

However, we think that there is a potential missed opportunity, in that the health economic model used in a single/multiple technology appraisal (STA/MTA) to determine whether or not a high-cost drug is 'cost-effective may point to its cost-effectiveness if an MTA is re-run for both biologic and biosimilar medicines combined (assuming that biosimilar medicines are relatively of lower cost). If only an STA has been carried out, then such direct comparisons would be missed.

Secondly, guidance by the MHRA is currently vague on how clinical trial evidence for efficacy in one indication should be extrapolated to other indications, as it is an area of uncertainty and considered to be something that will evolve over time. In practice, once a biosimilar has been licensed for one indication (e.g. infliximab for rheumatoid arthritis) it is likely that clinicians and CCGs will come under pressure to substitute this for the innovator product (in rheumatoid arthritis, psoriatic arthritis and psoriasis cases). Whilst this may be acceptable, it would nevertheless be very helpful if this is specifically considered when looking at the evidence in an MTA, i.e. reviewing evidence for efficacy in all indications.

We think that it would be prudent for NICE to evaluate these biosimilars robustly, as they have the potential to save costs.

We also think that there is likely to be a lot of concern amongst clinicians and patients about biosimilars, which may lead to them being under-used. NICE has a pivotal role to play.