|  |  |  |
| --- | --- | --- |
|  |  | |
|  | |

**Fast-track resubmission proforma**

This proforma should be completed for resubmissions where the **only** change to the original submission is a new or improved simple Patient Access Scheme (PAS) or confirmed list price reduction. For other resubmissions, refer to: ‘Guidance to submitting companies for completion of New Product Assessment Form (NPAF)’.

|  |
| --- |
| * + - 1. **Registration details:**   Approved name of medicinal product:  Brand name:  Licensed indication:  Pharmaceutical company: |
| * + - 1. **Proforma submitted by**:   Name:  Position:  Signature:  Date: |
| * + - 1. **Checklist for completion of the proforma**   Before submitting the proforma please ensure the following checklist is complete.  The proforma is complete.  New or improved concise PAS application or confirmation of list price reduction is enclosed.  A summary table showing updated cost effectiveness results using the new / improved PAS price or list price reduction (see section 2.2 of the guidance to submitting companies).  An appendix (or appendices) showing updated cost-effectiveness results using the new/ improved PAS price or list price reduction (see section 2.2 of the guidance to submitting companies).  A revised budget impact template for the new / improved PAS scenario or list price reduction.  A Word document showing the summary table from the budget impact template for the new/improved PAS scenario or list price reduction. |
| * + - 1. **Details of the original New Product Assessment Form (NPAF) and SMC advice**   Date SMC advice published:  SMC ID No: |
| * + - 1. **Provide the justification for requesting consideration of a resubmission via the fast-track route.** |
| The simple PAS has been improved and there is no other change to the submission  A new simple PAS has been submitted and there is no other change to the submission  A Department of Health confirmed list price reduction and there is no other change to the submission |
| * + - 1. **Tick to confirm that all of the following apply to the resubmission.**   The resubmission is provided 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 are reflected in the revised documents submitted.  Any changes to the list price of comparator medicines are reflected in the revised documents submitted.  There is no change to the proposed positioning of the medicine under review.  There is no change to any other aspect of the original submission.  There has been no previous fast-track resubmission for the medicine under review. |