**Reclassification Validation Checklist**

**Please provide this checklist when submitting your reclassification dossier to avoid the most frequent validation and request for further information issues**

**All applicants should complete Part A.**

**For simple reclassification variations, complete Part B.**

A simple reclassification is based on an analogous product which has already been reclassified. Simple reclassifications should be submitted as a Type IB or a Type II (analogous product) variation.

An analogous product is a medicinal product which has a valid marketing authorisation[[1]](#footnote-2) in the UK and:

-has the same active ingredient, route of administration and use

-has the same strength or a higher strength

-has the same dosage or daily dosage, or a higher dosage or daily dosage

-is for sale or supply at the same quantity or a greater quantity as the medicinal product in relation to which the application is made

**For major reclassification variations, complete Part C.**

A major reclassification application should be submitted when there is no analogous product to base the reclassification. Major reclassifications should be submitted as a Type II (POM-P) or Type II (P-GSL) variation.

|  |  |
| --- | --- |
| **PART A: Details of the product to be reclassified** | |
| Product name (as provided in Section 1 of the SmPC) |  |
| Marketing authorisation number |  |
| Marketing authorisation holder (MAH) |  |
| Legal status change | **POM to P**  **P to GSL**  **POM to GSL**  **P to POM**  **GSL to P**  **GSL to POM** |
| Summary of changes |  |
| Fees paid | **YES  NO** |
| Proof of payment provided | **YES  NO** |

|  |  |  |
| --- | --- | --- |
| **PART B: Analogous product reclassification variations** | | |
| **Type of variation** | **Type IB  Type II** | |
| Is this application combined with a simple abridged (only applicable for Type II variations) | **YES  NO** | |
| Analogous product name |  | |
| Analogous product marketing authorisation number |  | |
| **Document** | **Confirm present** | **Comments** |
| Cover letter |  |  |
| Application form |  |  |
| SmPC tracked version (Word format) |  |  |
| SmPC clean version (Word format) |  |  |
| Clean changed fragments of SmPC |  |  |
| PIL tracked version (Word format) |  |  |
| PIL mock-up (PDF) |  |  |
| Consolidated label tracked version (Word format) |  |  |
| Consolidated label mock-up (PDF) |  |  |
| Other (please specify) |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| **PART C: Major reclassification variations** | | | |
| **Type of variation**  For reclassifications that are combined with abridged please refer to the guidance on how to [Apply for a licence to market a medicine in the UK](https://www.gov.uk/guidance/apply-for-a-licence-to-market-a-medicine-in-the-uk) for information on abridged documentation | Major POM to P  Major POM to P combined with simple abridged  Major POM to P combined with standard abridged  Major POM to P combined with complex abridged  Major P-GSL  Major P-GSL combined with simple abridged  Major P to GSL combined with standard abridged  Major P-GSL combined with complex abridged | | |
| **Document** | **Confirm present** | **Not required**  *[if a document is not required, please provide an explanation for this in the ‘Comments’ column]* | **Comments** |
| Cover letter |  |  |  |
| Application form |  |  |  |
| SmPC tracked version (Word format) |  |  |  |
| SmPC clean version (Word format) |  |  |  |
| Clean changed fragments of SmPC |  |  |  |
| PIL tracked version (Word format) |  |  |  |
| PIL mock-up (PDF) |  |  |  |
| User testing report for leaflet |  |  |  |
| Consolidated label tracked version (Word format) |  |  |  |
| Consolidated label mock-up (PDF) |  |  |  |
| Justification for exclusion of user testing |  |  |  |
| Reclassification clinical overview |  |  |  |
| CV of reclassification clinical overview author |  |  |  |
| RMP tracked version (Word format) |  |  |  |
| RMP clean version |  |  |  |
| Additional risk minimisation measures, e.g. checklists/guides/training resources (please specify) |  |  |  |
| Justification for data exclusivity if requested |  |  |  |
| Justification for new invented name if applicable |  |  |  |
| Letter of authorisation (if using a contracted service include a letter of access for direct communication concerning the application) |  |  |  |
| Literature references |  |  |  |
| Other (please specify) |  | | |

1. The analogous product should have been on the market during the previous six months and must not have been removed for reasons of safety, quality, or efficacy. Exceptionally, it may be possible to accept certain products which have not been on the UK market for over 6 months as analogous products. Applicants are advised to contact the MHRA ([variationqueries@mhra.gov.uk](mailto:variationqueries@mhra.gov.uk)) to seek guidance on the eligibility of these products. In these circumstances, acceptance of the proposed analogous product will be determined on a case-by-case basis.  [↑](#footnote-ref-2)