

**CMDh GUIDANCE DOCUMENT FOR
DECLARATION FORM SUBMISSION DDPS (DETAILED
DESCRIPTION PHARMACOVIGILANCE SYSTEM) ALREADY
APPROVED BY A COMPETENT AUTHORITY (CA) of the EEA
(including Iceland, Norway, Liechtenstein and the EMA)**

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1. Introduction

All new applications require the submission of a detailed description of the Pharmacovigilance system (DDPS) 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 DDPSs, in case the different proposed local MAHs do not belong to the same mother company.

2. Declaration form submission DDPS

The DDPS of a proposed future MAH should be submitted as part of the MRP/DCP application at day 0 of the procedure.

It is **not possible** to include future MAHs in the application form, different from the applicant, with a DDPS which has **not been** approved by a CA of the EEA (including Iceland, Norway, Liechtenstein and the EMA).

~~2. Declaration form submission DDPS~~

To facilitate the assessment of the RMS a declaration form for the submission of the DDPS has been published on the CMDh website (<http://www.hma.eu/91.html>).

The applicant is requested to use this declaration form when submitting on behalf of the future MAHs a DDPS already approved by a CA, ~~both for the DDPS for the applicant and for future MAHs.~~ of the EEA (including Iceland, Norway, Liechtenstein and the EMA). ~~The Only one~~ declaration form should be ~~completed and submitted used~~ by the applicant ~~as an annex to the application form~~ completed for the information for both the applicant and, if applicable, for the future MAHs. The applicant should sign the form on behalf of the future MAHs.

The declaration form should be submitted in module 1.8.1.

The declaration form should also be used when submitting a type IB variation application (C.I.8.ab) to introduce a new Pharmacovigilance System in the dossier, which has been assessed/approved by ~~the relevant national~~ a competent authority of the EEA (including Iceland, Norway, Liechtenstein and the EMA) for another product of the same MAH.

Below some Q&As have been included, addressing some common questions on the use of the declaration form:

Question:

It is assumed that in case section 4 is filled in with yes, in section 6 it can be mentioned applicant and all future MAH's without going into any details who all these future MAH's are ? Or need they all to be listed separately?

Answer: In case section 4 of the declaration form is filled in with yes then there are no future MAHs different from the applicant so there will be no other future MAHs.

Question:

Only when section 4 is filled in with no, section 6 needs to be detailed with all future MAH information.

Answer: Yes.

Question:

For section 5.1 it is supposed that you fill in information under “current” if it is a new application at day 0 and that you will fill in “proposed” whenever a change is made during the procedure or when a variation is executed.

Answer: Yes: you have to fill in section 5.1 of the form

- DPC/MRP applications: when in the application form future MAHs are included different from the applicant

- type IB variation (C.I.8.b) to mention the new proposed MAH.

Question concerning the table in section 5.1 of the declaration form:

It is not clear if the whole table is to be filled in when you do a variation after closure of the procedure. Is it then sufficient to only provide the details of the member states where a change in MAH is taking place ?

Answer:

In case of a type IB variation (C.I.8.b), i.e. submission of an approved DDPS to the dossier, after finalisation of a DCP you don't have to fill in this table as the new MAH will then submit his own new DDPS.

Question

Who is considered to be the applicant in the following situation:

- RMS has MAH 1

- CMS 1 till 4 has MAH 2 (from same mother company)

- CMS 5 a transfer is needed from MAH 1 to MAH 3 which is not part of the same mother company.

Who is then considered the applicant? MAH 1, MAH 2 or MAH 3.
Or is it by definition the MAH in the RMS?

Answer: The applicant should be the same in RMS and CMSs, so MAH1 should be the applicant in RMS and CMSs. Concerning different MAHs belonging to the same mother company see also introduction of this Guidance document.

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 DDPS of this new future MAH is already approved by a CA of the EEA (including Iceland, Norway, Liechtenstein and the EMA);
- The declaration form submission DDPS is used.

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

- Day 60 of an MRP;
- Day 106 and day 160 of the DCP.

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)

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 DDPS for the new MAH has already been approved by a CA of the EEA (including Iceland, Norway, Liechtenstein and the EMA) but not yet listed in the final AR (as the new MAH was not included in the application form on day 0 of the procedure, or added during the procedure) the new MAH should then also confirm this by using the declaration form submission DDPS.

In case the new MAH has not yet an approved DDPS the transfer of the MAH should be dealt with after granting the national licence. Separate from the request to transfer the MAH a MRP type II variation should be submitted for the submission of a new DDPS in accordance with the Classification Guideline (variation C.I.8.a).

In case the MAH is changed in a CMS during the national implementation phase or after approval in a CMS, the CMS should request the new MAH to submit a variation procedure to change the DDPS in accordance with the Classification guideline. The CMS should also inform the CMSRMS of this request.