

# **PhVWP/HMA Working Group on PSUR synchronisation**

## **Explanatory Note on the additional list of harmonised birth dates and PSUR data lock points for products containing the listed active substances, dated 8 July 2008**

The additional list contains EU harmonised birth dates (HBDs) and harmonised PSUR data lock points (DLPs). Most of the proposals concern substances which were authorised in the EU before December 1976. However, also more recently authorised substances which were not included in the current list of HBDs and related DLPs for one reason or another are listed. The list has been compiled with input from representatives of EFPIA, AESGP and EGA. The Pharmacovigilance Working Party adopted the list on 24 June 2008, thereafter a few corrections were made.

Allergens and parenteral nutrition products: for the time being these have not been included because of the often complex composition of these products and the large numbers of products with slightly different compositions regarding the active substances.

Medical gases: for the time being these have not been included because until recently in several member states these have not been classified as medicinal products and the authorisations as medicinal products have not yet been completed in all member states. Discussions with the relevant marketing authorisation holders are ongoing.

Oral contraceptives and hormone replacement therapy products: The proposed harmonised DLPs are provisional. Further discussions with the relevant marketing authorisation holders will take place.

It remains possible to make proposals for HBDs and DLPs for substances which are authorised in more than one EU Member State and which are missing on the list. Furthermore it would be appreciated for you to draw our attention to obvious mistakes in the list. Comments can be sent by email to [HBDScomments@efpia.org](mailto:HBDScomments@efpia.org)

8 July 2008