

## JOINT CMDh/PhVWP WORKING GROUP

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In view of the tasks of CMDh and broader mandate of PhVWP it is important to have regular meetings between the two groups and agree on how safety recommendations with regard to products approved in Mutual recognition and Decentralised procedures can be best communicated.

The Task of the Joint CMDh-PhVWP working group will be to discuss issues of common interest between CMDh and PhVWP. The Joint Group will especially focus on new developments and new initiatives, taking into account the recommendations of HMA in this matter.

### MANDATE

**The Joint CMDh-PhVWP working group has the following Mandate:**

#### **1. Harmonised implementation and communication of pharmacovigilance recommendations**

The Joint CMDh–PhVWP working group will facilitate the discussions on implementation of Safety warnings for nationally approved products and exchange of information on ongoing procedures. PhVWP and CMDh have agreed on a template for interaction between the two groups. When the discussion on new safety information is finalised in the PhVWP the rapporteur sends a summary report to CMDh with recommendations for information in SPC and PL with a proposal for a timetable. After agreement on the implementation the CMDh will publish the information for MAH's on their website.

#### **2. New developments**

- Provide advice and/or Guidance papers on requests of CMDh, PhVWP or HMA.
- Development of procedures and tools to facilitate work tracking and worksharing.

#### **3. PSURs**

- Agree on procedures for efficient processing of periodic safety update reports (PSURs) across MS, making provision for work sharing when applicable, and synchronisation of birth dates if necessary.
- Maintain contacts with interested parties on procedures for synchronisation of birthdates.
- Implementation and evaluation of Work sharing procedures in assessment of PSURs.

#### **4. Risk management plans**

- Develop Guidance for handling and evaluation of Risk management plans in cooperation with PhVWP, CHMP, EMEA and European Commission.

#### **5. Other worksharing initiatives**

The Joint Working Group will initiate worksharing between Member States in suitable areas.