6 April 2011
EMA/131459/2011
Patient Health Protection

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

Report on ENCePP Activities in 2010

Executive Summary

Milestones

The year 2010 saw the achievement of a number of key milestones that put in place the cornerstones for the implementation of important initiatives developed by ENCePP, and the consolidation of the network.

At the beginning of the year the ENCePP Steering Group was established to oversee the mid to long-term implementation of the ENCePP project. The Steering Group (SG) is the highest authority of ENCePP and its final decision making body. Minutes of SG meetings are published on the ENCePP website. Important decisions taken by the SG during in 2010 include the adoption of the ENCePP Code of Conduct (together with an access to data policy and related implementing rules) and the adoption of the Checklist of Methodological Standards for ENCePP Study Protocols. Both documents were developed over a period of several months by dedicated ENCePP working groups, and had undergone public consultation.

The ENCePP database of research resources was launched in two stages: the centres & networks module was released in late January and the 'data sources' module in April 2010. This database is an electronic index of research organisations, networks and data sources in the field of pharmacoepidemiology and pharmacovigilance across Europe.

The electronic register (E-Register) of studies was launched in November 2010. It provides a free, publicly accessible resource for the registration of pharmacoepidemiological and pharmacovigilance studies.

The launch of the e-register of studies enabled the full implementation of the "ENCePP Study" concept, and with it the allocation of the 'ENCePP Seal'. ENCePP studies are conducted to high standards of transparency and scientific independence. Provided that the (primary) lead investigator belongs to an entity that is included in the ENCePP Inventory of Centres and Networks and that certain requirements are met, the study may be awarded the ENCePP Seal.

Last, but no least, the draft Guide on Methodological Standards in Pharmacoepidemiology developed by a dedicated working group was released for public consultation in December 2010. The Guide seeks to assure high quality pharmacoepidemiological ENCePP studies to fuel learned regulatory decision-

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8660
E-mail encepp_secretariat@ema.europa.eu **Website** www.encepp.eu

An agency of the European Union

making and to stimulate innovation that benefits patients and public health at large. It is expected to be finalised and adopted during Q1 2011.

Meetings and Networking

In addition to a number of Steering Group and Working Group meetings, the ENCePP Secretariat organised two ENCePP Plenary meetings in June and November respectively. More than 70 representatives from participating centres, networks and data providers attended these meetings which serve as a platform for the exchange of information, networking and collaboration. Minutes of the Plenary meetings are published on the ENCePP website.

The ENCePP website was developed further and a Partners' Forum was launched in April.

To promote the network and introduce it to a wider audience, ENCePP was presented at a number of international fora, most notably at various worldwide DIA events and ICPE (International Conference on Pharmacoepidemiology and Therapeutic Risk Management). In addition, the first "ENCePP Info Day" was held on 26 November 2010 in collaboration with DIA and targeted pharmaceutical industry with a view to publicising the use of the ENCePP research resources and the conduct of ENCePP studies. The Info Day was a success and it is intended to repeat this event in 2011.

ENCePP Databases

By end December 2010, the ENCePP database of research resources included a total of 102 entries (research centres, networks, data sources) from 17 European countries.

The E-Register of studies included a total of 9 entries, 3 of which were ENCePP studies which had been granted the ENCePP seal.