11 May 2017

ECH Secretariat
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Belgium
info@homeopathyeurope.org
www.homeopathyeurope.org

Dear Madam/Sir,

The European Committee for Homeopathy (ECH) represents all medical doctors specialized in homeopathy, organized in 40 associations in 25 European countries. It is aimed at

- Promoting the scientific development of homeopathy
- Ensuring high standards in the education, training and practice of homeopathy by medical doctors
- Harmonising professional standards in homeopathic practice across Europe
- Providing high-quality homeopathic care in a medical context
- Integrating high-quality homeopathy into European healthcare

The remit of the Pharmacy subcommittee of the ECH comprises the following responsibilities:

- To support the availability of safe high quality homeopathic medicines
- To develop a system of reporting suspected adverse reactions and the collation of a data base on this important issue
- To promote a harmonised system of nomenclature for homeopathic medicines to ensure that there is no confusion over the source material throughout Europe
- To maintain a consultative function on newly issued pharmacopoeia monographs and legislative documents affecting the availability of homeopathic medicines across Europe
- To raise the standards of homeopathic pharmacy practice by encouraging the development of appropriate harmonized training programmes for pharmacists and support staff across Europe
- To analyse the elements contributing to pharmaceutical quality of homeopathic medicines, which could lead to proposals for specific Good Homeopathic Practice and to evidence-based homeopathic pharmacy
- To stimulate the use of homeopathic treatment by supporting actions from practitioners, pharmacists and patient organisation

Regarding the Consultation – Options for the future regulation of low risk products, ECH recommends that "Option 2 Serious therapeutic claims must be supported by scientific evidence" is retained.

This is based on more than 50 years' experience of implementation of European Union (EU) legislation on homeopathic medicinal products (HMP). These are regulated in the EU by several directives, which are legally binding for the 28 Member States of the EU and have been transposed into national legislation.

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use divides HMPs in two groups:

- HMPs without approved therapeutic indications.
- HMPs with approved therapeutic indications.

The requirements for placing HMPs in the market are different for the two groups. The Directive details the requirements for authorization for placing in the market HMPs. The full text of the Directive is available from: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2001_83_consol_2012/dir_2001_83_cons_2012_en.pdf

The ECH is available to provide you with further information if required.

Best wishes.

Dr Jaume Costa
General Secretary of the European Committee for Homeopathy