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Questions and Answers on the EU Synchronisation of PSUR submission schemes of medicinal products authorised through national and mutual recognition procedures

Under the auspices of the “Heads of Medicines Agencies” an initiative has been taken to ensure that medicinal products with the same active substance follow the same Periodic Safety Update Report (PSUR) submission scheme in all EU Member States. The list of adopted EU Harmonised Birth Dates (HBDs) and accompanying DLPs for the forthcoming PSURs can be found on the HMA website [HYPERLINK].

When can companies start to submit PSURs based on the EU HBDs?

Immediately.

Where should the PSURs be submitted?

PSURs should be submitted simultaneously in all Member States where the product is authorised.

May PSURs be submitted on CD-ROM?

The submission requirements for PSURs as included in the current Vol. 9 of “The Rules governing medicinal products in the European Union” apply. The requirements will be updated in the new Vol. 9A which is likely to be published before the end of 2006.

At the time of publishing the list of EU HBDs and related DLPs several of the agreed DLPs have elapsed already for more than 60 days. Do Member States accept PSURs with a longer period than 60 days between DLP and submission date?

Member States have agreed to accept PSURs that are submitted more than 60 days after the harmonised DLP. Addendum PSURs may be added if considered appropriate, however, also in that case the following PSUR should have a DLP which is 3 years after the original agreed harmonised DLP. (New safety information which may emerge after the DLP used and which could have an impact on the risk-benefit balance should always be submitted to the competent authorities without delay.)

If PSURs have been submitted in the past on different dates because of different national birth dates, the first PSUR based on the EU HBD and related DLP will have an overlap with some PSURs that were submitted previously. Is that acceptable?

Yes, it is. It is inevitable that the first PSUR based on the EU HBD has an overlap with one or more PSURs submitted nationally in the past.

Should the EU HBDs also be used for PSURs of generic products?

It is strongly recommended that the EU HBDs and related DLPs are also used for the preparation of PSURs of generic products. There are considerable benefits of using EU HBDs for companies with generic products in more than one Member State. I.e. only one PSUR once every 3 year and which is valid in all Member States where the generic product is authorised. It may be advantageous to collaborate with other companies when preparing PSURs is an opportunity.

Which reference safety information is to be used in PSURs of generic products based on EU HBDs?

The reference safety information to be used in the PSURs of generics should be the safety information contained in the SPCs of the generic product which is common in all Member

States where the product is authorised (= the CSI) at data lock point. In addition an overview of the additional safety information in the different SPCs should be provided.