Guidance to submitting companies: fast-track resubmission process

1. Background

When the Scottish Medicines Consortium (SMC) issues 'not recommended' advice for a new medicine, the pharmaceutical company has the option to make a resubmission. Up to January 2020, resubmissions were assessed through standard SMC and Patient Access Scheme Assessment Group (PASAG) processes. The Scottish Government's review of access to new medicines noted that some stakeholders would welcome a simpler mechanism to allow pharmaceutical companies to review their pricing (www.gov.scot/Publications/2016/12/9192/0). SMC is therefore introducing a fast-track resubmission process from January 2020 for submissions where the only change is a new or improved simple Patient Access Scheme (PAS).

2. Process for fast-track resubmissions

If a company wishes to make a resubmission and the only change is a new or improved simple PAS, the company may submit using the fast-track process. This will allow a resubmission to proceed directly to the SMC committee with an overall assessment timeline of up to 14 weeks i.e. there is no consideration by the New Drugs Committee (NDC).

2.1 Key features of the fast-track resubmission process

To be considered for the fast-track resubmission process, all criteria listed should be met.

- The only change to the original submission is a new or improved simple PAS.
- The resubmission must be received within three months of the date the original SMC decision was issued to the company.
- Any changes to the list price of the medicine under review and/or to comparator medicines are reflected in the revised documents submitted.
- There is no change to any other aspect of the submission (including the proposed positioning of the medicine).
- There has been no previous fast-track resubmission for the medicine under review.

Resubmissions that do not meet these criteria may be considered through the standard process as described in the *Guidance to submitting companies for completion of the New Product Assessment Form (NPAF),* which can be found in the *Making a submission* section of our website.

2.2 Making a fast-track resubmission

Companies that wish to make a fast-track resubmission should provide the following documents to the SMC secretariat.

a) A completed fast-track resubmission proforma to confirm that the resubmission meets the criteria for the fast-track resubmission process. The fast-track resubmission proforma is available on the *Making a Submission* section of our website.

b) A new or improved concise PAS application.

c) Updated cost-effectiveness results as follows.

(i) **Submissions where comparators are not associated with a PAS**
- A summary table showing updated cost effectiveness results using the new / improved PAS price i.e. base-case and all sensitivity analyses presented in the SMC final advice.
- An appendix showing updated cost-effectiveness results using the new/ improved PAS price corresponding to all sensitivity analyses presented in the original NPAF plus any additional scenario/ sensitivity analysis requested during the original submission process.

(ii) **Submissions where the comparator(s) are associated with a confidential PAS**
For each comparator with a PAS:
- An appendix showing the relevant 5% to 95% analysis for the base case and all sensitivity analyses presented in the SMC final advice, as per SMC's standard process for dealing with comparator PAS as described in the *Guidance on comparator medicines with a PAS*, which can found in the *Patient Access Schemes* section of our website.
- A separate appendix showing the relevant 5% to 95% analysis for all sensitivity analyses reported in the original NPAF plus any additional scenario/ sensitivity analysis requested during the original submission process.

(iii) **Submissions where the new medicine is used in combination with another company's medicine which is subject to a confidential PAS**
Updated cost-effectiveness results should be presented as for (ii) above.

d) A budget impact template to reflect the new/ improved PAS.

e) A Word document showing the summary table from the budget impact template for the new/improved PAS scenario

3. SMC meeting

The SMC committee will be provided with the original SMC paperwork, the company's fast-track proforma together with updated economic data, an updated Detailed Advice Document (DAD), and a results for SMC decision-making document (if a comparator medicine is also available under a confidential PAS). Presentation of the resubmission at the SMC meeting will briefly

recap on the clinical data and the rationale for the original decision and then focus on the impact of the change in PAS on the cost effectiveness results.