

From: Johansson Tommy
To: SANCO PHARMACEUTICALS D5
Subject: 42 - PCPD/12/01 — Public Consultation on paediatric report - CMDh-EMA (A1701058)

Dear Sirs,

We would like to apologise for the late submission of this comments from the CMDh, as we are aware that the deadline was 28 November 2012, but hope that you would be willing to take this comment into account.

7. Articles 45/46: the hidden gem of the paediatric regulation

Consultation item No 7: Do you agree that Articles 45/46 have proved to be an efficient and successful tool for gathering and compiling existing paediatric data and making it available to the competent authorities and subsequently, via databases, to the interested public?

CMDh welcomes the comments in the Commission consultation on the value of the work-sharing project instigated by national competent authorities to assess existing paediatric information not previously reviewed. The work of the EMA in coordinating the exchange of information and publishing the Article 45 database is also to be commended. Up to October 2012, over 240 work-sharing procedures had been announced and 107 assessment reports published. Of the published recommendations, 11 were for new paediatric indications, 6 for additional safety information, 12 for additional study data and 47 to achieve consistent product information for all products across Member States. These are important outcomes for children who require medication. CMDh agrees that the challenge is to work with MA holders to update their product information in a timely manner and there needs to be further exploration of how this may be achieved successfully throughout the regulatory network.

A further challenge is keeping up the momentum of assessment of the large volume of data, particularly as there is pressure on current resources within competent authorities and the work is unremunerated. In 2012, CMDh began work on methodology to review and reprioritise the list of outstanding active ingredients and this will be applied in 2013.

Yours faithfully,

On behalf of: Peter Bachmann, Chair of CMDh

Tommy Johansson

CMDh (Co-ordination Group for Mutual Recognition and Decentralised Procedures - Human) European Medicines Agency
7 Westferry Circus, Canary Wharf
London E14 4HB - United Kingdom