

How to prepare the 'precise scope' section of the variation application form in the context of a Marketing Authorisation Variation

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Guidance to use

**e-AF v1.28.0.0 (Human Variation)
Current version**



**EMA/CDMh explanatory notes on
variation application form
(Human medicinal products only)**

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**Guidance for applicants for the
preparation of the 'precise scope'
section of the variation
application form**

12 February 2026 EMA/220707/2017
- Rev. 1.0 - Human Medicines
Division

Application processing

A submission of several variations of type IA to the terms of **ONE MA**, submitted as one single notification: **ANNUAL UPDATE**

Note1: Individual applications for type IA variations only may be accepted by the NCAs for the exceptional cases listed on Chapter 6 (BPGs).

Note2: Type IAin notifications should be submitted immediately after implementation. They may only be added to an annual update if this is submitted immediately after the implementation of the type IAin.

A submission of one or several (grouped) variations concerning **SEVERAL MA** of type IA and/or type IAin: **SUPER-GROUPING of type IA variation(s)**

A submission of a Grouping of variations concerning **ONE MA**, where at least 1 variation is type IB, II or extension: **GROUPING of type II/IB variation(s)**

A submission of one or several (grouped) variations to **SEVERAL MA** where at least one of the variations is a Type IB or Type II variation: **WORKSHARING**



**ONLY ONE APPLICATION
FORM IS NEEDED**

Key considerations when completing the application form:



The application form should be consistent with the cover letter.

Providing unclear or contradictory information may delay the procedure.



The “Precise Scope” section aims to provide a clear and concise description of the change(s) being applied for.



The changes for each variation should be explained under the “Precise Scope” and “Background for Change” sections.



All changes listed under the 'Precise Scope' section and in the 'Present and proposed' table should be reflected in the “Types of Changes” section, with their corresponding scope indentations.



Variation application form.

Section 3 - Types of Change(s)

Guidance for Applicants on the preparation of the 'Precise Scope' section of the Variation Application Form

1. Aims to support applicants in completing the following sections:

- **“Precise scope”**
- **“Background for the change”**
- **“Justification for G, SG, WS & classification for unforeseen changes”**

2. Provides guidance on the information to include in this section, along with examples of changes applied for each of the scopes listed.

3. To improve the description clarity of the exact change(s) applied for, and to facilitate the validation and review process of the application.



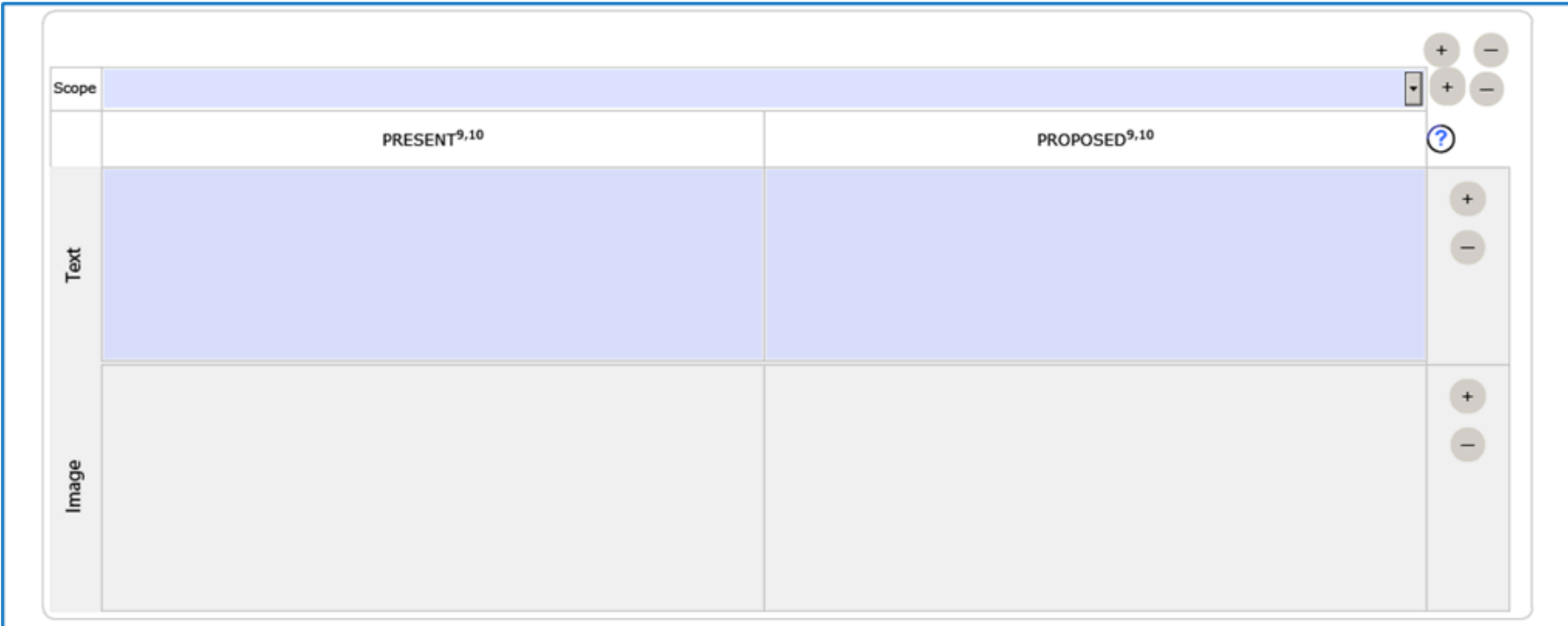
Check out **the application form** here

Variation application form.

Section 3 - Present/Proposed

TYPES OF CHANGE(S):

In the “Present/Proposed” table:



Scope	PRESENT ^{9,10}	PROPOSED ^{9,10}
Text		
Image		

- Specify the precise **present and proposed** wording or specification, including **dossier section** number(s) at the lowest possible level according to eCTD.
- For SmPC, labelling and package leaflet changes, underline or highlight the changed words presented in the table or provide as a separate Annex.

Variation application form.

Section 3 - Scope & Background



This free-text section should include a brief explanation of the change(s) applied for.



When the change(s) are submitted as a result of a previous regulatory procedure, a reference should be provided.



For grouped applications, a justification should be provided, with a reference to Annex III of the Commission Regulation, examples published by CMDh or the Agency, or any pre-submission contacts with the RMS/NCA or the Agency.



For worksharing procedures, the justification should refer to the letter of intent or the pre-submission contacts with NCAs/EMA.



For default Type IB ('z') variations (except those classified following a CMDh Art. 5 recommendation), a justification for the proposed classification must be provided.

Annex to the Guidance

Examples of “Precise Scope” section wording

The **Annex** provides a list of examples of wordings and details that applicants may consider for each category of the variation classification guideline.

For each type of variation, the description should be brief, specific, and complete, clearly outlining the change.

- ? **What changes**
- ? **In which part of the dossier**
- ? **Why submit changes**

Do you need **support with Variations?**

Contact us:
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