Agence nationale de sécurité du médicament et des produits de santé

Conformité de l’e application form (eAF)

GT Amélioration des Processus – 18 octobre 2023

Rappel exigences

- **Données eAF : doivent être synchronisées avec celles du module 3 = tout au long de la procédure**
- Recommandé par le CMDh depuis décembre 2020
- **Constat en septembre 2023 : trop de cas où cela n'est pas fait** => nécessité de rappeler l'information

NOUVEAU → Variation à soumettre si en fin de procédure de demande d'AMM si eAF non synchronisée avec le module 3 (section 2.5 + annexe 5.8)

Documents mis à jour

- **Mise à jour du eAF user guide**
- BPG du CMDh « **The Applicant's response document** » mis à jour

> The applicant should keep data synchronisation between module 3 and module 1.2~~.~~ (eAF section 2.5, annex 5.8). Data synchronisation has to be kept throughout the whole procedure.
>
> In this respect, the applicant should submit as part of the response document an updated application form, each time the information is modified.
> The addition of new manufacturing sites during the procedure is normally not foreseen unless they are added in response to the LoQ.
> He should indicate what the changes are, especially when these are related to manufacturers and he should submit the relevant annexes updated accordingly, in particular annex 5.8 ("*Flow-chart indicating all manufacturing and control sites involved in the manufacturing process of the medicinal product and the active substance*").
>
> Note for Applicant: Manufacturing sites that are not included in Module 1.2 (eAF section 2.5) at the end of procedure (EoP) cannot be considered for issuing the MA decision. If discrepancies between Module 3 and Module 1.2 are identified after the EoP, a variation application should be submitted according to the relevant category in the classification guideline including all relevant documentation. The variation application has to be submitted, even if the error relates solely to the function/role, name or address of the manufacturing sites.

- **Applicant's responses template** => confirmation à apporter

> ☐ Confirmation that module 1.2 (eAF) is up to date and data of the eAF are synchronized with module 3 and the rest of the relevant documentation

Rappel exigences nouvelle demande d'AMM

- **eAF section 4 : OTHER MAKETING AUTORISATION APPLICATIONS** informations sur les autres demandes soumises/AMM déjà octroyées => souvent incorrectement renseignées

4.1 FOR NATIONAL/MRP/DCP APPLICATIONS, PLEASE COMPLETE THE FOLLOWING IN ACCORDANCE WITH ARTICLE 8(j)-(l) OF DIRECTIVE 2001/83/EC

4.1.1 Is there another Member State(s) where an application for the same* product is pending**?

○ Yes ○ No ○ Not Applicable

If yes, section 4.2 must be completed

4.1.2 Is there another Member state(s) where an authorisation is granted for the same* product?

○ Yes ○ No

If yes, section 4.2 must be completed and copy of authorisation provided

Are there any differences which have therapeutic implications between this application and the applications/authorisations for the same product in other Member States (for national applications, Article 17 or 18 of Directive 2001/83/EC shall apply).

○ Yes ○ No

4.2 MARKETING AUTHORISATION APPLICATIONS FOR THE SAME PRODUCT IN THE EEA (SAME QUALITATIVE AND QUANTITATIVE COMPOSITION IN ACTIVE SUBSTANCE(S) AND HAVING THE SAME PHARMACEUTICAL FORM FROM APPLICANTS BELONGING TO THE SAME MOTHER COMPANY OR GROUP OF COMPANIES OR WHICH ARE "LICENSEES").

☐ Authorised

☐ Submited

☐ Refused

Rappel exigences modifications d'AMM

- eAF : informations sur soumissions parallèles à renseigner / modifications de type II

  If the same type II variation application for the same medicinal product[1] has also been submitted in other Member State(s) not involved in the current procedure. If yes, the applicant has to specify in which Member State it has been submitted and when; the status of the variation should also be stated. If the same variation has been submitted in several Member States, the section should be duplicated by using "+" button.

- eAF: préciser si une procédure d'harmonisation des RCP/notice/étiquetage a eu lieu

  If the product information of the concerned MA(s) has/have been (partially) harmonised by an Article 30 or 31 referral or that harmonisation of a section / some sections of the product information has been achieved through a variation worksharing procedure. The latter concerns both worksharing variations dedicated to (partially) harmonise previously disharmonised product information (as detailed in Q4.21 of the CMDh Q&A on variations), as well as worksharing variations aimed to add new information in a harmonised way.

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Avertissement

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