

How to select the correct Procedure and the correct Variation procedure number in the context of a Marketing Authorisation Variation

Keys to improve and maximize Variation Strategies for Marketing Authorization Holders

by **Ana Viñas**



Reference framework

for the classification,
preparation & submission of
post-authorisation variations at
EU level

The responsibility for determining the appropriate procedure remains with the MAH, who must provide a robust justification.

From Regulation to Guidelines

Commission Delegated Regulation (EU) 2024/1701

European Commission Guidelines (C/2025/5045)

Minor variations of
Type IA

Submission
of Type
IA/IAin

GROUPING

Minor variations of
Type IB

Submission
of Type IB

SUPER-GROUPING

ANNUAL UPDATE (mandatory)

Major variations of
Type II

Submission
of Type II

GROUPING / WORKSHARING (mandatory)

GROUPING / WORKSHARING (mandatory)

Variation request strategy:

Feature	Type IA Annual Update	Super-grouping	Worksharing
Number of MAs involved	One MA	Multiple MAs	Multiple MAs
Basis of grouping	Variation(s) implemented over time	Variation(s) across multiple MAs	Variation(s) across multiple MAs
Submission timeframe	9-12 months after variation implementation	Anytime	Anytime
Variation type	Type IA	Type IA and/or IAin	IB, II or grouping including IB or II
Authorization types	Only NP or only MRP/DCP. Do not combine	MRP/DCP; Combination MRP/DCP and NP; NP in several Member States (no CP)	CP/DCP/MRP/NP
Variation procedure number	European: Assigned by RMS Nationals: blank	Assigned by RMS Format: CC/D/nnnn/qq/vvv/G where: nnnn = xxxx	Assigned by RMS (MRP/DCP) or EMA (CP) Format: CC/D/nnnn/qq/vvv where: • qq = WS • nnnn = xxx
Advantages	<ul style="list-style-type: none"> • Reduces the administrative burden associated with minor variations • Improves traceability and regulatory oversight. 	<ul style="list-style-type: none"> • Only one submission for multiple MAs and harmonization across EU Member States • Reduction of duplicated work for both MAH and authorities • Now allowed for NP too 	<ul style="list-style-type: none"> • WS Reduces interpretational differences between authorities • Ensures consistent regulatory decisions across the EU.

Management of Type IA Variations

ANNUAL UPDATE

- Type IA variations must be bundled and submitted as part of an annual update.
- The annual update (**mandatory**) consists of a grouped submission covering all **Type IA variations relating to the same MA** and must be submitted between 9 and 12 months after implementation of the first IA variation.
- The type IA variations included do not need to be related to each other.

Exceptions: submissions outside the annual update



- Type IA in changes must still be notified without delay.
- In duly justified exceptional circumstances—*e.g., supply shortages, public-health emergencies, explicit requests from the authorities, or resubmission of an IA previously rejected within an annual update*—an individual application remains possible.
- When a Type IA variation is submitted together with a Type IB or Type II variation as part of a duly justified grouping of related changes.
- When the variation is included in a “super-grouping”

Annual Update Submission Procedure:

1. Telematic submission:

Through **CESP** using the standard process:

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- Add the description “Annual Update” in the free text sections.
- Only one CESP, one CESP number, one e-AF and if applicable, “n” sequences (zip)

2. Variation procedure number:

Unique number: can be allocated by the MAH itself.

- NP: Blank (assigned by NCA)
- MRP/DCP: identical to the MRP/DCP variation number (e.g. DE/H/0450/IA/070/G).

3. Cover letter

- Include confirmation “*within 12 months following the implementation of the first type IA variation*”
- Include implementation date

Sequence: include dossier section number(s) at the lowest possible level according to eCTD.

4. e-Application form:

- Section 1: NOT checkbox currently (*Note: inclusion expected in the second quarter of 2026*)
- Section 3: complete both current & proposed sections to show exactly what is changing.
- For ‘do and tell’ variations the implementation date needs to be specified.

Management of Type IA and IAin Variations

SUPERGROUPING

- The SG procedure consists of a grouped submission of **one or several variations of type IA and/or type IAin to the terms of several marketing authorisations of the same holder.**
- The type IA variations included do not need to be related to each other.
- A super-grouping may cover for same MAH / several Member States:
 - Several MRP/DCP Marketing authorisations.
 - Combination of national and MRP/DCP Marketing authorisations.
 - Several purely national procedures.



SG cannot combine centrally authorised products with national or MRP/DCP products within the same submission.

Supergrouping Submission Procedure:

- ① **1• Telematic submission:**

Through **CESP** using the standard process.
Only ONE CESP, ONE CESP number, ONE e-AF and “n” sequences (zip).
- ② **2• Variation procedure number:**

Assigned by the RMS: CC/D/nnnn/qq/vvv/G, where nnnn = XXXX (if > 1 MA)

 - *The chosen RMS needs to be contacted well in advance by submitting the "letter of intent for type IA super-grouped procedures" using the CMDh template.*
- ③ **3• Cover letter**
 - Indicate: *the application concerns <Grouping of variations>*
 - **Sequence:** include dossier section number(s) at the lowest possible level according to eCTD.
- ④ **4• e-Application form:**
 - Section 1: fill SG checkbox
 - Section 3: complete both current & proposed sections to show exactly what is changing.
 - For ‘do and tell’ variations the implementation date needs to be specified.

Management of Type IB/II Variations

WORKSHARING

- A MAH is required to submit the **same type IB or type II variation, or the same group of variations affecting more than one marketing authorisations from the same holder** in one application via a worksharing procedure.
- If a change has already been submitted outside a worksharing procedure but later falls within its scope, it must be aligned with the worksharing process to ensure consistent assessment and decision-making across all affected MAs.
- MAHs and concerned Member States are informed of the schedule by the reference authority at the start of the procedure.



Worksharing Submission Procedure:

- ① **1. Telematic submission:**
 - Through **CESP** using the standard process: Only ONE CESP, ONE CESP number, ONE e-AF and “n” sequences.

- ② **2. Variation procedure number:**

Assigned by the RMS: CC/D/nnnn/qq/vvv/G, where qq: procedure qualifier for WS procedure = “WS”

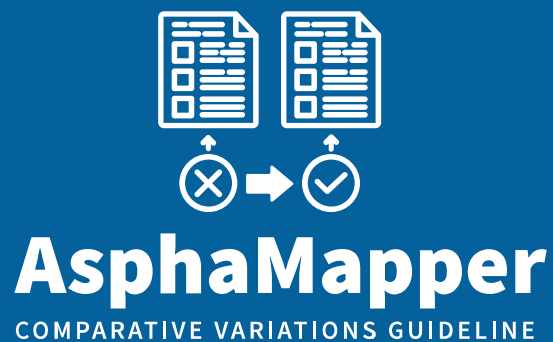
 - *contact the Reference Authority (MRP/DCP) or EMA (CP) prior to submission, by using the “letter of intent” for worksharing procedures.*

- ③ **3. Cover letter**
 - Indicate: the application concerns <Worksharing>

- ④ **4. e-Application form:**
 - Section 1: fill WS checkbox
 - Section 3: complete both current & proposed sections to show exactly what is changing.
 - The implementation date for the Type IB and Type II variation(s) need(s) to be indicated.
 - Additional declaration to be ticked “the MAs concerned belong to the same MAH”.

Do you need support with Variations?

Contact us:
info@asphalion.com



Check out our [AsphaMapper](#)
free tool and compare the
old and new EU Variations
Guidelines!