

MCA Statement on Kava-kava in response to article in the Guardian 10 May 2002

Concerns about 30 cases of liver problems in Germany were first raised in late November 2001. Since then one case of liver problems possibly associated with Kava-kava has been identified in the UK and this case is currently being followed up.

The Medicines Control Agency (MCA) sought the advice of the Committee on Safety of Medicines (CSM) who in December 2001 advised that, on the evidence so far available, the risk of hepatotoxicity (serious liver problems) appeared to outweigh the potential benefits of Kava-kava use.

On the basis of this advice many manufacturers, retailers and practitioners in the herbal sector took a responsible and prudent course of action and voluntarily withdrew Kava stocks pending further clarification of the safety issue. The MCA and CSM welcomed this action.

Limitations in the evidence available meant that the risk evaluation was complex and unclear. The CSM set up an expert Working Group, including experts in hepatotoxicity, herbal medicine and clinical pharmacology. The Working Group endorsed the CSM's view that in a significant proportion of the European cases identified the liver problems had a probable or possible association with Kava-kava.

Assessment of this complex safety issue continues and is a high priority. The MCA and CSM will consider all available evidence, including several new analyses received recently, in order to reach a well based conclusion on what regulatory action may be most appropriate. We note that in several other EU Member States various forms of temporary regulatory or voluntary action has been taken on Kava-kava pending further review of the evidence.

The MCA has worked closely with the herbal sector throughout. The Agency has held meetings with them on this issue to discuss the evidence; it has sought and received additional evidence from the sector; representatives from the sector were invited to present oral evidence to a Working Group which the CSM set up to examine the safety of Kava. At that meeting representatives from the herbal sector helpfully identified possible additional sources of information and analysis. The MCA agreed to consider this further evidence, the most recent instalment of which was provided in late April.

At a meeting in March MCA gave an in-depth presentation to trade associations and other herbal interest groups on the emerging evidence.

When CSM have completed their safety assessment and given further advice we will need to consider whether there is a need for regulatory action. Any such proposals which involved statutory restrictions on Kava would require formal public consultation. In the meantime, we are reliant on a voluntary agreement with the herbal sector. Such an approach was taken in relation to St John's Wort where a voluntary agreement to include specific warnings about interactions with other prescription medicines has generally been observed by the herbal sector. Given the

current situation, we have written to the trade associations and other herbal interest groups urging that they ask their members to adhere to the voluntary agreement in the interests of protecting public health.

The Guardian raises the issue of whether the MCA has sufficient powers to protect the public. There are widely acknowledged weaknesses in the regulation of unlicensed herbal remedies. However, where there is a major threat to public health we are in a position to, and do, take immediate regulatory action. For example, in the case of *Aristolochia* where there is an established association with renal failure and cancer, we put in place an emergency prohibition, in advance of public consultation.

However, in other situations where the evidence is less clear and does not justify an emergency prohibition Order, we cannot require immediate withdrawal of unlicensed herbal remedies containing a particular ingredient.

There is clearly a need for improved regulation. The MCA has been lobbying hard in Europe over several years for a better regulatory regime for traditional herbal remedies and we are pleased that European Commission has recently brought forward proposals for a Directive on Traditional Herbal Medicinal Products. This would put in place altogether more systematic arrangements for assuring the safety and quality of traditional herbal medicines. The MCA is encouraged from the feedback we are getting in response to public consultation that many UK manufacturers of herbal remedies, among other interest groups, are supportive of the need to introduce effective standards on quality and safety for these remedies.