GUIDANCE ON REGULATION OF UNLICENSED HERBAL MEDICINES MADE UP BY A 3RD PARTY FOR USE BY PRACTITIONER IN A ONE TO ONE CONSULTATION: ARRANGEMENTS PENDING POSSIBLE REFORM OF REGULATION

Q. What is the regulatory position where companies supply manufactured unlicensed herbal medicines to herbal practitioners for use in their one to one consultations?

A. Where a 3rd party is marketing unlicensed herbal medicinal products to herbal practitioners the regulatory position is no different to that where such products are placed on the market in other ways, eg via supply to retailers or direct to the public. In other words, the medicinal product would require a marketing authorisation or traditional herbal registration and there would be a requirement for manufacturer's and wholesaler' licences as appropriate. If, however, the product was legally on the UK market on 30 April 2004 complying with the requirements of s12(2) of the Medicines Act 1968 it may benefit from transitional protection until 30 April 2011 while it continues to comply with the requirements of s12(2).

Q. Is the position likely to change?

A. The MHRA is working on proposals arrangements which could be introduced, subject to agreement from Ministers and Parliament, linked to the proposed statutory regulation of the herbal medicine profession. The broad thrust of these proposals is that, subject to various safeguards, it would be possible for a statutorily registered practitioner to commission a 3rd party to make up manufactured unlicensed herbal medicines to meet the special needs of individual patients.

Q. Why is this change under consideration?

A. The MHRA recognises that it is not necessarily realistic, or indeed desirable on public health grounds, to expect that practitioners will always make up on their own premises the remedies they use in their one to one consultations. Likewise, it would probably not be realistic to assume that the range of herbal medicines with a marketing authorisation or traditional herbal registration will be sufficient to cover the full range of special patient needs.

The supply of unlicensed herbal/traditional medicines intended for use in one to one consultation is an area of known public health risk (as reflected on MHRA's Herbal Safety News). There is a need to update the regulatory framework in the interests of public health protection.

MHRA, July 2006