November 2024

Information Technology
EMA/477434/2020

eAF Release Notes v1.27.0.0

The scope of release v1.27.0.0 covers the following fixes and features:

1. US 216232 [Human Variation] - [eAF] Variation regulation changes in human variation eAF form

Additional details can also be found in the release notes accessed here: eAF esubmission website.

1. **US**216232 **[**Human Variation**] Human Variation form -** Variation regulation changes in human variation eAF form
   In Human Variation form the following are implemented:

1) For any of the following cases selected:

- National Authorisation in MRP/DCP and/or National Authorisation OR
- EU Authorisation

below "worksharing" existing check box a new checkbox "Super-grouping" is added.

The business rules related with this new check box are:

- this is a non mandatory check box
- if this new check box is selected, only Type IA or Type IAIN are enabled to be selected and the user is able to select either "group of variation" and "Super-grouping" or single variation" and "Super-grouping".
- It is not possible to select both "Worksharing" and "Super-grouping".

2) When Type II or Type IB or Type IB unforeseen or Type II Art29 (or any combination of those e.g. Type IA and Type II) is/are selected then the following apply:

The declaration and harmonisation section is applicable and is moved at DECLARATION OF THE APPLICANT section (before existed at "SIGNATURE" section). The visibility rule of this section is modified in order to be displayed also for only CAPs variations

For any authorization type selected at section 1:

a) The label of the section bold header is "Declaration of the application about the submission(s) of the same variation (or group of variations) in other Member States / EMA"

b) The label of the text to the tick box is " 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 variations)". A “Note” field is added that it is mandatory only in case the applicant doesn’t tick the box. So if the tick box is ticked, then the note field is available, but optional, if the tickbox is not ticked, in case of EU authorisation only, or mixed, then the note field is mandatory. Also, when this tick box is unticked (default value) then the section of the fields “Country”, “Invented name”, “Date of submission” etc is displayed. If this tick box is ticked then the section of the fields “Country”, “Invented name”, “Date of submission” etc is not displayed.

3) The 'last' of the current tickboxes in the section “Declaration of the Applicant)” is updated as: For mandatory worksharing or (super-)grouped variations affecting more than one MA: the MAs concerned belong to the same MAH.

4) The following notes are updated:

- The veterinary medicinal product part of Note 1 is deleted and replaced with "A MAH shall follow the worksharing procedure, where applicable. The worksharing procedure is optional where it involves more than one MA not belonging to the same GMA"
- Wording under note 5, note 6 and Declaration of the applicant to be updated as "grouped variations' to become "(super)-grouped variations"
- Wording under note 13 to be updated as "(super-)grouped variations affecting more than one MA, if appropriate.
- Note 7 is updated to delete the text: “Veterinary products only: If this list is very extensive it may be added as annex to the application form.” And “For MRP/DCP procedures, “list of concerned products” can be provided as Annex to the application form”.