

The “traditional use” Directive - where are we now?

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What is a medicine?

The MCA classification of borderline products is based on the definition of a medicine as set out in European law. Recent MCA guidance to companies gives additional clarification in this difficult area. A new procedure is in place to give additional transparency to the arrangements. Herbals are classified on the same basis as any other product.

How are herbal medicines regulated?

There are two regulatory options:

- licensed medicines, meeting the normal requirements of safety, quality and efficacy
- unlicensed herbal remedies (active ingredients herbal only, made by simple processes, with no brand names and no indications for use)

Public health issues with unlicensed herbal remedies

There is a lack of specific safety and quality safeguards; there is evidence that standards vary. Issues such as poor labelling, contamination and substitution of ingredients and the use of *Aristolochia* have been identified.

The case for a traditional medicines directive?

In the UK this rests on the public health difficulties with the regime for unlicensed herbal remedies. This regime also lacks clarity in some important respects and does not provide an incentive for companies to meet acceptable standards. The AESGP report (early 1999) highlighted that comparable issues applied in many other Member States. The outgoing UK

Government took the view that the public should have access to a wide range of safe herbal remedies of acceptable quality and with appropriate information about the use of the product. In practice, the system for licensed herbal medicines provided public protection but, by itself, insufficient consumer choice, whereas the regime for unlicensed herbal remedies provided consumer choice but insufficient protection.

Commission Directive 99/83/EC

This was the first response to the problems identified in the AESGP report. The Directive gave greater flexibility in the use of bibliographic data in relation to safety and efficacy. But views on the implications of the Directive varied among Member States and the UK public position was that a more fundamental initiative was also needed. The MCA put the case for early progress on a possible directive on traditional medicinal products, and accordingly agreed to act as rapporteur for the Pharmaceutical Committee’s expert group on this issue.

Main features of 2nd draft of directive

It is not yet clear whether the directive would apply to other traditional medicines beyond herbal remedies. It does not apply to products which “can be” authorised under 65/65/EEC. Traditional use is based on 30 years use in the EU, with up to 15 years non EU use taken into account. An expert report on safety is required, the regulatory authority can ask for additional data if not satisfied as to the safety of the product. There would be a European scientific committee to develop monographs and guidelines. A quality dossier would be required, with compliance with relevant EP monographs. There is a possibility

of simplified dossiers for defined categories of products such as herbal teas.

There is the possibility of positive lists. POM medicines are not covered by the directive; reasons for refusal include if the pharmacological effects or efficacy are “not plausible”. The labelling statement should make clear that the efficacy is not proven but relies on long use and experience. Member States can require the label to state the nature of the tradition. Relevant provisions of other directives, for example pharmacovigilance are imported into the directive. There would be a 5 year transitional period once the directive came into force.

MCA comments on the draft directive

These were set out in a letter to the European Commission of 30 April 2001. The MCA was supportive of the priority which the Commission had given to developing the draft directive. The MCA:

- argued the need to accommodate genuinely traditional medicines from non EU traditions provided safety and quality was fully satisfied
- supported the case for a European positive list of substances/ingredients provided there was scope for national positive lists as well
- argued that scope of the possible restriction under traditional use on products which “can be”

registered under 65/65/EEC needed to be clarified and made more specific

- noted the disparate views of Member States on whether, and if so how, the directive should go beyond herbals. Possibly there was scope for some national flexibility
- raised issues on the definition of traditional use
- supported back up provisions for regulatory authorities to require additional data where there were concerns about safety
- suggested essential oils and plant juices as possible categories where simplified quality dossiers might be appropriate
- considered that the reference to “plausibility” as a possible criterion for refusing application was unclear
- sought further information on the proposed European scientific committee
- welcomed the recognition of the need for a significant transitional period.

Other issues

Some companies were hoping that the directive would be a vehicle for product innovation.

The extent and pace of harmonisation in relation to herbal medicines.

Linkages with the proposed directive on food supplements.

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