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RESPONSE TO: Commission Public Consultation: An Assessment of the Community System of Pharmacovigilance

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Type: Academic (pharmacist)

Comments:
The pharmacovigilance of herbal medicines present particular challenges because such preparations are available from a wide range of outlets typically (with the exception of pharmacies) where there is no healthcare professional available, i.e. most purchases are outwith even the conventional OTC environment. Against a background of lack of regulation of herbal medicinal products (the new EU directive on traditional HMPs has a transition period until 2011), and safety issues arising from poor-quality and inherently toxic products (likely to still be a problem up to the end of transition period and possibly beyond if the regulations are not adequately enforced, and with consumers sourcing poor-quality products via the internet and mail order), there is a real need to monitor safety of HMPs comprehensively.

Issues include poor quality of information given to consumers by staff in health food stores, by herbal-medicine practitioners and by pharmacists; there is a lack of research examining the quality of advice on HMPs given by doctors, nurses and other healthcare providers, but there are likely to be similar deficiencies. It is well-known that users of HMPs often do not disclose use of these products to healthcare professionals, and are not asked by healthcare professionals about their use of these products. Even if information on use is provided, most healthcare professionals knowledge of these products is inadequate, they do not know what are reliable sources of information to use to increase their knowledge and, in many cases (e.g. efficacy of specific products, interactions between herbal and conventional medicines), reliable information in any case does not yet exist.

Research has identified possible user bias against reporting suspected ADRs (even serious) associated with herbal medicines, and under-reporting by healthcare professionals of suspected herbal ADRs, possibly because they are unaware that spontaneous reporting systems accept reports associated with herbal medicines, or for other reasons. At the same time, the quality of herbal spontaneous reports can be poor reporters often use common or vernacular names for herbal medicines (e.g. echinacea but several species of Echinacea are used medicinally, and different parts of the plant, and there are chemical differences between them). Spontaneous reporting forms themselves are not design to collect information on herbal medicines, and the reporter needs to be prompted for the specific information required. A modified reporting form that can better collect information on suspected herbal ADRs is desirable. The WHO has published such a modified template reporting form.
Statistical generation of signals from the database of spontaneous reports also raises questions for herbals should signal generation for herbals be done against the background of the whole database, or against the b/g only of other herbal reports? The WHO-UMC is investigating this question using its database.

The value of patient and herbal-medicine practitioner reporting of suspected herbal ADRs using spontaneous reporting systems needs further investigation. There are several herbal-sector initiated schemes in the UK, but herbal practitioners are not yet formally recognised as reporters (although they will be when the practitioners become statutory regulated).

There is current interest in the use of observational data in herbal PhV, and pilot studies are underway of modified prescription event monitoring using herbal practitioners, and of a model using community pharmacies to recruit consumer-purchasers of specific HMPs with consumer follow up using questionnaires.

Communication of information on herbal safety concerns to the range of stakeholders also raises numerous issues. Many consumers have the belief that herbal medicines are safe, so do we need to communicate herbal safety issues in a manner different to that for conventional medicines (which are widely perceived to be unsafe). Many consumers may be hard to reach through the usual healthcare professional channels (eg pharmacies) as they do not obtain their products from there, so we need to examine communication with stakeholders such as herbal practitioners and more isolated groups eg shops selling Traditional Chinese herbal medicines. Research in some of these areas is ongoing.

Consumers may report ADRs to individuals, eg health food store staff, outside the spontaneous reporting scheme we do not know much about this, although I have some anecodotal reports that consumers have been directed to a pharmacy if a problem has arisen with a product sold by a healthfood store.

Given that there are so many issues that are unique to herbal medicines, I recommend a separate consultation on how best to carry out pharmacovigilance for these products.

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