

Abbreviated
Submission Form

September 2024



# Abbreviated Submission Form

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| --- | --- |
| 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 confidential information should be underlined and shaded (blue highlighting for Commercial-in-Confidence (CIC) and pink highlighting for Academic-in-Confidence (AIC) data). Information that is CIC or AIC will not be included in the published Detailed Advice Document (DAD).*

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| --- | --- |
| 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 uploaded to the Egress Secure Workspace |  |

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 his.smcsubmissionportal@nhs.scot

1. **Registration details**

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| * 1. Medicine (generic and brand name)
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| * 1. Formulation, strength(s), route of administration
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| * 1. Full licensed indication (as described in the summary of product characteristics)
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| * 1. If the submission positions the medicine for use in a sub-population of the licensed indication, please state clearly the context in which you wish SMC to consider use of the medicine
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|  |
| * 1. Dose
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|  |
| * 1. Licensing / anticipated date of marketing authorisation in UK (including web links where available)
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|  |
| * 1. Launch or product availability date in UK
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1. **Medicine and background information to support an abbreviated submission**

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| * 1. Provide the basis for the submission and justification for applying via the abbreviated route.
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| [ ]  New formulation of an existing medicine, with limited net budget impact[ ]  New combination medicine of existing medicines, with limited net budget impact[ ]  Licensed medicine of an established unlicensed preparation, which costs the same or less or has limited net budget impact[ ]  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 limited net budget impact[ ]  Other: please state |
| * 1. Provide background details for the medicine plus web links and references where appropriate in relation to regulatory information (e.g. medicine or reference medicine).
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|  |
| * 1. Provide details of existing therapy in particular what therapy/ies may be replaced in Scottish practice, if this differs from the reference medicine. This should include volume-share of different therapies where relevant.
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| * 1. Provide details of previous SMC advice for any reference medicine, alternative formulation or existing therapy if applicable.
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| * 1. Provide a brief demonstration in simple terms of similar clinical effectiveness, or where appropriate bioequivalence, to a reference medicine or non-inferiority to existing therapy e.g. through published direct or indirect treatment comparison. This should be fully referenced.
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| * 1. Provide the medicine acquisition cost (list price and patient access scheme [PAS] price where relevant) for the medicine and list price for existing therapy/ies in the cost table below. Other associated costs should not be included.
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| **Medicine** | **Formulation** | **Dose** | **Cost per**\* |
| **Unit\*\***  | **Course/month/year** |
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|  |  |  |  |  |
| \*complete as appropriate\*\* Please specify unit of measurement |
| * 1. 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. (If a PAS is available for the existing therapy this will be taken into account by SMC).
* Describe any additional benefits in simple terms that might justify this cost premium, e.g. preservative-free, liquid formulation. **A cost premium that requires analysis of benefit is likely to require a full submission.**
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| * 1. Patient Access Schemes (PAS):
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| If the submission is for a new formulation of an existing medicine, is a PAS already available for the existing formulation?  | YES/NO |
| Has a PAS application been submitted for this submission? (This should be a concise PAS application). | YES/NO |
|  |
| * 1. Please provide the following estimates for NHSScotland for years 1 to 5.

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| --- | --- | --- | --- | --- | --- |
|  | **Year 1** | **Year 2** | **Year 3** | **Year 4** | **Year 5** |
| Estimated number of patients eligible for treatment each year |  |  |  |  |  |
| Estimated number of eligible patients treated with the new medicine each year  |  |  |  |  |  |
| Estimated discontinuation rate  |  |  |  |  |  |
| **Number of patients treated in each year** |  |  |  |  |  |

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| * 1. Please provide any information specific to this product and relevant to the review that may not be covered by other sections of this form.
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1. **References**

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