Guidance to companies on medicines outwith SMC remit

Some medicines are considered outwith SMC remit and a submission is not required. Before making a submission to SMC, the Marketing Authorisation Holder (MAH) should consider whether any of the following exclusion criteria apply. If you are unsure whether a product falls within these exclusion criteria, please contact the SMC Secretariat for advice.

1.	**The medicine was initially licensed and made available to the market prior to 31 January 2002, for the indication in question, i.e. prior to the inception of SMC.** A submission may be required for additional formulations licensed after 31 January 2002 depending on cost per patient. Please refer to note 14.
2.	**The medicine is not a Prescription Only Medicine (PoM).** The SMC remit covers proprietary medicines categorised as PoMs only and excludes Pharmacy and General Sales List medicines.
3.	**The medicine is used in immunisation and guidance on its use is issued by the Joint Committee on Vaccination and Immunisation.**
4.	**The product is a medical device and is not licensed as a medicine by MHRA**
5.	**The product is used in diagnosis not treatment.** SMC does not consider medicines licensed for use only in a diagnostic setting.
6.	**The product is classified as a blood product (excluding anti-bradykinin and C1 inhibitor therapies).** SMC reserves the right to request a submission for a new blood derived product if an assessment of clinical and cost effectiveness is required by NHS Boards. Please consult the SMC secretariat for further advice.
7.	**The product is a medical gas.**
8.	**The product is a parenteral preparation for fluid and electrolyte imbalance or parenteral nutrition.**

9.	**The product is used as a supportive intervention in surgical procedures/wound management** Please consult the SMC secretariat for further advice**.**
10.	**The product is used for the acute treatment of poisoning.**
11.	**The product is a medicine used in tropical diseases.**
12.	**There has been a change to the MAH, trade name or manufacturer, with no increase in product cost.**
13.	**The Marketing Authorisation is solely for a new strength or new presentation of an existing proprietary medicine(s) (accepted for use by SMC/HIS or which pre-dates SMC), with no associated change to the licensed indication or route of administration and the new product costs the same per patient or less.** Please note that if a Patient Access Scheme (PAS) is in place for the existing proprietary medicine then the MAH is asked to contact the PASAG secretariat at nss.np-pasag@nhs.scot to update the existing PAS application to include the new product.
14.	**The product is a new formulation (or combination) of an established medicine which is either:** • **An oral formulation of an established generic medicine intended for patients unable to swallow tablets or capsules, or;** • **An alternative formulation of an established medicine (accepted for use by SMC/HIS or which pre-dates SMC) which costs the same per patient or less.**
15.	**The product is a generic or branded generic medicine.** Please note that submission requirements for hybrid medicines are considered on a case-by-case basis. If required please contact SMC secretariat for further advice
16.	**The product is a biosimilar medicine and the reference product has been accepted by SMC/HIS for the same indication(s) and in the same population or pre-dates SMC.** SMC statement regarding biosimilar medicines.
17.	**In certain circumstances, where there are no patients in Scotland who are eligible for treatment a submission may not be required.** Please consult the SMC Secretariat before assuming that this criterion is satisfied.
18.	**For some products where there is a large number of branded medicines with the same active substance(s) and similar costs SMC may occasionally advise Area Drug and Therapeutics Committees (ADTCs) that these are outwith remit. ADTCs should make local decisions on these products as required. These products are testosterone products for testosterone replacement therapy in male hypogonadism (from June 2019), ursodeoxycholic acid products (from February 2016), colecalciferol products for vitamin D deficiency (from February 2015), some combined oral contraceptives (from April 2012), and some preparations of mesalazine (from January 2011).** Please consult the SMC secretariat for further advice on medicines in these categories.

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