Healthcare Improvement Scotland | SMC Advice on new medicines

Abbreviated Submission Form

May 2018

NHS SCOTLAND

Abbreviated Submission Form

Approved name of medicinal product:
Brand name:
Company:

Submitted by:

Name:
Position:
Signature:
Date:

For further information please contact:

Name:
Position:
Address:
Phone number:
E-mail:

Freedom of Information (FoI)

The Freedom of Information (Scotland) Act 2002 (FoI) came into force on 1 January, 2005, and enables any person to obtain information from Scottish public authorities, giving legal right of access including all types of recorded information of any date held by Scottish public authorities.

As such all information received may be subject to disclosure under the Freedom of Information (Scotland) Act 2002.

On receipt of a request for information, the SMC secretariat will contact your designated company representative to confirm that you agree to the release of the information being requested and to give you the opportunity to identify information that is deemed as commercial in confidence.

To ensure prompt attention on receipt of a FoI request, and to allow for deadlines for response to be met (20 working days from receipt of request), please identify a contact within your company who will deal with such requests.

Name:
Position:
Address:
Phone number:
E-mail:

Checklist for completion of the abbreviated submission

Before submitting the abbreviated submission please ensure the following checklist is complete: failure to complete any of these may delay processing of the abbreviated submission.

All sections of abbreviated submission completed	
Signed electronic copy of abbreviated submission and appendices (if relevant) enclosed	
Electronic Summary of Product Characteristics enclosed	
References provided in a RIS formatted file with a copy of all references (pdfs) provided either via email and contained in zipped files or on a CD ROM along with the abbreviated submission	

Submitting the abbreviated submission to the secretariat

The secretariat will accept the electronic version of the abbreviated submission as the master document, provided that the person responsible for compiling the submission has entered a scanned signature on the front page.

Please email your completed abbreviated submission to Catherine Tait (catherine.tait@nhs.net).

Contact Address:
SMC Secretariat
Scottish Medicines Consortium
Healthcare Improvement Scotland
8th Floor, Delta House
50 West Nile Street
Glasgow G1 2NP
Tel: 0141 225 6874 / 5552

1. Registration details

1.1.	Medicine (generic and brand name)
1.2.	Formulation, strength(s), route of administration
1.3.	Full licensed indication (as described in the summary of product characteristics)
1.4.	If the submission positions the medicine for use in a sub-population of the licensed indication, then provide details of the proposed positioning e.g. subpopulation of the licensed indication, only part of the licensed indication.
1.5.	Dose
1.6.	Licensing / anticipated date of marketing authorisation in UK (including web links where available)
1.7.	Launch or product availability date in UK

2. Medicine and background information to support an abbreviated submission

2.1. Provide the basis for the submission and justification for applying via the abbreviated route.

- ☐ New formulation which costs the same or less than the existing medicine
- ☐ New formulation of an existing medicine, with limited budget impact
- ☐ New combination medicine which costs the same or less than the existing medicines
- ☐ New combination medicine of existing medicines, with limited budget impact
- ☐ Licensed medicine of an established unlicensed preparation, which costs the same or less or has limited budget impact
- ☐ New licence extension for children or adolescents
- ☐ Other: please state

2.2. Provide background details for the medicine plus web links and references where appropriate in relation to regulatory information (e.g. medicine or reference/parent medicine).

2.3. Provide details of existing therapy in particular what therapy/ies may be replaced in Scottish practice, if this differs from the reference/parent medicine.

2.4. Provide details of previous SMC advice for any parent/reference medicine, alternative formulation or existing therapy if applicable.

2.5. Provide a brief demonstration in simple terms of similar clinical effectiveness or where appropriate bioequivalence to a parent/reference medicine or non-inferiority to existing therapy. This should be fully referenced.

2.6. Provide the medicine acquisition cost (list price) only for the medicine and existing therapy in the cost table below. Other associated costs should not be included.

Medicine	Formulation	Dose	Cost per unit/course/month/year*

*complete as appropriate

2.7. If you consider that this medicine may be appropriate for an abbreviated submission but the medicine acquisition cost, as detailed in the table above, is more than the reference/parent medicine or existing therapy: • Estimate any net budget impact with reference to medicine costs only. • Describe any additional benefits in simple terms that might justify this cost premium, e.g. preservative-free, liquid formulat**ion. A cost premium that requires analysis of benefit is likely to require a full submission.**
2.8. Patient Access Schemes (PAS): • Has this medicine previously been associated with a PAS for a different formulation or indication? • Will this same PAS be available for this new formulation/indication? • Will a new PAS be available?
2.9. Please provide any information specific to this product and relevant to the review that may not be covered by other sections of this form.

3. References
