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Representing Homeopaths in Europe

A response from ECCH to the EU Commission Consultation on legislative proposals to strengthen and rationalise the EU system of pharmacovigilance

Introduction to ECCH

The European Council for Classical Homeopathy is a council of 27 professional associations of homeopathy practitioners active in 23 European countries including 16 EU member states. Established in1990 it has a secretariat based in the UK and is run by a small executive of part-time paid officers. ECCH is a member of the European Public Health Alliance (EPHA), the European Forum for Complementary and Alternative Medicine (EFCAM), a Corresponding Member of the European Coalition for Anthroposophical and Homeopathic Medicinal Products (ECHAMP) and has NGO Participatory Status with the Council of Europe. This response can also be considered the formal response from the European Forum for Complementary and Alternative Medicine (EFCAM) of which ECCH is a member. **Both ECCH and EFCAM advocate for a more holistic and integrated approach to health based primarily in prevention and secondarily utilising the best practices of conventional and complementary health care for each patient based on individual needs.**

ECCH's Response to the EU Consultation on Pharmacovigilance

1) ECCH welcomes the proposals from the Commission to strengthen and simplify pharmacovigilance legislation for the EU. Given the fact that adverse reactions for pharmaceuticals are the 5th highest cause of death in hospitals, that deaths of patients in the community from adverse reactions are highly underreported and that significant numbers of patients suffer unduly from adverse reactions to pharmaceuticals, it is right that the matter of pharmacovigilance is placed on more formal, robust footing within the EU than it is at present.

2) The statement in the consultation document that ' *the existing 'Pharmacovigilance Working Party' at the EMEA informally discusses important safety issues but its conclusions are frequently not implemented and certainly not implemented comprehensively across all Member States (as they are not legally binding on the Member States or companies).* surely indicates an abrogation of an appropriate level of responsibility in the Agency which at the same time has the responsibility for licensing pharmaceutical products across the whole EU.

3) ECCH welcomes the proposals for the legal establishment of a separate formal Committee for Pharmacovigilance within the EMEA. This separation of the responsibility for pharmacovigilance from the Committee for Human Medicinal Products is a necessary step in clarifying the roles, boundaries and responsibilities of each committee and their members.

4) ECCH welcomes the creation of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (EnCEPP). This network will be the spokes of an information exchange wheel at which the proposed EMEA Pharmacovigilance Committee will be the centre, acting as the central collecting, collating and analysing point for information sent in from members of EnCEPP. In depth study of the problem of ADRs is essential to more accurately identify the nature and extent of the problem that currently is hugely under reported and under researched.

5) Information exchange mechanisms on ADRs between Member State Medicines Agencies and the EMEA need to be strengthened and simplified. It would seem appropriate for a common template for data collection to be developed centrally for use by the agencies so that the information is provided in a uniform way to facilitate efficient central collection, collation and processing of data. Furthermore we would recommend that all data is submitted in the common language of English so as to avoid errors of translation as much as possible centrally. There would be an onus on the Member State's agencies to employ a good English speaker to do this.

6) Pharmaceuticals in the Environment: tons of pharmaceutical products are daily absorbed and then excreted into the environment through human and animal excreta. There is growing evidence that certain categories of pharmaceutical may be having epidemic effects on the population through their re-ingestion in drinking water and food products by humans and animals. e.g hormones from contraceptive and HRT products. It would seem appropriate that these effects were also studied and included as a form of 'macro pharmacovigilance' information and therefore included within the remit of the new committee..

7) ECCH is surprised to find no mention of homeopathic medicinal products (HMPs) in the documentation concerning these proposals despite their being referred to in EU Pharmaceutical legislation. We can hypothesise why this is. Perhaps because

i) the EMEA does not currently have a remit from the Commission for HMPs
ii) the Commission does not consider HMPs to be likely to produce adverse reactions due to their dilute nature
iii) there is an understanding that any reaction to an HMP is a temporary aggravation of the symptoms of a patient as they experience a healing response to its stimulus
iv) there is so far no record of any adverse reactions to HMPs
v) the Commission does not take homeopathic medicines seriously

Irrespective of which of these reasons may be the cause(s) for the omission we assert nonetheless that HMPs should come under the aegis of pharmacovigilance provisions. Millions of people across the EU use them, they are covered in the basic EU pharmaceutical legislation and lower potency HMPs contain small amounts of physical content of their source materials. As a bottom line the system should be open to receiving reports of reactions to HMPs even if they may be relatively rare.

8) ECCH calls for clarification of the role of CAM healthcare professionals in reporting notification of perceived ADRs in their patients. CAM healthcare professionals, particularly homeopaths, are in a strong position to identify ADRs as they usually take a very detailed case history and are able to clearly differentiate what the symptoms of a patient's condition are from symptoms they may be suffering as a reaction to pharmaceutical products they are taking. As well as recommending the patient to speak to their prescribing physician about any possible reaction they may be having to a product, the CAM professional should also be able to report a reaction directly to their national medicines authority. We recommend that all CAM professional training courses should include modules on pharmaceuticals and students should be made familiar with using the national formulary of their particular country in their daily practice with patients.

9) ECCH is surprised to see that on page 2 of the consultation paper the Commission has omitted to mention the role of NGOs representing patients and health care professionals as significant stakeholders involved in the pharmacovigilance. As an active member of the European Public Health Alliance(EPHA) we consider that NGOs have an important intermediary role to play in representing the interests of their members to bodies such as the EMEA and the Commission.

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