EMEA/CMDh SUB-GROUP ON PAEDIATRIC REGULATION

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BACKGROUND

The Regulation of the European Parliament and of the Council (EC) no 1901/2006 on medicinal products for paediatric use, as amended by Regulation (EC) No 1902/2006 entered into force 26 January 2007.

Several Articles, especially Article 45 and 46 refer to submission and assessment of paediatric data from products that have already a marketing authorisation. To coordinate the work between national competent authorities and EMEA a Subgroup on Paediatric Regulation was established in March 2007.

MANDATE

The mandate of the EMEA/CMDh Sub-group on Paediatric Regulation is:

1. Responsibility for the organisation of assessment of paediatric data of products already on the market and procedures for updating SmPC and PL in accordance with Article 45 and 46 of the Paediatric Regulation.

2. To provide support to the EMEA, who have the legislative responsibility, for the practical arrangements for exchange of information for procedures resulting from Article 45 and 46.

3. To be a forum for discussion if Member States have differences in scientific opinions with regard to outcome of assessment, updating SmPC, PL and labelling with the aim to achieve consensus.

4. Preparation and update of Guidance for industry on the submission of paediatric data in accordance with legislative requirements for which CMDh has responsibility.

5. To have contact with interested parties, in an appropriate way and time to ensure that their views will be considered.

6. To agree with EMEA a common approach in the validation and check of compliance in validation of Paediatric data.

7. Close liaison with the Paediatric Committee (PDCO) is maintained to ensure common objectives are achieved.

8. To encourage and share best practice in assessment between Member States through training and exchange of information.

9. To be a forum for discussion between Member States and EMEA on any issues arising from the Paediatric Regulation.