Guidance to submitting companies on abbreviated submissions

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Introduction

The abbreviated submission process allows SMC to honour its published remit and track all products. SMC will issue advice on all new chemical entities (or new active substances) and all new indications for established products through the full submission process. An abbreviated submission may be made when a company considers that a full submission is not required. If the company is in doubt about the submission process to be followed, guidance should be sought from the SMC Secretariat by completing the Company Information Request Form, available on the SMC website.

The abbreviated process requires companies to complete and submit an Abbreviated Submission Form. The Abbreviated Submission Form template is available on the SMC website. In order that SMC can meet its remit of advising on new products as close as possible to the product being available for use in NHS Scotland, Abbreviated Submission Forms should be sent to the SMC Secretariat ideally around the time of positive opinion.

Medicines that may be suitable for the abbreviated submission process

Key considerations for deciding whether an abbreviated submission may be appropriate are:

- The medicine's likely impact on budgets and resource allocation across NHS Scotland. If a medicine could potentially have a significant budget impact, a full submission should be made. Guidance can be sought from the SMC Secretariat, by completing the Company Information Request Form.
- That similar clinical effectiveness can be demonstrated briefly, in simple terms.

Examples of medicines that may be suitable for an abbreviated submission are given in the table below.

Medicine marketing authorisation for:	**Type of submission required:**
1. New active substance – even if the number of potential patients is small and the expected budget impact is low	Full
2. Additional indication / licence extension approved by the Medicines and Healthcare products Regulatory Agency (MHRA)/European Medicines Agency (EMA) - even if the number of potential patients is small and the expected budget impact is low	Full
3. Biosimilar medicine where the reference medicine is not recommended by SMC/Healthcare Improvement Scotland (HIS) for the same indication(s) and in the same population	Full

4. New formulation (e.g. slow release presentation, liquid) at pro rata cost or less relative to the existing formulation, which has been accepted for use by SMC/HIS or predates SMC establishment (31 January 2002) for the same indication	Abbreviated
5. New formulation (e.g. slow release presentation, liquid) at more than pro rata cost relative to the existing formulation, which has been accepted for use by SMC/HIS or predates SMC establishment (31 January 2002) for the same indication	Please complete the Company Information Request Form to obtain advice from SMC on submission requirements once final details of product pricing are available.
6. Combination medicine of established medicines, which have been accepted for use by SMC/HIS or predate SMC establishment (31 January 2002) for the same indication	Please complete the Company Information Request Form to obtain advice from SMC on submission requirements once final details of product pricing are available.
7. Licensed medicine of an established unlicensed preparation	Please complete the Company Information Request Form to obtain advice from SMC on submission requirements once final details of product pricing are available.
8. Marketing authorisation for medicine has been extended for use in children or adolescents, where product has previously been accepted by SMC/HIS in the same indication for use in adults or the indication in adults predates SMC establishment (31 January 2002)	Abbreviated submission may be appropriate. Please complete the Company Information Request Form to obtain advice from SMC.

Scheduling of abbreviated submissions

Companies will be informed of scheduling once the SMC assessment team has confirmed acceptability of the submission for the abbreviated submission route, which will be within three weeks from receipt of the abbreviated submission.

SMC reserves the right to request a full submission in relation to any medicine in the event that it is anticipated to have an impact on NHS Scotland resources which has not been fully taken into account by the submitting company or if similar clinical effectiveness has not been demonstrated briefly, in simple terms. The decision of the SMC in this respect is final and binding.

Abbreviated submissions will generally be considered by the New Drugs Committee (NDC) and the Scottish Medicines Consortium (SMC), in the same timeframe as a full submission (except for abbreviated submissions for paediatric extensions where additional time is required for expert consultation). SMC advice in relation to abbreviated submissions will be published on the SMC website in the form of a one page product update.