EUDRAVIGILANCE R3 FAQ – FAMHP

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1. Receiving FAMHP cases

Q:
Will FAMHP stop sending ICSRs to marketing authorisation holders?

A:
From 22 November 2017 onwards marketing authorisation holders will no longer receive regulatory cases directly from FAMHP. The cases will be made available to MAHs via the EudraVigilance system in ICH E2B(R3) format. In order to comply with their pharmacovigilance obligations, it is important that marketing authorisation holders have the right access to EudraVigilance. This access is granted on the basis of the product data supplied by the EMA in accordance with Article 57 (2) of Regulation (EU) No. 726/2004. **It is therefore essential that marketing authorisation holders ensure that data in the Art 57 database is always complete and up to date**.

Q:
Will non-serious FAMHP cases be available for download from EudraVigilance?

A:
Yes, marketing authorisation holders will have standard access in EudraVigilance to both serious as well as non-serious reports, including the FAMHP reports.

Q:
Which E2B message format will FAMHP use for their submissions to EudraVigilance? This is important to assess the impact on data when loading ICSR into our system with a Backwards Forwards Compatibility tool.

A:
From 22 November 2017 onwards the ICSRs submitted to EudraVigilance will have the ICH E2B(R3) message format. EudraVigilance will make the ICSRs available for download in E2B(R3) format as well.

Q:
Will FAMHP cases downloaded from EudraVigilance contain a case narrative?

A:
The download of FAMHP cases according to Level 2A access (see EudraVigilance access policy: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2016/12/WC500218300.pdf) does not provide case narratives.
Marketing authorisation holders can request access to an extended subset of ICSR data elements including case narrative ('ICSR data set level 2B') when a review of ICSR data is warranted in the context of signal management (GVP Module IX), a pharmacovigilance assessment procedure such as the PSUR or when required by the PRAC in a referral or signal assessment procedure.

Access to Level 2B is granted by the QPPV or deputy QPPV within your organisation. Level 2B requests can be made by entering a list of worldwide unique case identifiers for which the corresponding ICSRs can be downloaded in one zipped file with the exported E2B(R3) files. Each request requires the confirmation of the confidentiality

undertaking. The following eLearning course shows how to make a Level 2B request:
https://www.youtube.com/watch?v=huVGOfhx9Ug

Q:
As a MAH, how many FAMHP cases can we expect to become available to us via EudraVigilance?

A:
Unfortunately it is not possible to give estimates of how many cases would be relevant for each individual MAHs product portfolio. In 2017 (first semester) FAMHP received about 1/4 serious cases and 3/4 non-serious cases.

Q:
What is the process for requesting follow-up for FAMHP cases?

A:
As stated in GVP Module VI (Rev 2) the routine request for follow-up by the marketing authorisation holder is not foreseen. If the follow-up of an ICSR is necessary for a specific situation, a justification should be provided with the request, which should be addressed to FAMHP (adr@fagg-afmps.be).
For each case, the assessor determines if a follow up request is useful. In case of the points mentioned below, no follow up is requested to the reporter. This concerns:

- information such as medical history, risk factors, concomitant medication and other information which is already asked in the initial reporting form.
- medical confirmation for consumer reports
- a consent form for consumer reports to bring his/ her Health Care Professional directly in contact with the Marketing Authorisation Holder
- follow up information from which it is not likely the reporter has that type of information, e.g. an ECG and a pharmacist as reporter.

Only one request per case should be made.

Only specific questions should be asked (no questionnaires).

You will be informed if (a part of) the follow up information will be requested within a month. Received follow up will be added to the report and sent to EudraVigilance.

Q:
Which language is used in the FAMHP reports?

A:
FAMHP uses the E2B(R3) message format which allows information in different languages. In principal all data-elements will be in English language, with exception for the following data-elements:

- Name of medical product as reported by primary source (G.k.2.2.)

- Indication as reported by primary source (G.k.7.r.1)
- Reaction as reported by primary source in native language (E.i.1.1a)
- Case summary reporter's comments (H.5.r.1a)
- Narrative (partially)

Q:
A downloaded FAMHP case appears to be a duplicate of a case that the MAH also has submitted to EudraVigilance. How should the duplicates be managed?

A:
If there is a suspicion that two or more cases are duplicates of one another, please send an email to the EMA (duplicates@ema.europa.eu) with information on which cases are suspected to be duplicates.

If the EMA confirms that the cases are indeed duplicates, a master case will be created and this Master case will also be made available for download.

For more information, see GVP Module VI Addendum I – 'Duplicate management of suspected adverse reaction reports':
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2017/08/WC500232765.pdf

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2. Submitting ICSRs to EudraVigilance

Q:
What to do in case of system failure (e.g. EVWEB, gateway are not available)?

A:
Please follow the instructions provided by the EMA:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000686.jsp&mid=WC0b01ac0580a69261#What to do in case of system failure.

There is no need to inform the FAMHP separately.

Q:
Is there a requirement to use Dutch/French language when submitting ICSRs to Eudravigilance?

A:
No, there is no such requirement. Both English and national languages are acceptable.

Q:
When submitting literature cases to EudraVigilance, is there a national requirement to submit the published article as well?

A:
No, there is no such requirement. The published article only needs to be submitted upon request.

Q:
When downloading a FAMHP case from EudraVigilance we noticed that we have received the same case, but we have not yet submitted this ICSR to EudraVigilance. We are approaching the 15-day deadline for submission. How should we proceed to avoid duplicates in EudraVigilance?

A:
As not to compromise legal expedited reporting timelines, it is recommended to submit the case to EudraVigilance. Subsequently inform EMA (duplicates @ema.europa.eu) to initiate the appropriate step for managing the duplicates. For more information, see GVP Module VI Addendum I – 'Duplicate management of suspected adverse reaction reports':
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2017/08/WC500232765.pdf

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Q:
We have downloaded a non-serious FAMHP case which would be considered serious according to our own internal policies. Do we need to submit this as a serious case to EudraVigilance?

A:
No, this upgraded version should not be submitted to EudraVigilance.
