DTMHP. Letter from MCA to Herbal Interest Groups, 08 May 2002

Dear Colleague

Proposed Directive on Traditional Herbal Medicinal Products – Quality and Manufacturing Standards

Important questions relating to quality and manufacturing standards proposed in the draft Directive on Traditional Herbal Medicinal Products have been raised recently by several interest groups. Since the issue is, as a consequence, likely to have a raised public profile I thought it would be helpful to provide a current perspective on the position.
First I will set out Ministers' position and then I will elaborate in a little more specific detail.

Ministers' position

Ministers' position, recently reaffirmed, on quality and manufacturing standards is as follows

"UK manufacturers of traditional herbal remedies and others in the herbal sector have told us repeatedly that there is a pressing need to require systematic quality standards throughout the supply chain to protect the public and the reputation of the sector. Trade in herbal remedies is international and in recent years there has been a range of incidents around the world, including the UK, the USA and the Far East, where similar looking, but toxic or potent, herbal ingredients have been found to be substituted for the correct ingredients. Contaminated or adulterated remedies have been identified on other occasions. The MCA continues to identify such remedies on the UK market. We take seriously the warnings from many of the most experienced people in the herbal sector that the world-wide popularity of herbal medicines and the weakness of regulation has led to an increase in low grade herbal material and products circulating on the international markets, including that of the UK.

The proposed Directive would put in place important quality and manufacturing requirements. These include: reliable identification of materials; use of good quality herbal ingredients; systematic checks to ensure there are not unacceptable pesticide residues, heavy metals or other forms of contamination; data to support the proposed shelf life of the product; adequate premises and equipment; proper record keeping; a suitably qualified person to take responsibility for the release of batches onto the market.

We do not accept the argument which certain interest groups are putting forward that such standards, as proposed in the Directive, are somehow inappropriate or inapplicable to herbal medicines. On the contrary, these kinds of standards are what is required to protect the public and remove the current perverse incentives under the system which favour companies which do not wish to operate to high standards. Moreover, the proposed standards are those which are already successfully met by various UK manufacturers of traditional herbal remedies, including small and medium sized businesses. This latter point has not been addressed by those who are saying the proposed standards are unrealistic."

Additional MCA comment

As indicated above, important points have been raised by interest several groups. Consumers for Health Choice is circulating a leaflet inviting the public to ask their MP/MEP to oppose the proposed Directive on Traditional Herbal Medicines. The leaflet asks the public to point out that:

"*UK law already requires that ….natural remedies are safe and appropriately labelled.*" In similar vein the National Association of Health Stores is arguing that the Directive "*seeks to force safe herbal remedies that have been used for millennia into the regulatory environment of inherently toxic pharmaceutical drugs.*"

The MCA's clear view is that effective public protection in relation to herbal remedies can be achieved only by systematic quality control and quality assurance through the supply chain. Our understanding is that there are many experienced operators in the herbal sector who take a similar view. Examples of what can go wrong where such controls are lacking include:

- Aristolochia species have been mistakenly included in remedies instead of Stephania, Clematis etc. This has affected many countries including the UK. This has led to cases of renal failure and cancer
- use of Teucrium species instead of Scutellaria has been known to occur in the UK. Teucrium species have been linked with cases of liver toxicity
- use of Podophyllum root instead of Gentian has been reported in Hong Kong. Internal use of Podophyllum can cause serious toxicity and may be fatal
- cases of serious cardiac arrhythmia were reported in USA following accidental substitution of Digitalis for Plantain
- Japanese Star Anise, known for its convulsant effect, was recently found in remedies in place of Chinese Star Anise in several European countries.

The MCA takes the view that herbal remedies are genuine medicines which have an effect on the body. Like any such medicine there is potential for adverse effects or interactions with other medicines (as illustrated by St John's Wort).

It is also important to correct any misunderstanding that the proposed quality and manufacturing standards in the Directive are ones designed without reference to herbal remedies. ***Key parts of the regulatory framework have been designed explicitly for herbal remedies***. These include: the European guidelines on the quality of herbal medicines; the European Pharmacopoeia general monographs on products of herbal origin, and the European guidelines on Good Manufacturing Practice for herbal medicines.

The MCA is not clear on the basis on which certain interest groups are currently arguing that these standards, designed specifically for herbal remedies, are somehow inappropriate or unnecessary.

As we have made clear, the quality and manufacturing standards in the proposed Directive are those which currently apply to licensed herbal remedies (modified as necessary to reflect the position that the primary consideration under the Directive would be safety rather than safety *and* efficacy).

In the interests of avoiding any misunderstanding the MCA would find it most helpful if any interest groups which oppose the introduction of the proposed standards could identify as soon as possible which of the specific quality and manufacturing standards, as currently applied to licensed herbal remedies, they believe to be unnecessary or inapplicable in relation to traditional herbal remedies – and why.

Issues relating to the safety of the public, and the wider reputation of the sector as to its approach on quality and safety, potentially can of course affect many interest groups operating in this area. ***The MCA would therefore also welcome views from groups or individuals that may support the introduction of the proposed requirements for systematic quality controls through the supply chain.***

I hope this information about Ministers' and MCA's position is helpful.
Yours sincerely
Richard Woodfield
Group Manager Herbal Policy