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Position paper

3rd July 2020

AnimalhealthEurope comments to the EMA advice to the European Commission on the Pharmacovigilance System Master File

Implementing measures under Article 77 (6) of Regulation (EU) 2019/6 as regards "Format and content of the pharmacovigilance system master file and its summary".

General comments

AnimalhealthEurope would like to thank the EMA expert group for the investment in their time and the Commission for the opportunity to provide comments on this important document.

AnimalhealthEurope would like to bring to the attention of the Commission the main points where we believe further clarification and discussion would be beneficial to all stakeholders and necessary in order to take into account the needs of marketing authorisations holders.

In the "Overview of recommendations, considerations and rationale" section we have noted:

- The development of guidelines with the objective to ensure that the system is adaptable and flexible to the needs of all stakeholders and provide the appropriate details, is appreciated. This is supported, as these guidelines would be expected to bring more clarity on the processes referred to in this document. AnimalhealthEurope would very much appreciate the opportunity to contribute to the early development of these important guidelines to ensure they will provide the necessary additional clarity for all stakeholders as soon as possible.
- Throughout the document the recommendation mentions 'lists' to host various datasets. AnimalhealthEurope understands that it would be beneficial to allow other systems as an alternative, where the required information is kept, as long as these alternative systems fulfill the same objectives. This comment is particularly relevant to Section 3: Content of the annexes to the pharmacovigilance system master file (PSMF).
- At the current time, it is not entirely clear to AnimalhealthEurope how changes to the summary of the PSMF will be managed, as the information will appear in a number of different places: the application dossier for new products (EU 2019/06 Art 8.1(c)), the Union Product Database (UPD), Vet IG Chapter 2: section 1.7, the Union Pharmacovigilance Database (EU 2019/06 Arts 74.1/77.8) as well as in the MAH maintained PSMF.

  Never-the-less, the important point is that any change to this information should only lead to a single variation which varies every instance of this information (and not multiple variations as is currently required with the Detailed Description of the Pharmacovigilance System). AnimalhealthEurope believes that this process needs to be identified at this early stage so that the necessary steps are built into the understanding and functional specifications for each of these different systems.

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Specific Comments/Questions

3. Content of the annexes to the pharmacovigilance system master file

- 1: It should be made clear that the list of all VMPs refers to all VMPs covered by the PSMF, i.e. that it means just the EEA products (and does not mean VMPs registered globally).

  It seems there is duplication of the requirement to submit this data to UPhVD in GVP:

  - If information on VMPs is provided to UPhVD then the requirement to separately maintain a list in the PSMF annexes should be deleted; if kept in the PSMF annexes, then the requirement to add to the UPhVD should be deleted (such lists should only be maintained in one place).
  - If the list is kept in the PSMF annexes – a virtual list should also be allowed (i.e. the extract from a query which is run as needed). In addition, MAHs should be allowed to generate any such a list from either the MAH database or the UPD (and must not be mandatory to use the UPD).

- 5. We understand that the overview contracts and agreements with subcontracted third parties should be limited to the EEA and detailed at a high level only. Collating such an overview for third countries in the annex of the PSMF would be a significant administrative burden.
- 8. We understand that the list of local or regional representatives (i.e. a nominated person for pharmacovigilance contact with national authorities within a Member State) should be limited to the EEA. Collating such a list for third countries in the annex of the PSMF would be a significant administrative burden.

4. Content of the summary of the pharmacovigilance system master file

- 1: A signed statement from the applicant and the qualified person for pharmacovigilance (QPPV) is required. This should only be signed by the applicant, not by the QPPV. Most importantly, any change should only lead to a single variation in order to avoid increasing the administrative burden for MAHs and authorities. As identified in the general comments, this is considered a very important principle.
- 3&4: A primary objective of the review of the legislation leading to Regulation 2019/6 was to reduce administrative burden. The very purpose of a master file system is to contribute to that objective by removing the need for variations to multiple MA dossiers. The relevant primary point of legislation is Regulation 2019/06 Art 8.1(c), which requires the dossier to contain "a summary of the pharmacovigilance system master file." The contents of the summary is not specified.

  To fulfil this objective, it is essential that the information in the summary of the PSMF is stable and will not be subject to variations. The name, contact details and place of operation of the QPPV as well as the PSMF location should be in the UPhVD. Adding these details to the summary of the PSMF represents duplication of data, and a potential source of inaccuracies. In particular the name of the QPPV should not appear in the MA dossier as this is information that is almost certain to change (often), triggering the need for numerous variations.

5. Maintenance of the pharmacovigilance system master file

- 4: AnimalhealthEurope is very concerned that variations to all MAs will be required following changes to the summary of the PSMF, as the summary is part of the MA application dossier. AnimalhealthEurope strongly recommends that the summary of the PSMF only contains the signed statement and the PSMF number. Agency systems should be set up so that all MSs are automatically notified of changes to the PSMF without the need for the MAH to introduce multiple variations (as currently in place for changes applicable to the Detailed Description of the Pharmacovigilance System, which is seen as a significant administrative burden).

6. Format of the pharmacovigilance system master file

- 2: We understand that this should allow PDF printed and potentially other document formats such as Excel files. However, there seems to be a contradiction on this printed copy requirement at point 4 section 8. This needs clarification.
- 2: We also understand that the requirement for a printed copy made available for audits and inspections only refers to the Core part of the PSMF as it may be very difficult if not impossible to print the annexes.

8. Location and availability of the pharmacovigilance system master file

- 1: AnimalhealthEurope strongly recommends that the summary of the PSMF does not contain information that may require a variation. Therefore, clarification is needed as to whether a change to the location of the PSMF would result in variations for each MA involved. We believe this should not be necessary, as the PSMF should be used as the 'master' information. As previously identified, AnimalhealthEurope strongly recommends that any change to the PSMF should only result in a single variation to the PSMF itself, which covers all systems (and products).
- 4: This bullet point is inconsistent with point 2 of section 6 (as further discussed above).