

Guidance to submitting companies on abbreviated submissions

May 2021

Introduction

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 for some new medicines when a company considers that a full submission is not required due to a low net budget impact. Guidance should be sought from the SMC Secretariat by completing the Company Information Request Form, available on the *Making a Submission* section of 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 *Making a Submission* section of the SMC website. In order that SMC can advise 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.

* For an interim period in the context of the COVID-19 pandemic, new medicines where alternatives within the same therapeutic class have previously been accepted for use (or restricted use) by SMC may be eligible for the abbreviated submission process.

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.

Companies must provide the basis for the submission and justification for applying via the abbreviated route (see below). Guidance should be sought from the SMC Secretariat as outlined above in advance of making a submission.

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*

<p>3. New medicine where alternatives within the same therapeutic class have previously been accepted for use (or restricted use) by SMC and the new medicine costs the same or less or has a limited net budget impact*</p>	<p>Please complete the Company Information Request Form to obtain advice from SMC on submission requirements once final details of product pricing are available. See section below on interim abbreviated submission process (therapeutic class).</p>
<p>4. 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</p>	<p>Full</p>
<p>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</p>	<p>Please complete the Company Information Request Form to obtain advice from SMC on submission requirements once final details of product pricing are available.</p>
<p>6. Combination medicine of established medicines at more than pro rata cost relative to the existing medicines, which have been accepted for use by SMC/HIS or predate SMC establishment (31 January 2002) for the same indication</p>	<p>Please complete the Company Information Request Form to obtain advice from SMC on submission requirements once final details of product pricing are available.</p>
<p>7. Licensed medicine of an established unlicensed preparation</p>	<p>Please complete the Company Information Request Form to obtain advice from SMC on submission requirements once final details of product pricing are available.</p>
<p>8. Marketing authorisation for medicine has been extended for use in children or adolescents, where advice has previously been issued for the same indication in adults or the indication in adults predates SMC establishment (31 January 2002)</p>	<p>See section below on paediatric licence extensions.</p>

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Interim abbreviated submission process (therapeutic class)

For an interim period, new medicines where alternatives within the same therapeutic class have previously been accepted for use (or restricted use) by SMC may be eligible for the abbreviated submission process. Before making a submission through this route, the company should complete a Company Information Request Form to obtain advice from SMC on submission requirements once final details of product pricing are available (available on the *Making a Submission* section of the SMC website).

When making an abbreviated submission (therapeutic class) to SMC, the company should consider the following.

- Similar clinical effectiveness to other medicines within the same therapeutic class must be demonstrated briefly and in simple terms. An indirect treatment comparison (published or in-house analysis) may be provided to demonstrate similar clinical effectiveness within class where required.
- The new medicine must cost the same or less or have a limited net budget impact (with PAS where relevant) compared with comparators within the same therapeutic class.
- Any restriction that is applied to comparators within the same therapeutic class is usually applied to the new medicine.

If the medicine is not eligible for the abbreviated submission process, the company has the option to either apply again by providing a new or improved Patient Access Scheme (PAS) or provide a full submission. If the company is unable to make a submission in an acceptable timeframe, SMC will consider the need to issue advice to NHS Scotland indicating that the medicine is not recommended for use. This does not preclude a submission at a later date (see *Process for issuing not recommended advice due to non-submission* in the Policies & publications page of our website).

Paediatric licence extensions

From January 2020, SMC no longer requests abbreviated submissions for paediatric licence extensions where advice has already been issued for the corresponding indication in adults. Area Drug and Therapeutics Committees (ADTCs) in Scotland have been advised that they may make formulary decisions on paediatric licence extensions for medicines that SMC has previously accepted for use (or restricted use) in adults. Where relevant, the company should liaise with the Patient Access Scheme Assessment Group (PASAG) to ensure that any PAS is extended to include the younger age group. Medicines that are not recommended by SMC for use in adults are also not recommended for use in children.

Note that SMC reserves the right to request a submission if an assessment of clinical and cost effectiveness is later required by NHS boards

If the company wishes to make a submission for a paediatric licence extension where the product is not recommended for use in adults then a full submission is likely to be required. Please seek advice from the SMC Secretariat.

Patient Access Schemes

If a patient access scheme (PAS) is available for the existing formulation (previously accepted for use by SMC) or for the parent medicine (a product whose marketing authorisation has been extended to include new paediatric age groups within an existing indication) then the PAS should be extended for the medicine under review. This requires companies to submit a new PAS application, see the Patient access schemes page via the *Making a submission* section of the SMC website for further information.

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**. SMC advice in relation to abbreviated submissions will be published on the SMC website in the form of a one page product update.

** For an interim period in the context of the COVID-19 pandemic, advice for abbreviated submissions will be issued following SMC executive review rather than full committee consideration.