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CMDh Guidance document for Submission of Summary of the Pharmacovigilance System

1. Introduction

All new applications require the submission of a summary of the Pharmacovigilance system (sPhVS) in section 1.8.1.

When submitting a new application via the DCP/MRP procedure, the application may include more than one future MAH different from the applicant (included in section 2.4.1 of the application form), since future MAHs could be applied for in each member state. This entails the submission of different sPhVS, in case the different proposed local MAHs do not belong to the same parent company.

2. Submission of summary of the Pharmacovigilance system at day 0

The sPhVS of the applicant and proposed future MAHs if different from the applicant should be submitted by the applicant as part of the MRP/DCP application at day 0 of the procedure.

The RMS should assess all sPhVS submitted in module 1.8.1 and mention this in the overview AR.

3. Change of future MAH during the DCP/MRP procedure

It is possible to change the future MAHs during the DCP/MRP procedure provided that:

- This change is included in an official response document submitted during the procedure;
- The sPhVS of this new future MAH should be submitted in module 1.8.1.

This means that changes to the future MAHs can only be submitted on:

- Day 40 of an MRP;
- Day 106 and day 160 of the DCP.

The RMS should assess the newly submitted sPhVS in the day 120 or day 180 AR (DCP) or RMS's position on the day 40 responses (MRP).

NB: A future MAH can be changed only once per MS during a MRP/DCP procedure.

4. Change of the (future) MAH during the national implementation phase (after day 90/210) or transfer MAH after granting of the marketing authorisation

The applicant should discuss with the particular Member State whether or not a change of the future MAH can be handled as part of the national implementation process.

In case the MAH is changed in a CMS during the national implementation phase or after granting of the marketing authorisation in a CMS, the MAH should submit a type IAin variation procedure (category C.I.8.a) via MRP to change the sPhVS. See CMDh Q&A 2.8 on variations).

NB: Also in case the marketing authorisation is transferred to another MAH but, the first/previous MAH remains responsible for ALL Pharmacovigilance activities, a sPhVS signed by the new MAH should be submitted via a type IAin variation application C.I.8.a (see CMDh Q&A 2.8 on variations)

5. Repeat use MRPs: submission of summary Pharmacovigilance system

In case the MAH wishes to submit a repeat use MRP with a future MAH in the new CMSs, which is not included in the dossier yet, a sPhVS for this new future MAH(s) should be submitted as part of the repeat use MRP. The RMS should then include this new sPhVS in the updated AR.

In order to keep the dossier harmonised, the old CMS(s) need to receive the sequence with the new sPhVS no later than by the time of the next common submission.