

Guidance to manufacturers on medicines outwith remit

Some medicines are considered outwith 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 the product clearly satisfies one or more of the exclusion criteria, a submission is not required and no further action is needed. 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. In making a judgment, please refer to note 12, in relation to available equivalent products. Where no equivalent licensed product is available a submission will normally be required.

- 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/EMA.**

- 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 donor derived. However SMC reserves the right to request a submission for a new blood derived product or advanced therapy medicinal product (ATMP) 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 an intervention in surgical procedures/wound management.
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 change to the licensed indication, formulation, pharmacokinetics /pharmacodynamics, posology and no increase in product cost.
13.	The Marketing Authorisation is solely for a new presentation or strength of an existing proprietary medicine, with no associated change to the licensed indication and the new product costs the same or less. This includes new devices for the administration/delivery of established medicines.
14.	The product is an oral formulation of an established medicine, available as a generic, intended for patients unable to swallow tablets or capsules.
15.	The product is a generic or branded generic medicine authorised under Article 10 (1) of Directive 2001/83/EC.
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 was initially licensed and available prior to 31 January 2002. For the SMC's policy on biosimilars, please see the Policies and publications section of our website.
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 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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