

## **Guidance on use of HMPC Monographs to demonstrate safety and traditional use**

### **When preparing an application for a traditional herbal registration, can I refer to monographs prepared by the Committee on Herbal Medicinal Products (HMPC) in order to demonstrate safety and traditional use?**

It is important first to be clear on the significance of entries on the Community "list of herbal substances, preparations and combinations" (Art 16f (1) of Directive 2004/24/EC). An applicant who can demonstrate that a proposed product for registration falls within the parameters set out in the Community list is under no legal requirement to present evidence as to the safety and traditional use of the product. The MHRA would not ask for such evidence.

In contrast, a herbal monograph prepared by the HMPC (under Art 16h (3) of the Directive) is not similarly legally binding; it is possible that the MHRA (or indeed regulatory authorities in other Member States), may not agree with every single aspect of a monograph. Therefore, each application would have to be considered on its merits. However, the MHRA may take monographs into account and indeed expects that it may be frequently, wholly or largely, in agreement with the terms of an HMPC monograph prepared in relation to traditional use.

Where the HMPC adopts a monograph, the EMEA follows the practice of also publishing an assessment report prepared by the HMPC. Where there is such an assessment report, the MHRA may accept that it is sufficient for an applicant seeking a traditional registration for a product in the UK, to refer to, and rely on, the EMEA assessment report, (in order to meet the requirement in Directive 2004/24/EC that an applicant must present evidence to demonstrate the traditional use and safety of the product). In this situation applicants should use the clinical overview to justify their view that their product complies with the monograph. Applicants who may want to refer to an HMPC monograph in this way, are strongly encouraged to contact the MHRA at an early stage, using our pre-application notification scheme.

This provides an early opportunity for the MHRA to discuss a number of issues with the applicant. For example, relevant issues might include: whether the proposed product would comply with the monograph or in cases where the monograph was applicable, whether the applicant would need to provide additional points on traditional use or safety (for example on genotoxicity) beyond what is set out in the HMPC assessment report.