C.I.P.H.

COMITE INTERNATIONAL DES PHARMACIENS HOMEOPATHES

CIPH comments on the European Commission Concept paper implementing measures in order to harmonise the performance of pharmacovigilance activities provided for in Directive 2001/83/EC and Regulation (EC) No. 726/2004

Reference: PCIM/11-01 – Public consultation on implementing measures for pharmacovigilance

November 7th 2011

The CIPH (*International Committee of Homeopathic Pharmacists*) is a professional organisation gathering pharmaceutical laboratories specialised in Homeopathy.
Since the implementation of Directive 92/73/EC, 164 marketing authorisations and 1904 registrations were obtained by the CIPH members.

We thank the European Commission for the opportunity to take part in this public consultation on the different implementing measures related to the application of Directive 2001/83/CE and Regulation (EC) n° 726/2004.

Our comments concern the application of these measures to homeopathic medicinal products.

- **Consultation item N°1**

We would like to specify the field of application of the pharmacovigilance system master file regarding homeopathic medicinal products.
The regulation 726/2004 as amended, specifies in Article 57 (c) that "marketing authorisation holders shall, by 2 July 2012 at the latest, electronically submit to the Agency information on all medicinal products for human use authorised or registered in the Union, using the format referred to in point (a)".
However, as homeopathic medicinal products can be authorised by a simplified registration (under article 14 of Directive 2001/83/EC) or a marketing authorisation (under Article 16 of directive 2001/83/EC) , it seems important to clarify that the pharmacovigilance measures shall only apply to homeopathic medicinal products granted a marketing authorisation under Article 16 of Directive 2001/83/EC.
Indeed, Article 16.3 of Directive 2001/83/EC clearly states that "Title IX shall apply to homeopathic medicinal products, with the exception of those referred to in article 14(1)".
In these conditions, we propose to clearly mention the exemption of registered homeopathic medicinal products under Article 14 of Directive 2001/83/EC.

- **Consultation item N°2**

To our point of view, only significant modifications to the PSMF should be notified to EMA. We therefore suggest defining a comprehensive list of the significant modifications where the notification would be required.

- **Consultation item N°11 & 12**

We noticed that the proposed terminology does not take into account any of the characteristics of homeopathic medicinal products.
For example, the "Controlled vocabularies for structured substance information version 1.0" (EMA/720984/2011, 1st September 2011) does not foresee information on the degree of dilution of the homeopathic active substances.
An adaptation of the terminology to homeopathic medicinal products would be much appreciated.

- **Consultation item N°16**

We propose to clearly mention the exemption of registered homeopathic medicinal products under Article 14 of Directive 2001/83/EC.

The CIPH remains at your disposal for developing the homeopathic section of these measures.

Yours faithfully,

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