



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Questions and Answers on variations to an existing pharmacovigilance system as described in the DDPS (update, July 2013)

1. General

1.1. How should MAHs use the revised Variations Guidelines?

MAHs should identify all changes to the DDPS reflecting changes in the pharmacovigilance system and classify them as much as possible under the defined scopes of the Variations Guidelines. For unclassified changes, a Type IB variation may be appropriate, unless the change may have a significant impact on quality, safety or efficacy, in which case a Type II variation will be appropriate. For existing Marketing Authorisations of human medicinal products, the MAHs have the obligation to keep the DDPS up-to-date until the summary of the pharmacovigilance system is introduced.

For further information on grouping and worksharing please refer to EMA [Q&A on grouping](#) and [Q&A on worksharing](#).

For further information on the requirements for variation submission in the case of changes to the DDPS or introduction of the summary of the applicant's pharmacovigilance system resulting from a MA transfer please refer to [EMA Q&A on transfer](#).

1.2. Who should sign the statement on the availability of the services of the Qualified Person for Pharmacovigilance (QPPV) and the proof that the MAH has the necessary means for the collection and notification of any adverse reaction??

The required statement must be signed by the QPPV and the (legal representative holding a relevant position within the organization, of the) MAH of the specific product. Please note that the concept of same applicant/same MAH as defined in the Commission Communication 98/C229/03 (according to which "Applicants belonging to the same mother company or group of companies and applicants having concluded agreements or exercising concerted practices concerning the placing on the market of the relevant medicinal product have to be taken as the same MAH"), does not apply to the



aforementioned statement and only the signature of a legal representative of the specific MAH for the concerned product can be accepted.

2. Related to C.I.9 - Changes to an existing pharmacovigilance system as described in the DDPS

2.1. Is it acceptable to submit a number of changes to the DDPS (i.e. change in the safety database, change in the major contractual arrangements and other changes) under variation C.I.9.c?

Variation C.I.9.c) covers other changes to the DDPS that do not impact on the operation of the pharmacovigilance system, but it cannot be used for changes in the DDPS falling under other categories indicated in the Variations Guidelines. Such changes should be submitted under the relevant indent. For example, a change in the QPPV and/or QPPV contact details (C.I.9.a) should be declared as a separate variation category in the application form when applying for variation.

2.2. Which variation category should be submitted in relation to a change of the deputy QPPV?

The deputy QPPV is considered a back-up procedure. In case the deputy QPPV name and/or contact details are part of the DDPS document and these change, then the DDPS needs to be updated and a variation should be submitted as a C.I.9.a) Change in the QPPV and/or QPPV contact details and/or back-up procedure.

2.3. When can a variation under category C.I.9.d) be filed?

C.I.9.d) can only be used to introduce changes in the DDPS of a medicinal product following approval (i.e. a positive EMA notification or a Commission Decision has been issued, as applicable) of the same changes in the DDPS of another medicinal product from the same MAH requested in the framework of the assessment of a DDPS submitted as part of a new MAA (only for veterinary medicinal products)/extension/variation (cfr. note to C.I.9.d) of the Variation Guideline).

In case a positive EMA notification or a Commission Decision has not been issued yet, indent C.I.9.d) cannot be used; however, the applicant/MAH may submit an independent application for the change(s) to the DDPS through the appropriate indent(s) of the Variations Guidelines.

2.4. How to submit a change to a product specific addendum?

The product specific addendum usually provides information on contractual arrangements and in this case it can be varied under C.I.9.b). In all other cases the classification will depend on the information included in the addendum.