

New Product   
Assessment Form

December 2022

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## NEW PRODUCT ASSESSMENT 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: |  |

This New Product Assessment Form (NPAF) should be used for all full submissions UNLESS the medicine is a ultra-orphan and the company is submitting for assessment as part of the ultra-orphan pathway.

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

* Supplement for medicines eligible for the interim acceptance decision option (medicines with Great Britain (GB) conditional marketing authorisation, included in the MHRA Innovative Licensing and Access Pathway (ILAP) and/or have a positive MHRA Early Access to Medicines Scheme (EAMS) scientific opinion (via the *Making a submission* section of our website).
* 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).*
* Resubmissions where the only change is a new or improved simple Patient Access scheme (via the *Making a submission* section of our website).

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 decision making 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 in the final SMC advice.

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

Is the medicine subject to a confidential PAS? No  Yes

If Yes, I confirm that appropriate reference to the with-PAS ICERs can be made at the SMC meeting and included in the final published SMC advice (please check appropriate box):

Yes

\*No

\*If No, detail reason in table above

## Budget Impact Templates

In the event of SMC accepting the medicine for use, the budget impact template(s) would be shared, in confidence, with NHS Boards. Please confirm SMC can release this information to health boards if the medicine is accepted for use (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 uploaded to the Egress Secure Workspace. |  |

## 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 to [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 GB marketing approval, and if this is a conditional marketing authorisation.

In the event of New Drugs Committee preliminary ‘not recommended’ advice, eligible medicines (described below) have the option of a Patient and Clinician Engagement (PACE) meeting.

If you wish SMC to assess eligibility for a PACE meeting please answer Yes or No to each of the following:

Is this submission for:

i) an end of life medicine: a medicine used to treat a condition at a stage that usually leads to death within three years with currently available treatments?

YES / NO

ii) a medicine with GB orphan marketing authorisation (i.e. conditions affecting fewer than 2,500 people in a population of 5 million) or a medicine to treat an equivalent size of population (<5 per 10,000) irrespective of whether it has designated orphan status?

YES / NO

*Supporting evidence and rationale for end of life and orphan status must be included in section 2.*

*The definition of orphan status is based on the full population of the licensed indication relevant to the submission, irrespective of whether or not the company wishes SMC to consider the product when positioned for use in a sub-population of the licensed indication. The definition of end of life medicine may be based on a sub-population of the licensed indication where the submission is positioned for use in this subgroup and the submitting company provides adequate justification.*

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 the positive opinion date.

Does the product have an ‘Innovation Passport’ allowing entry into the MHRA Innovative Licensing and Access Pathway (ILAP)? If YES, please include the date the IP was granted.

Has the product been designated a biosimilar medicine for the indication(s) detailed in the submission?

Does the product require a diagnostic test (e.g. somatic, germline or biomarker test) in order to identify patients eligible for treatment?

*If yes, and this represents a* ***change in clinical practice****, Appendix A – Diagnostic Testing (e.g. somatic, germline or biomarker test) 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).

##### Has a Patient Access Scheme (PAS) been included within the submission? YES/NO

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

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, including the anticipated dates for receipt of the draft first Appraisal Consultation Document (ACD) or Final Appraisal Document (FAD) from NICE.

Provide details of any upcoming data cuts or additional clinical trial results relating to the indication(s) detailed in the submission that are expected to become available within the next six months.

Please confirm that an executable electronic copy of the economic model been provided with the submission, with full access to the programming code.

*Please note: The content of the submission and the content of the economic model should match.*

# 2. Overview and positioning

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

If the product is eligible for the option of a PACE meeting and a new/revised PAS post NDC in the event of NDC preliminary ‘not recommended advice’ (section 1.e), in **no more than two pages,** please provide supporting evidence and rationale for this designation.

# 3. 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 theseare not available, details of placebo-controlled or uncontrolled studies 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).

##### If the medicine has a GB conditional marketing authorisation then provide details of the evidence required to meet the Specific Obligations set out by the MHRA.

##### If the medicine has an ‘Innovation Passport’ and is included in the MHRA ILAP, or had a positive EAMS scientific opinion please provide details of key efficacy data awaited from ongoing studies in this indication.

##### **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 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 described previously.

# 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 complete the following checklist to show on what page of the NPAF the points have been addressed. (Information can either be included in the main document or as an Appendix.)

|  |  |  |
| --- | --- | --- |
|  |  | **Page no. in submission** |
| 1. | What type of indirect comparison has been performed?  Describe and justify the methods used. |  |
| 2. | What are the comparators?  Give the rationale for selecting these comparators, with reference to the clinical and economic case |  |
| 3. | Have the results of this indirect comparison been used in the economic analysis? (base case / sensitivity analysis). |  |
| 4. | Describe the target population, this should match the clinical and economic case. |  |
| 5. | Provide details of the data sources used and the search strategies employed. |  |
| 6. | Provide a PRISMA diagram showing studies included and excluded from the indirect comparison (i.e. studies which were eligible for inclusion in the systematic review and were excluded from the analysis) |  |
| 7. | Where additional eligibility criteria were used to inform study selection for the indirect comparison please specify. |  |
| 8. | Provide a tabulated list of studies excluded from the indirect comparison with reasons for exclusion in accordance with PICOS. |  |
| 9. | Which individual studies (and not records) have been used in the indirect comparison? |  |
| 10. | Provide a diagram of the complete network showing the connection between treatment nodes and provide a network diagram of any restricted networks used in any sensitivity analyses. |  |
| 11. | Provide a quality assessment of included studies indicating which tool has been used. |  |
| 12. | Do some studies include patients outside the target population? Have subgroups of some studies been used? |  |
| 13. | Briefly describe the methods used for the indirect comparison.  Include details of any statistical or clinical assumptions made. |  |
| 14. | Include evidence to support choice of fixed or random effects model (for example goodness of fit statistics, DIC). |  |
| 15. | What clinical and safety outcomes have been assessed in the indirect comparison? Provide adequate justification. |  |
| 16. | Provide tabulated details for each treatment group of each study included in the indirect comparison including:   * number of patients in each treatment group or relevant subgroup * patient characteristics * baseline severity of condition * previous treatments * interventions and any additional medication used * length of follow-up and/or data maturity * primary outcome (with definition) |  |
| 17. | If a matching-adjusted indirect comparison has been performed, please state how many baseline characteristics have been matched, provide details of the treatment group before and after matching and of the weights applied. |  |
| 18. | If a simulated treatment comparison has been undertaken, please outline the baseline characteristics identified and include the degree of systematic error for the analysis. |  |
| 19. | Provide tabulated details of data input to the analysis for each treatment group (and relevant subgroups when appropriate) of each study included in the indirect comparison and the time-point at which these results were assessed. |  |
| 20. | Comment on any differences between the included studies in terms of:   * study methods * patient or disease characteristics * previous treatments * interventions and assessment time-points * outcomes or durations of follow-up * common comparator used * results in common comparator groups * statistical analysis |  |
| 21. | Provide the results of the indirect comparison in terms of the relative treatment effect of the medicine under review versus the selected comparators. |  |
| 22. | Where relevant, describe any evidence of inconsistency between direct and indirect results. |  |
| 23. | Report any measures or assessment of heterogeneity. |  |
| 24. | Provide details of any sensitivity analyses performed to explore uncertainty, including justification and relevance to the economic analysis. |  |
| 25. | Conclusions of the indirect comparison. |  |

##### 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.

# 5. Clinical effectiveness

Describe any limitations of the study methodology and conduct affecting the quality of the evidence of clinical benefits and adverse effects 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.

##### 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.

##### If the medicine has an ‘Innovation Passport’ and is included in the MHRA ILAP, or had a positive EAMS scientific opinion please outline how further data 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 Scottish clinical practice.

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

##### Provide details of any advantages or disadvantages, other than clinical benefits and adverse effects 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.

##### 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

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

# 6. Pharmaco-economic evaluation

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 re-submissions, including those for medicines that will be used to treat orphan conditions. 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.

# 7. Resource implications

As part of the SMC process, you are required to complete a standardised Excel template to show an estimate of the budget impact associated with introduction of your product. In the event of an accepted or restricted accepted decision being made by SMC, 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 same time as the submission is made. 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. Where a Patient Access Scheme (PAS) has been proposed, 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.

# 

# 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 about either how to complete or use this form, please contact the SMC Public Involvement Team at: [his.SMCPublicInvolvement@nhs.scot](mailto:his.SMCPublicInvolvement@nhs.scot)

Name of medicine:

|  |
| --- |
|  |

Submission date:

|  |
| --- |
|  |

Name of pharmaceutical company making submission:

|  |
| --- |
|  |

## Who is the main contact for patient groups, should they wish to obtain more information about the medicine? (optional – this information will be shared with submitting patient groups)

|  |  |
| --- | --- |
| 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?

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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?

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| --- |
|  |

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

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|  |

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 uploaded to the Egress Secure Workspace.**

### Appendix A – Diagnostic Testing (e.g. somatic, germline or biomarker testing)

Please complete the following summary table if the medicine under review requires a diagnostic test in order to identify the patients eligible for treatment within the marketing authorisation / 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.

**SMC will share this information in confidence with the Scottish Genomic Test Advisory Group (SG-TAG) or Scottish Pathology Network (SPaN), as appropriate, who will advise SMC on the diagnostic testing 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 somatic/germline/biomarker across Scotland? |  | |
| 1. What is the estimated prevalence of this diagnostic test in those who would be tested? |  | |
| 1. What proportion of samples is likely to be of insufficient size and quality to support the diagnostic test? 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 diagnostic test)? |  | |
| 1. **Service issues** | | |
| * 1. Are there likely to be any specific service issues associated with the introduction of the test in NHSScotland? If so, please describe (e.g. additional biopsies etc.) | |  |
| * 1. Are these service issues included in the budget impact templates submitted to SMC? | |  |