**Checklist for product information - established active substance MAAs**

Version 1.0

Date effective: 19/OCT/2023

# Introduction

There are common pitfalls in regulatory submissions related to proposed product information for established active substance MAAs. The purpose of this checklist is to promote ‘right first time’ submissions. Submission of this checklist is optional.

**Scope**:

* Generic MAAs - Regulation 51 of the Human Medicines Regulations 2012 (previously Article 10.1 of Directive 2001/83/EC)
* Hybrid MAAs - Regulation 52 of the Human Medicines Regulations 2012 (previously Article 10.3 of Directive 2001/83/EC)
	+ Only if the product information is intended to be closely aligned with that of a reference product
* Well-established use MAAs - Regulation 54 of the Human Medicines Regulations 2012 (previously Article 10a of Directive 2001/83/EC)
	+ Only if the product information is intended to be closely aligned with that of a licensed product
* Informed consent MAAs - Regulation 56 of the Human Medicines Regulations 2012 (previously Article 10c of Directive 2001/83/EC)

**Action**: Applicants should complete this checklist, and the ‘comparison documents’ (described in Q10 of the checklist), and submit all as ‘working documents’ in Microsoft Word format in the initial sequence. The documents should be titled ‘ProductInformation\_Checklist’, ‘Comparison\_SmPC’, and ‘Comparison\_PIL’, respectively. A pdf version of the documents should be submitted in Module 1 of the eCTD in the ‘m1-additional-data’ folder.

When completing the checklist, please note that:

* For well-established use MAAs (Regulation 54 of the Human Medicines Regulations 2012), the ‘reference product’ described in the below checklist should be the licensed product with which the proposed product information is closely aligned (there is no legal reference medicinal product under well-established use).
* For informed consent MAAs (Regulation 56 of the Human Medicines Regulations 2012), the ‘reference product’ described in the below checklist should be the authorised ('cross-reference') product for which consent has been given by the existing marketing authorisation holder to use their data in support of the application.

# Product information checklist

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| 1. Product details  | PL Number: <> Name: <>Active substance(s): <>Strength(s): <>Dosage form: <> |
| 2. Reference product, for purpose of product information alignment  | PL Number: <> Name: <>Active substance(s): <>Strength(s): <>Dosage form: <> |
| 3. Has proposed product information (i.e., proposed SmPC, package leaflet and labels) been provided in line with the latest version of the reference product and QRD templates? Have these been provided in MS Word format (clean and tracked changes) as working documents? Has a separate SmPC been provided for each strength? | Yes/ No\*Yes/ No\*Yes/ No\* |
| 4. Are ‘Microsoft Word’ headings in line with the MHRA ‘SPC template’ found on this page: <https://www.gov.uk/guidance/apply-for-a-licence-to-market-a-medicine-in-the-uk> ?  | Yes/ No\**Microsoft Word ‘headings’ should be in exactly the correct format as per the SPC template – please copy and paste these headings from the SPC template. This will help with the compliance checks if the MAA is approved, and will reduce the risk of error.* |
| 5. Is the proposed SmPC in line with the Reference SmPC? | Yes/ No\**Please bring section 4 and 5 of the proposed SmPC exactly in line with the latest updated Reference SmPC unless there is a very strong reason to amend the text. Minor stylistic changes should not be made to the Reference text.* *Exceptions: Overt errors in the Reference SmPC may be corrected. Text which is specific to the proposed product (for example in relation to excipient warnings, or different dosage form) may of course be different from that of the Reference SmPC.**If there are other intentional differences with the Reference SmPC, please provide adequate justification. Major differences should be justified in the Clinical Overview.*  |
| 6. Is the proposed PIL in line with the Reference PIL? | Yes/ No\**Please bring sections 1-4 of the proposed PIL exactly in line with the latest updated reference PIL unless there is a very strong reason to amend the text. Minor stylistic changes should not be made to the Reference text.**Exceptions: Overt errors in the reference PIL may be corrected. Text which is specific to the proposed product (for example in relation to excipient warnings, or different dosage form) may of course be different from that of the Reference PIL.**If there are other intentional differences with the Reference PIL, please provide adequate justification. Major differences should be justified in the Clinical Overview.* |
| 7. In the proposed SmPC/PIL, do you refer to the active substance name (rather than the full product name) wherever possible to improve readability? | Yes/ No\**In section 4 and 5 of the proposed SmPC, and sections 1-4 of the proposed PIL, please refer to the active substance name rather than the full product name, wherever possible to improve readability.* *Exceptions: Text which is specific to the proposed product (for example in relation to excipient warnings) should use the full product name (e.g. including strength and pharmaceutical form).* |
| 8. Has formatting of the SmPC/PIL been reviewed, to ensure of high-quality?  | Yes/ No\**Please amend any errors in paragraph formatting, for example with erroneous or inconsistent spacing, or paragraph markings.*  |
| 9. If there are multiple strengths of the proposed products, have you ensured that there are no inadvertent errors or inconsistencies between the SmPCs of different strengths? | Yes/ No\**Please use the MS Word ‘compare two versions of a document’ function to ensure consistency.*  |
| 10. Have ‘comparison documents’ been provided, comparing the proposed SmPC and PIL with the Reference SmPC and PIL? | Yes/ No\**These documents are generated using the MS Word ‘compare two versions of a document’ function, with the Reference SmPC/PIL as the ‘Original document’ and the Proposed SmPC/PIL as the ‘Revised Document’. The ‘comparison settings’ should be ‘moves’, ‘tables’, and ‘headers and footers’, with changes shown at ‘word level’.* *The above will generate a document, showing any differences between the Reference SmPC/PIL and the Proposed SmPC/PIL. Once saved, tracked changes will show these differences.* *The final comparison documents should be titled ‘Comparison\_SmPC’ and ‘Comparison\_PIL’ and submitted as ‘working documents’ in Microsoft Word format in the initial sequence. A pdf version of the documents should be submitted in Module 1 of the eCTD in the ‘m1-additional-data’ folder.*Source (webpage) of Reference SmPC:Source (webpage) of Reference PIL:Date of Comparison:**Comparison completed by**Name: Organisation: Role:Signature: |

# Additional comments

*In the following box, please add any additional comments, for example related to intentional differences with the Reference product information. For questions from the above checklist where the option selected has red text with an asterisk (\*) this represents an approach which frequently requires additional justification. Please list these question numbers in the section below, providing justification.*

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# Checklist completed by:

Name:

Role:

Organisation:

Date:

Signature: