Regulating herbal medicines in the UK

A specific committee could help to distinguish unproved herbal therapies from more rational treatments

Medicines derived from plants, such as digoxin, morphine, and vincristine, are important in conventional Western therapy. These examples also demonstrate that natural is not synonymous with innocuous, since these medicines have narrow safety margins. However, as with other conventional medicines, their licensing is based on three criteria: efficacy in a given indication; acceptable safety in usual therapeutic use; and quality of manufacture. Should we judge herbal medicines by the same criteria?

There are some herbal medicines of demonstrable efficacy: for example, in one trial a standard extract of *Hypericum* (St John's wort) was as effective as paroxetine in depression.[1] For most herbal treatments, however, good trials of efficacy are lacking, and conducting them would be expensive. Ernst noted two years ago that systematic reviews provided good evidence of efficacy for just 11 herbal medicines and had found "promising but not convincing" results for nine more.[2] Herbalists since the Englishman Nicholas Culpeper in the 16th century have held forth promises, but most therapeutic claims remain unsubstantiated.[3]

Without evidence of efficacy, it is hard to judge the safety of herbal medicines, not least because the risk of an adverse effect that might be acceptable for an effective treatment will be unacceptable for an ineffective one. The nephrotoxicity and carcinogenicity of *Aristolochia* and hepatotoxicity of *Piper methysticum* (kava) show how harmful herbal products can be.[4,5] Quality of manufacture is also a serious problem. If the plant itself is used, then the precise chemical content depends on the variety and the growing conditions, processing, and storage. These basic botanical principles are generally accepted, if incompletely understood (for example, the concept of *terroir* in the science of winemaking). The concentrations of compounds in unstandardised herbal products can vary several hundredfold.[6] Also, while commercially grown plants may be reliably identified, plants gathered in the wild may not be, and toxic species may be substituted for innocuous ones.[3] An additional, and apparently common, hazard, is the adulteration of "herbal" medicines with active drugs such as corticosteroids and toxic substances such as heavy metals.[7,8]

The United States Food and Drug Administration (FDA) operates under the 1994 Dietary Supplement Health and Education Act.[9] This regards herbal medicines as dietary supplements, not medicines. Such products must not bear claims that they can prevent, treat, cure, mitigate, or diagnose disease unless the claims are substantiated by scientific evidence. In 2003, recognising the difficulties of regulating herbal medicines, the FDA proposed rules on good manufacturing practice for dietary supplements.[10]

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The European Union has now taken a hand in the regulation of herbal products. Directive 2004/24/EC envisages a special, simplified registration procedure for certain medicinal products, particularly herbal ones, that have a long tradition of use.[11] In this context, a long tradition of use is one that goes back 30 years, of which at least 15 years are within the EU. The argument seems to be that longstanding use and experience make efficacy plausible, and that only safety need therefore be considered. Since plausible traditions such as using emetics, purgatives, and leeches persisted for much of the past millennium, to the great detriment of patients, the arguments against an evidence based approach seem weak.

In the United Kingdom the Medicines and Healthcare products Regulatory Agency (MHRA) is consulting on a proposal for a Herbal Medicines Advisory Committee.[12] The MHRA initially proposed a Herbal Medicines Advisory Group that would report to the soon to be established Commission on Human Medicines,[13] which in turn would advise ministers on all medicinal products for human use. But the agency now proposes that the Herbal Medicines Advisory Committeewith members representing Western, Chinese, and ayurvedic herbalism, as well as lay members and experts on conventional medicinesshould advise ministers directly on the regulation of herbal medicines, thus bypassing the new commission.

At first sight, this seems perverse, because the advisory bodies are there to ensure that medicines are reasonably safe, effective, and of good quality. It is difficult to think of good reasons why some products that make medicinal claims should be able to satisfy the advisory bodies by relying on folklore. Perhaps, though, it is appropriate that alternative medicines should be judged by a separate committee that relies on plausibility rather than analysis. After all, Chinese and ayurvedic medicine do not fit the orthodox medical paradigm, but rest on theoretical foundations that are, perhaps, closer to the thinking of ancient Greek fathers of medicine, Hippocrates and Galen.

Herbal products for which there are reliable data could be granted standard marketing authorisations. If the rest were judged by a separate body, and by different criteria, we could clearly distinguish rational therapies based on good evidence of efficacy and safety from products that lack those attributes. Advocates of the use of unproved herbal products would be able to take separate and full responsibility for them, and for making decisions on their safety and efficacy in the absence of information from satisfactory clinical trialsor, indeed, any evidence at all.

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Competing interests: KB and REF are members of the Committee on Safety of Medicines (CSM) subcommittee on pharmacovigilance, and of CSM working groups. The views expressed here are personal and do not represent the views of the committee or subcommittee.

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