Appendix One: BOPA Biosimilar Monoclonal Antibodies (MABs) Position Statement:

1. BOPA believes oncology pharmacy teams are key to ensuring the safe, successful and rapid adoption of rituximab and trastuzumab biosimilars (the first two oncology biosimilars MABs to market).
2. NICE and SMC have confirmed that their decisions on the originator molecules, apply to relevant licensed biosimilar monoclonal antibody products which subsequently appear on the market (1,7)*.
3. BOPA's position is that biosimilar monoclonal antibodies (MABs) are therapeutically equivalent to the originator molecules (4) and can and should be used for all commissioned indications, provided pharmacovigilance safeguards are in place, e.g. branded prescribing.
4. BOPA acknowledges that biosimilar MABS cannot be automatically substituted (2,10,13). However switching from originator to biosimilar (or biosimilar to biosimilar) is acceptable and can be recommended as part of a medicines optimisation strategy.
5. BOPA believes oncology pharmacy teams are key to ensuring pharmacovigilance monitoring is in place to ensuring all biosimilars are prescribed by brand and batch numbers are tracked.
6. BOPA believes biological medicines in general are safe and well tolerated, with the potential for immunogenicity the main safety concern and that adverse reactions are likely to be batch related and not product related (12). Biosimilar MABs will be black triangle drugs so all adverse events must be reported in line with organisational policy and the MHRA Yellow Card Scheme.
7. BOPA believes oncology pharmacy teams have a key role in helping clinicians initiate or switch patients to biosimilar MABs, either by directly supporting clinicians when seeing patients in clinic or indirectly by counselling patients in pharmacy, on wards or chemotherapy day units.
8. BOPA recommends that NHS stakeholders work together to provide National Patient Information Leaflets on biosimilars to avoid duplication and ensure a consistent message is given to patients. BOPA believes all patients should be given appropriate information on biosimilar MABS and have the opportunity for discussion with a member of the pharmacy team, who can assure them starting on or switching to a biosimilar MAB will not impact on the outcome of their cancer treatment.
9. Switching must be undertaken with the involvement of pharmacy to ensure patients and prescribers are involved in deciding to switch and any concerns about the efficacy and safety as result of switching are addressed by discussion with patients on the benefits and evidence of biosimilars.
10. BOPA believes all patients switched from originator to biosimilar, or between biosimilars should be monitored and that the biosimilars SmPC guidance on administration rates should be followed. This will ensure that the evidence base for safe switching is increased.
11. BOPA acknowledges that the NHS is encouraging competition in the oncology biosimilar MABS market and that products that have been through NHS procurement pathways and found to deliver best value to the NHS should be used.
12. BOPA believes that the savings achieved by rapid adoption of biosimilar MABs are an opportunity to safeguard NHS budgets and create headroom to ensure that new innovative cancer medicines are affordable. Thus benefiting patients and clinicians as well as significantly reducing NHS expenditure.
13. BOPA acknowledges that in future switching between biosimilars following NHS contract awards may be necessary **but** the significant amount of pharmacy time needed to manage the switch must be accounted for in the contracting/commissioning process. This includes changing e-prescribing systems for each different brand and encouraging clinician /patient acceptance and engagement.