Règlement «variations» modifié : infos pratiques & rappels

Direction des autorisations

Comité d'interface – Sous-groupe Amélioration des processus

12 février 2025

Modalités de soumission : annual update

- **Réglementation :** 1 annual update par AMM/produit (par NL)
- **Soumission CESP :**

  Cas d'un eCTD qui concerne plusieurs NL, et l'annual update est identique pour tous les NL :

  - déposer 1 séquence par NL
  - chaque séquence fera l'objet d'1 dépôt sur le CESP
  - dans la cover letter, préciser que l'annual update est identique dans les séquences n°xxx, n°yyy, n°zzz etc (à désigner)

Formulaire de demande

- **Version en vigueur à utiliser (à date) : 1.27.0.0.**

A défaut, il s'agit d'un motif de non-recevabilité, conformément au « Position paper common grounds seen for invalidation/delaying day 0 for variations ».

- **Produits concernés par la demande (ex: supergrouping, WS) :**

Les produits doivent être listés dans l'eAF (pas listés en annexe).

- **La section « Declaration of the applicant about submission(s) of the same variation (or group of variations) does not apply to any other member States »** doit être systématiquement complétée pour les modifications de type IB ou II, à défaut ce sera un motif de non-recevabilité.

Declaration of the applicant about the submission(s) of the same variation (or group of variations) in other Member States / EMA.

☒ **The applicant confirms that the same variation (or group of variations) does not apply to any other marketing authorisation held by the same holder *(only applicable for Type IB and/or Type II***

ansm

RETEX dépôts début 2025

Les modifications de type IA mises en œuvre en 2025 doivent être soumises conformément au règlement modifié.

Par conséquent :

- **Pas de dépôt de modifications de type IA isolées,** sauf cas dérogatoires décrits au BPG Chapitre 6 « CMDh Best Practice Guide for the processing of (super-)grouped applications in the Mutual Recognition Procedure » ;
- **Pas de dépôt de grouping de type IA/IA ni IA/IAIN**

Rappels : Q&A - List for the submission of variations for human medicinal products according to Commission Regulation (EC) 1234/2008 as amended (CMDh/132/2009, Rev.63) (1/2)

En anticipation des dépôts de modifications cliniques, une harmonisation de(s) section(s) du RCP de plusieurs AMM nationales approuvées dans différents états membres est possible:

4.21. Is it possible to use the worksharing procedure to harmonise different nationally approved stand-alone ("originators") product informations and if so how should they be submitted?

Answer:

The CMDh has introduced the promotion of the worksharing procedure for the harmonisation of medicinal products in its workplan 2020. It is therefore encouraging applicants to **make use of the worksharing procedure for a complete harmonisation of the product information** in these cases. For all other changes to the product information of several MAs owned by the same holder a worksharing submission is anyway mandatory according to Art. 20 (4) of the Variation Regulation (EU) 1234/2008 as amended.

The member states (MS) have already agreed to accept worksharing in the situation **where the intention is to harmonise different nationally approved, stand alone, SmPCs of the same MAH**. The main prerequisite for these procedures is a harmonised product information as the outcome of the worksharing procedures.

Changes that are so far not approved in any of the member states are not accepted in these worksharing procedures for harmonization of the product information. They should be submitted as separate worksharing applications including the respective documentation to support these changes and regular handling as possible grouped variation would be applicable (see Q&A 4.14 and 4.17).

Rappels : Q&A - List for the submission of variations for human medicinal products according to Commission Regulation (EC) 1234/2008 as amended (CMDh/132/2009, Rev.63) (2/2)

4.11. Must all changes in a grouped application according to article 7 or in a worksharing application according to article 20 of the Regulation (EC) 1234/2008 as amended apply to all strengths and pharmaceutical forms that have been included in this group?

Answer:

Yes, all the changes in one variation application must apply to all the products that are listed in the application form. It is not allowed that single changes of a grouped application or a worksharing do only concern parts of the list of products.

However, **in case some changes are already implemented in parts of the products in certain member states, these should be included in the worksharing to achieve a complete harmonisation of all products concerned.**

Merci pour votre attention

Avertissement

- Lien d'interêt : personnel salarié de l'ANSM (opérateur de l'Etat).
- La présente intervention s'inscrit dans un strict respect d'indépendance et d'impartialité de l'ANSM vis-à-vis des autres intervenants.
- Toute utilisation du matériel présenté doit être soumise à l'approbation préalable de l'ANSM.

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