

New Product   
Assessment Form   
for Ultra-Orphan   
Medicines

May 2025



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## NEW PRODUCT ASSESSMENT FORM

|  |  |
| --- | --- |
| Approved name of medicinal product: |  |
| Brand name: |  |
| Company: |  |

### Submitted by:

|  |  |
| --- | --- |
| Name: |  |
| Position: |  |
| Signature: |  |
| Date: |  |

*I understand that the following are conditions of the ultra-orphan pathway:*

* *To offer a Patient Access Scheme (PAS) that complies with the standard terms and conditions considered acceptable by the Patient Access Scheme Assessment Group (PASAG)*
* *To support data collection arrangements that meet the evidence generation requirements for assessment under the ultra-orphan pathway*

|  |  |
| --- | --- |
| Name: |  |
| Position: |  |
| Signature: |  |
| Date: |  |

### For further information please contact:

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

This New Product Assessment Form (NPAF) is for medicines that have been validated as ultra-orphan and where the company is able to meet other conditions of the ultra-orphan pathway specified by Scottish Government (see above).

This NPAF must be completed to allow initial assessment by SMC before the medicine can be made available within the ultra-orphan pathway. The NPAF should then be updated to allow SMC to reassess the medicine post evidence generation.

Please refer to general Guidance to submitting companies for completion of the New Product Assessment Form (NPAF) and the following supplements:

• Submissions for medicines for extremely rare conditions (ultra-orphan medicines)

• Submissions for medicines where the comparator is available through a confidential Patient Access Scheme (PAS)

These documents can be found in the *Making a submission* section of our website.

## Information for submitting patient groups

Understanding the experiences of patients, their families and carers is a key element in the SMC assessment process. Patients, family members and their carers provide unique knowledge about what it is like to live with a condition. They can give their perspective on the advantages and disadvantages of medicines and other treatments that may not be available in the published literature or reflected within standard quality of life measures.

SMC works in partnership with patient groups to gather this information through patient group submissions.

It is important that submitting patient groups fully understand how a new medicine works, as this helps to ensure the information they submit is accurate and informed.

Companies must provide a Summary Information for Submitting Patient Groups form as part of the submission to SMC, [see section 8](#_8._Summary_Information). This completed form will then be provided to submitting patient groups to assist them in the preparation of their submission.

SMC worked in partnership with The Association for British Pharmaceutical Industry (APBI) to produce this form, and it is compliant with the Prescription Medicines Code of Practice. Guidance is provided on how to complete the form in the *Guidance to submitting companies for completion of the New Product Assessment Form (NPAF).*

## Checklist of Confidential Information

The Checklist of Confidential Information should be completed for all Commercial-in-Confidence (CIC) and Academic-in-Confidence (AIC) data, including the reasons why the data are CIC/AIC and the timescale within which they will remain confidential. All confidential information should be underlined and shaded in the NPAF (blue shading for CIC; pink shading for AIC). If the medicine is subject to a confidential Patient Access Scheme (PAS), SMC preference is to publish the with-PAS incremental cost-effectiveness ratio (ICER). If you do not agree to public disclosure of the with-PAS ICERs, the reasons should be detailed in the Checklist of Confidential Information. (If a comparator medicine has a Patient Access Scheme in place, please refer to the supplement Submissions for medicines where the comparator is available through a confidential PAS (via the *Making a submission* section of our website, on the *Patient Access Schemes* page.)

NOTE: If this checklist is not completed, all information contained in the New Product Assessment Form will be considered NOT CONFIDENTIAL and may be published.

Does the New Product Assessment Form (NPAF) contain any confidential information? (please check appropriate box):

No

Yes

If yes, please complete the table below in full (insert or delete rows as necessary) and ensure that relevant sections of the NPAF are clearly highlighted and underlined, and match the information provided in the table.

|  |  |  |  |
| --- | --- | --- | --- |
| Page number\* | Nature of confidential information | Rationale for confidential status | Timeframe of confidentiality restriction**‡** |
|  | Commercial-in-confidence†  Academic-in-confidence† |  |  |
|  | Commercial-in-confidence†  Academic-in-confidence† |  |  |

\* Reference page(s) of your NPAF where the confidential information appears.

† Check box as appropriate

‡Please state whether the timeframe given is exact or approximate. For AIC material, state either the date and title of the conference at which the information will be made public, or the date of submission and title of the journal to which the relevant paper has been submitted, together with the journal’s stated turnaround time. If the conference or journal details are not finalised, state the company’s commitment to publish and the target date for the same.

As agreed with ABPI, AIC information may be presented verbally during the public sessions of the SMC meetings. Please indicate in the table above if this is not acceptable (e.g. if the data belong to a third party).

## Patient Access Schemes

A Patient Access Scheme (PAS) is a condition of the ultra-orphan pathway specified by Scottish Government. I confirm that appropriate reference to the with-PAS ICERs can be made at the SMC meeting and published by SMC (please check appropriate box):

Yes

\*No

\*If No, detail reason in table above

## Freedom of Information (FoI)

The Freedom of Information (Scotland) Act 2002 (FoI) came into force in 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 CIC.

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 New Product Assessment Form

*Before submitting the New Product Assessment Form (NPAF) please ensure the following checklist is complete: failure to complete any of these may delay processing of the submission.*

|  |  |
| --- | --- |
| All sections of NPAF completed |  |
| Signed electronic copy of full NPAF and appendices enclosed |  |
| Electronic Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) 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 NPAF. |  |

## Submitting the NPAF to the secretariat

The secretariat will accept the electronic version of the NPAF 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 NPAF [his.smcsubmissionportal@nhs.scot](mailto:his.smcsubmissionportal@nhs.scot)

# 1. Registration details

State the indication(s) for the product detailed in the submission, as described in the Summary of Product Characteristics.

If the submission positions the medicine for use in a sub-population of the licensed indication, please state the focus of the submission clearly and the context in which you wish SMC to consider the use of the medicine.

State any other indication(s) for the product that fall within the remit of SMC. If not previously reviewed by SMC, please provide details of timelines for submission(s).

Provide details of the licence status of the product for the indication(s) detailed in the submission, including dates of granted or expected UK marketing approval.

Does the medicine have a conditional marketing authorisation from the MHRA?

Has SMC confirmed that this medicine has been validated as an ultra-orphan?

If NO, please note that you should not submit an NPAF until validation has been completed. Please complete the proforma available on *Making a submission* section of the SMC website.

##### A Patient Access Scheme (PAS) is a condition of the ultra-orphan pathway specified by Scottish Government. Has a PAS has been included within the initial submission?

##### If YES, please specify if this is a simple or complex scheme: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Has the product received a positive MHRA Early Access to Medicines Scheme (EAMS) scientific opinion for the indication(s) detailed in the submission? If YES, , please include the EAMS number and positive opinion date

Does the product require a companion diagnostic test in order to identify patients eligible for treatment?

If YES, and this represents a change in clinical practice, Appendix A – Companion Diagnostics should be completed

Provide details of the confirmed or estimated UK launch date for the product in the indication(s) detailed in the submission.

Provide details of the formulation(s) of the product that are or will be licensed for the indication(s) detailed in the submission and the confirmed or anticipated list price(s).Provide details of any relevant active comparator(s) for the product in the indication(s) (with respect to any positioning, if relevant) detailed in the submission and indicate whether any of these comparators are available under a PAS.

Provide details of any scheduled or ongoing health technology assessment of this product in the UK.

# 2. Overview and positioning

In **no more than one page** describe the context for this submission and the proposed position of the ultra-orphan medicine in the pathway of care.

# 3. Nature of the condition

1. Provide a description of the disease or condition, including symptoms, severity, and effect on morbidity and mortality.
2. Provide a commentary on the effect of the condition on the patient’s quality of life and that of families/carers.
3. Provide a description of the current treatment options and their limitations, and the level of unmet need in NHSScotland.

Refer to the Supplement for medicines for extremely rare conditions (ultra-orphan medicines) *via the Making a submission* section of our website for further guidance on what should be included in this section.

# 4. Impact of the new technology

## **4.1 Direct evidence: efficacy**

##### Provide details of studies which evidence the clinical benefits of the medicine in the indication(s) under review relative to active comparator(s) used in clinical practice. The most relevant are active-controlled studies but if these are not available, details of placebo-controlled or uncontrolled studies (including outcomes from disease registries or early access schemes where relevant) should be included. Placebo-controlled and uncontrolled studies can also be included if they provide evidence of relevant clinical benefits not demonstrated in active-controlled studies.

##### If the clinical and / or economic case is made for only part of the marketing authorisation or if SMC is requested to consider the use of the medicine in a specific population of patients narrower than that covered by the marketing authorisation, the clinical evidence base to support the use of the product in that population should be described.

##### Provide details of ongoing studies that should provide additional evidence on the medicine in the indication(s) under review and when this further data is expected (i.e. within up to 5 years).

**4.2 Direct evidence: patient reported outcomes**

1. Describe the effect of the medicine on health-related quality of life if this was studied alongside efficacy endpoints in the pivotal trial(s).
2. Provide details of controlled or observational studies designed to explore the effect of the medicine on validated Patient Reported Outcome Measures (PROMs), for example health-related quality of life, health status, physical functioning, activities of daily living, adherence to treatment, patient satisfaction with treatment etc.

Refer to the Supplement for medicines for extremely rare conditions (ultra-orphan medicines) for further guidance on what should be included.

**4.3 Direct evidence: safety**

##### Provide details of studies which provide evidence of the adverse effects with the medicine in the indication(s) under review relative to active comparator(s) used in clinical practice. The most relevant are active-controlled studies. However, if active-controlled studies are not available, details of placebo-controlled or uncontrolled studies (including outcomes from disease registries or early access schemes where relevant) should be included.

1. For studies primarily designed to investigate differences between the medicine under review and a placebo or active-comparator in a safety outcome as the primary endpoint, provide complete details of the study, as described above in section three.
2. For active-controlled studies which primarily assessed an efficacy outcome, provide details of any analyses, indicating significant differences in adverse event rates between the medicine under review and an active comparator.
3. For placebo-controlled and uncontrolled studies which primarily assessed an efficacy outcome, provide details of the type and frequency of adverse effects that might be expected in clinical practice with the medicine in the indication(s) under review.

##### Provide details of any additional safety issues for the medicine in the indication(s) under review compared to relevant active comparator(s), which were not identified in the studies

**4.4 Indirect evidence**

##### If results from indirect or mixed treatment comparisons have been used in the economic model to define clinical benefits and adverse effects to be expected in practice with the medicine and relevant comparator(s) in the indication(s) under review:

##### Provide an overview and brief details of the presented analysis.

##### Provide details of the search strategies and rationale for identification of data sources used in the indirect or mixed treatment comparison, detailing inclusion and exclusion criteria, to provide evidence of clinical benefits and adverse effects.

##### Provide a diagram of the network and a table with details of the data sources used in the indirect or mixed treatment comparison(s) to provide evidence of clinical benefits and adverse effects. Include an assessment of the quality of the data sources and specific reasons for excluding any additional studies.

* + 1. Provide results (hazard ratios and 95% confidence or credible intervals) and where appropriate include ranking of treatments, a measure of heterogeneity or sensitivity analysis to account for heterogeneity, description of evidence consistency, use of random or fixed effects or other relevant information.

**4.5 Clinical effectiveness**

##### Describe any limitations of the study methodology and conduct affecting the quality of the evidence of clinical benefits, adverse effects and health-related quality of life with the medicine in the indication(s) under review (with respect to the proposed positioning of the product within the submission, if relevant).

##### Relative to relevant active comparator(s).

##### Describe the relevance of the outcomes assessed in clinical studies to clinical benefits, health-related quality of life and adverse effects expected in practice and how the medicine would be expected to address any areas of unmet need

##### Describe any factors that may influence the applicability of study results to patients in routine clinical practice in Scotland.

1. Outline the key uncertainties in relation to the medicine’s clinical effectiveness and how any ongoing studies are expected to address these.
2. If the medicine has a GB conditional marketing authorisation outline how the data requirements for the Specific Obligations could address key uncertainties in the clinical evidence.

The following questions should be completed to provide a balanced account of the advantages and disadvantages of the medicine in the indication(s) under review relative to relevant active comparator(s).

##### Provide details of the main alternative treatments used for the indication(s) under review within clinical practice in Scotland.

##### Provide details of relevant guidelines and protocols relating to the ultra-orphan condition, including previous SMC guidance for medicine(s) that may also be used for the indication(s) under review.

##### If an indirect or mixed treatment comparison has been conducted:

##### Discuss details of any relevant differences between the data sources providing evidence of clinical benefits and adverse effects with the medicine in the indication(s) under review and those providing evidence for indirect comparator(s). These would include, but not be limited to, differences in terms of (a) patient populations; (b) baseline severity of conditions; (c) interventions; (d) any additional treatments used; (e) outcomes measured; (f) methodology; (g) length of study; (h) results; and (i) study limitations.

##### Provide a conclusion detailing any limitations in terms of the evidence synthesis or extrapolation to the Scottish population.

i) Are there any potential equality issues that should be taken into account when considering this condition and medicine?

**Guidance notes:**

These would include, but not limited to, any potential equality issues that affect groups of people:

* Who share the protected characteristics of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, and sexual orientation.
* Who may be affected by health inequalities (especially if these involve one or more protected characteristics)
* With the condition who have difficulties using currently available treatments
* With the condition who may have difficulties using the new medicine

# 5. Value for Money

##### The economic evaluation supporting the submission can either be included below or attached as an appendix to the submission. An appropriate economic evaluation is required for all full submissions and resubmissions, including those for medicines that will be used to treat ultra-orphan conditions. This should take the format of a full economic evaluation; a cost or budget impact analysis only is not acceptable for SMC’s ultra-orphan pathway.

Please refer to the checklist below, the *Guidance to submitting companies for completion of the New Product Assessment Form (NPAF)* and the supplements for further details.

In this section you must complete the following checklist to show in which paragraph and / or page the following points have been addressed:

|  |  |  |
| --- | --- | --- |
| **The design of the evaluation** | | **Page no. in submission** |
|  | The alternatives compared are clearly described. |  |
|  | The rationale for choosing the alternative programmes or interventions compared is stated. |  |
|  | The patient group(s) considered in the economic evaluation is (are) clearly stated and justified. |  |
|  | The viewpoint of the analysis is clearly stated and justified. |  |
|  | The time horizon over which costs and benefits were calculated is stated and justified. |  |
|  | The primary outcome measure(s) for the economic evaluation is clearly stated and justified. |  |
|  | Evidence is provided linking proxy or disease-specific outcomes to final health outcomes. |  |
| **Data collection** | |  |
|  | The source(s) of effectiveness estimates used is (are) stated and cross-referenced to the clinical section of the submission. |  |
|  | Methods to value health states and other benefits are stated and details of the subjects from whom valuations were obtained are given. |  |
|  | Quantities of resources are reported separately from their unit costs. |  |
|  | Methods for the estimation of quantities and unit costs are described. |  |
|  | If a model is used, the choice of approach is justified. |  |
| **Analysis and interpretation of results** | |  |
|  | The approach to sensitivity analysis is stated. |  |
|  | The choice of variables for sensitivity analysis and the ranges over which the variables are varied is stated and justified. |  |
|  | Major outcomes are presented in a disaggregated as well as aggregated form. |  |
|  | The relevance (generalisability) of the analysis to Scotland is discussed. |  |
|  | Any equity implications of the analysis are discussed. |  |

Authors may enter N/A only for items 7, 9, 12 and 17.

# 6. Costs to NHS and Social services

The company requires to complete a standardised Excel template to show an estimate of the NHS Scotland budget impact associated with introduction of your product. The completed template will be shared in confidence with NHS Boards.

The current version of the budget impact template can be downloaded from the *Making a submission* section of the SMC website.

The Excel workbook contains full guidance notes for completion. On completion, the results should be copied into the appropriate sections below and the completed Excel workbook must bereturned to the SMC Secretariat alongside the completed NPAFat the time of submission. Failure to do so may result in a delay to the scheduling of the submission through the SMC process.Please ensure you return the template as a separate Excel file; do not embed the completed budget impact template within the completed NPAF.

##### Copy and paste the net budget impact result table from the “Summary” spreadsheet within the SMC budget impact template. Results tables should be provided separately for with- PAS and without- PAS scenarios. Comparator medicines should be included at list price, i.e. there is no requirement to incorporate any PAS applicable to comparators.

##### Copy and paste the service implications table from the “Summary” spreadsheet within the SMC budget impact template. If there are no service implications, please state nil.

##### If any alternative budget impact estimates have been made in addition to the base case estimate above, copy and paste the net budget impact result table(s) below. Please state the rationale and justification for any additional budget impact estimates that you provide.

##### Does the budget impact estimate template contain any commercial or academic-in-confidence data or results? If so, please provide details of which worksheets contain such data or results.

##### Please provide a summary of the key uncertainties in relation to the budget impact.

In addition to completing the template to show the impact of the technology on NHS budgets, please provide an assessment of any significant budget impacts falling on any non-NHS organisations

# 7. Impact beyond direct health benefits and on specialist services

##### Provide details of any advantages or disadvantages, other than clinical benefits, adverse effects and on health-related quality of life with the medicine in the indication(s) under review compared to usual clinical practice with the relevant active comparator(s). These would include, but are not limited to, differences in terms of: (a) tests or investigations for selection or monitoring of patients; (b) routes or schedules of administration; and (c) service changes.

* 1. Provide details of the potential impact of the medicine in allowing patients to contribute to society, improve family functioning, and continue in employment or education.
  2. Provide details of the potential impact of the medicine on the patient’s family or carers, including carer quality of life and ability to work.
  3. Provide a summary of the impact of adopting a wider perspective on the cost effectiveness of the medicine (where undertaken as a sensitivity analysis in the economic evaluation).
  4. Provide an assessment of the potential impact of the medicine on NHS staffing, infrastructure and training requirements in relation to delivering the treatment.

Refer to the Supplement for medicines for extremely rare conditions (ultra-orphan medicines) for further guidance on what should be included in this section.

# 

# 8. Summary Information for Submitting Patient Groups:

*The Pharmaceutical Company Perspective*

The Scottish Medicines Consortium (SMC) is committed to working in partnership with patient groups to capture patient and carer experiences, and use these to inform decision-making.

This information has been provided by the pharmaceutical company which has submitted to SMC. Its purpose is to help inform patient groups about the advantages and disadvantages of the medicine, its licensed indication, and how it is intended to help patients and carers in Scotland. This information may assist patient groups with their submissions to SMC or Patient and Clinician Engagement (PACE) meetings.

You can find more information about how SMC works with patient groups here: [www.scottishmedicines.org.uk/Public\_Involvement](http://www.scottishmedicines.org.uk/Public_Involvement)

Contact us

If you have any questions on how to complete this form, please contact the SMC Public Involvement Team on [his.SMCPublicInvolvement@nhs.scot](mailto:his.SMCPublicInvolvement@nhs.scot) or phone:0141 414 2403.

Name of medicine:

|  |
| --- |
|  |

Submission date:

|  |
| --- |
|  |

Name of pharmaceutical company making submission:

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| --- |
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## Who is the main contact from your company, should patient groups wish to obtain more information about the medicine?

|  |  |
| --- | --- |
| Name: |  |
| Position held in organisation: |  |
| Email address: |  |
| Phone number: |  |

1. What condition is this medicine to be used for? (focus only on the exact submitted indication. If the submission positions the medicine for use in a sub-group of the licensed indication, explain the relevant sub-group and why it has been selected)

|  |
| --- |
|  |

1. How is this condition currently managed in Scotland?

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| --- |
|  |

1. How does the medicine work? (please don’t use overly technical language)

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| --- |
|  |

1. How effective is this medicine and is it different from other medicines currently available to treat this condition? (detail any unmet need along with advantages and any disadvantages)

|  |
| --- |
|  |

1. How is the medicine administered and how will this affect patients and carers? (include details such as form, frequency, handling and self-administration/or otherwise)

|  |
| --- |
|  |

1. What are the side effects of this medicine and how are they managed?

|  |
| --- |
|  |

1. What is the quality of life impact of this medicine on patients and their carers?

|  |
| --- |
|  |

1. Are there any potential equality issues that should be taken into account when considering this condition and medicine?

|  |
| --- |
|  |

Please use the space below to provide signposting to online information about this medicine which patient groups may find useful. (for example reference points, resources, published clinical trial data, local clinical trial centres, information materials and websites)

|  |
| --- |
|  |

# References

Please provide a list of all references in the Vancouver style, numbered and ordered strictly in accordance with their numbering in the text. Author / date styles of referencing should not be used.

**Note:** **References must also be 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 NPAF.**

### Appendix A – Companion diagnostics

Please complete the following summary table if the medicine under review requires a companion diagnostic test in order to identify the patients eligible for treatment within the licence / target population and this represents a change in clinical practice.

Please note that the information below should be based on the data used in the economic and budget impact models. **This information will be shared in confidence with pathology specialists who will advise SMC on companion diagnostic aspects of the economic case.**

|  |  |  |
| --- | --- | --- |
| **Approved name of medicinal product:**  **Brand name:**  **Indication:**  **Company**: | | |
| 1. **Test strategy** | | |
| 1. Describe the test / test sequence included in the economic analysis. |  | |
| 1. Is this a patented test? |  | |
| 1. Does the Summary of Products Characteristics (SPC) for the medicine require this specific test to be used? |  | |
| 1. **Patient numbers** | | |
| 1. How many patients will require to be tested for this molecular biomarker across Scotland? |  | |
| 1. What is the estimated prevalence of this molecular biomarker in those who would be tested? |  | |
| 1. What proportion of samples is likely to be of insufficient size and quality to support biomarker testing? Please provide further details |  | |
| 1. **Accuracy of test** | | |
| 1. What is the accuracy of the test / test sequence (i.e. sensitivity, specificity, positive and negative predictive values)? |  | |
| 1. **Costs** | | |
| 1. What is the cost per test used in the economic model? Please provide a breakdown of the total cost including staffing, consumables and equipment. |  | |
| 1. What is the cost per patient included in the economic model (i.e. cost per patient identified with this molecular biomarker)? |  | |
| 1. **Service issues** | | |
| * 1. Are there likely to be any specific service issues associated with the introduction of the test in NHS Scotland? If so, please describe. | |  |
| * 1. Are these service issues included in the budget impact templates submitted to SMC? | |  |

**Document control sheet**

|  |  |
| --- | --- |
| **Title:** | *20250502 New Product*  *Assessment Form*  *for Ultra-Orphan*  *Medicines* |
| **Document type** | *Submission proforma* |
| **Reviewer** | *Jennifer Dickson* |
| **Peer reviewer** | *Shabana Khan* |
| **File location** | *N:\SMC\Process\Process docs\Ultra-orphan Processes* |

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| --- | --- | --- | --- | --- |
| **Revision History** | | | | |
| **Version** | **Date** | **Summary of Changes** | **Name of reviewer** | **Changes Marked** |
| 0.1 | 02/05/2025 | Section 8 – contact information updated | Shabana Khan | Yes |
|  |  |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Approval** | | | |
| **Name** | **Title** | **Date** | **Version** | |
| *Jennifer Dickson* | Public Involvement Manager | 02/05/2025 | Changes suggested on SK version appropriate | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Distributed to/uploaded to SMC site by** | | | | |
| **Name** | **Title** | **Date of distribution/ upload** | **Version** | **Date for next review** |
| Secretariat |  | 02/05/2025 | V1.0 | May 2027 |

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| --- | --- |
| **Linked documentation** | |
| **Document title** | **Document file path** |
| Budget impact template | [\\hislfspri01\share\SMC\Process\Process docs\Budget Impact Template](file:///\\hislfspri01\share\SMC\Process\Process%20docs\Budget%20Impact%20Template) |
|  |  |