Medicines and Healthcare products Regulatory Agency

Proposals for the reform of the regulation of unlicensed herbal remedies in the United Kingdom made up to meet the needs of individual patients

Summary of responses to consultation document MLX299

January 2005

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Introduction

Consultation document MLX299 on "Proposals for the reform of the regulation of unlicensed herbal remedies in the United Kingdom made up to meet the needs of individual patients" was launched by the Medicines and Healthcare products Regulatory Agency (MHRA) on 2 March 2004. This document sought views on a number of outline proposals and ideas for regulatory reform of unlicensed herbal remedies supplied following a one to one consultation by a herbalist. The responses to MLX299 are summarised below.

Background

The proposals set out in MLX299 follow concerns raised by the House of Lords Select Committee on Science and Technology on Complementary and Alternative Medicine, in its report published in November 2000. In it, the Select Committee identified the unregulated herbal sector as posing a risk to public health and urged that all legislative avenues be explored to ensure better controls in the interests of public health. Ministers consequently invited the Herbal Medicine Regulatory Working Group (HMRWG) to make proposals as to the statutory regulation of the herbalist profession and to recommend any changes needed to medicines legislation to assure the safety and quality of herbal remedies supplied under Section 12(1) of the Medicines Act.

The HMRWG made a number of recommendations in its report of September 2003 which aim to provide freedom of choice whilst addressing the current weaknesses in the level of public health protection afforded by Section 12(1) of the Medicines Act. These included:

- encouraging voluntary self regulation to clear standards of training and validation
- extension of the scope of Section 12(1) to allow registered practitioners to supply traditional remedies of non-plant origin, provided that the remedies are safe and subject to the required quality assurances
- updating of legislation to restrict the use of potent herbs, not suitable for over-the-counter (OTC) supply, to usage by registered practitioners with appropriate training.

The MHRA welcomed these recommendations as a good basis for considering reform of the relevant medicines legislation and these have been used as a starting point for MLX299. The MHRA also identified several possible additions which were incorporated into the consultation document. This consultation was run in conjunction with a separate, but parallel consultation "Regulation of herbal medicine and acupuncture – proposals for statutory regulation", run by the Department of Health. A separate report of the results of this consultation has also been published.

Responses to the consultation

A total of 77 responses have been received, of which 65 had substantive comments. Responses expressing views came from wide range of interests including groups representative of: herbal practitioners from a range of different traditions; various other complementary medicine practitioners; those involved in the manufacture and supply of products; Royal Colleges and others representative of orthodox medicine; and interest groups associated with specific therapeutic areas. A number of individuals also commented.

Overview of Responses

Most responses appeared broadly supportive of the overall proposed direction of reform. This included representative umbrella bodies such as the European Herbal Practitioners Association (EHPA) and the Herbal Forum as well as a range of individual organisations such as the National Institute of Medical Herbalists (NIMH). Overall, in the responses there was little if any challenge to the need for reform and no one advanced the case that overall the status quo was acceptable as a regulatory regime. Where comments could be construed as challenging the basis of the reforms, such criticism came mainly from some within orthodox medicine where a view was advanced that some of the proposals lacked sufficient rigour as compared with the standards demanded of orthodox medicine. The British Pharmacological Society considered that an opportunity had been missed to define acceptable levels for the effectiveness of herbal remedies. The Royal College of Physicians (Edinburgh) and the General Practitioner Committee (Wales) welcomed what they saw as long overdue regulation of the sector but considered that the proposals could have gone substantially further in improving the safety of these products.

A number of responses came from within the ethnic medicine sector. Practitioner representatives from within traditional Chinese Medicine (TCM), such as the Register of Chinese Herbal Medicine (RCHM) and the Association of Traditional Chinese Medicine (ATCM), were overall generally supportive of the proposals, albeit having various specific comments and concerns. Some, particularly from the suppliers side of TCM, were less supportive suggesting for example that the quality requirements could be over-regulatory if requirements were put on a statutory footing. The Chinese Medicine Association of Suppliers (CMAS) argued that some of the requirements were prejudiced in favour of large manufacturers. Responses from the Ayurvedic sector were also broadly supportive, although the International Ayurveda Foundation had wider concerns, arguing that the proposals would be detrimental to that tradition.

Specific Issues

Unregistered Practitioners

It was clear that a fundamental issues for many respondents was whether, and if so in what circumstances, practitioners *not* on the proposed statutory of herbal practitioners should be permitted to continue to operate under Section 12(1). There were considerable divergences of view, with strong opinions expressed.

Many respondents, including herbal practitioner organisations from a range of traditions and representatives from other statutorily regulated healthcare professions, took as a starting point that in future membership of the statutory professional register

was the agreed way to identify practitioners recognised to have the necessary competence to practise herbal medicine. On that basis they argued that it was not in the interests of public health for unregistered complementary medicine practitioners to be allowed indefinitely to operate under Section 12(1) Some herbal practitioner representatives argued that if use of Section 12(1) was not restricted to registered practitioners this would create an unfair situation for herbal practitioners given their investment in training to reach the required standards for registration. A number of bodies, including the EHPA and the Guild of Healthcare Pharmacists, stressed the importance of allowing an adequate transitional period. The Royal Pharmaceutical Society of Great Britain (RPSGB), while expressing a strong preference to see preparation and supply of herbal remedies under Section 12(1) under the control of statutorily regulated professionals, recognised that self-regulation (if effective) may be appropriate during a short-term transitional period.

Several responses sought explicitly or implicitly to draw a distinction between different levels of expertise and regulation required, depending on how activity was carried out under Section 12(1). An argument was mounted that if a practitioner was seeking to diagnose before deciding what medicine to make up and supply then it was right that they should come within full statutory professional regulation. However, this was not necessary if the Section 12(1) operator was explicitly not diagnosing and, moreover, was operating within clearly defined limits of competence.

Aromatherapist interests expressed considerable concerns about how the proposals would apply to their activity. The argument was mounted that, although many aromatherapists operated within Section 12(1), the differences as between conventional herbalism and the practice of aromatherapy were sufficiently great as to make a number of the proposals unnecessary or inappropriate if applied to aromatherapy. It was argued, for example, that pharmaceutical Good Manufacturing Practice (GMP) standards were unnecessary for essential oils intended for external use only.

The General Naturopathic Council expressed concerns about the possibility of naturopaths being prevented from carrying out activities that were restricted to registered practitioner only, for example use of potent herbs. Likewise several bodies representing the interests of traders expressed concerns about the potential impact of changes on shopkeepers who make up and supply remedies to the public.

Overall, representatives of various groups, aromatherapists, naturopaths, and retailers, argued that to prevent unregistered practitioners from operating under Section 12(1) would have an adverse effect on the livelihoods of these practitioners, many of whom were operating within well established traditions and patterns of activity. Several individual herbal practitioners also suggested that they might be unlikely to join the statutory register.

A number of commentators expressed considerable doubts as to whether voluntary self-regulation would be pursued effectively by practitioners who did not join the proposed statutory register. Various groups who saw their members as being possibly adversely affected by changes limiting activity to registered herbalists, recognised the whole issue was difficult to resolve and expressed willingness to engage in further work to investigate possible solutions. The Foundation for Integrated Health

suggested that a working group be set up to look at the implications for complementary therapies not on the statutory register with the view to statutory self-regulation of these groups. They suggested that a more structured approach should be taken to the issue of Complementary and Alternative Medicine practitioners outside statutory registration and offered to help.

Groups representing homeopaths and homeopathic manufacturers felt that their activities fell outside the scope of these proposals and were content with that. They were however concerned that the production of some of their remedies may be affected due to the use of non-herbal or potent ingredients in stock tinctures.

Quality

There was extensive support for introducing better regulation of quality standards in relation to remedies made up by practitioners, both from within the sector and from other interested parties such as Royal College of Physicians. There was a wide agreement that partially processed ingredients used in remedies should comply with GMP. Many, such as NIMH and the National Eczema Society, felt that such an obligation should be compulsory, or compulsory following a period of notice. The British Contact Dermatitis Society said that it was necessary for products used topically to be made by licensed manufacturers. Others, such as CMAS, felt that the costs of a scheme to achieve compliance with GMP might outweigh the benefits. There was general support also for ensuring that imported products and ingredients were of acceptable quality, although a number of issues were raised about the practical arrangements needed to achieve this. The General Council of Traditional Chinese Medicine suggested setting up mutual recognition with China, The International Ayurveda Foundation thought that GMP requirements should be based on those of the county of origin of the product.

There was support for registered herbalists operating to a code of practice.

Safety

There was wide support for the proposal that use of potent herbs in Section 12(1) remedies should be restricted to registered herbalists, although the General Council of Naturopaths expressed concern about the proposal and an individual herbalist argued that the issue should be left to market forces. The EHPA and the Herbal Forum suggested that in order to enhance safety the herbal profession could set up an advisory committee to maintain some form of positive list of ingredients acceptable for use in Section 12(1) medicines. This Committee could also liaise with the MHRA on safety issues such as herbs that are subject to statutory restrictions. The EHPA and the Herbal Forum considered that the costs of running such a committee should be funded by the Government.

Labelling

The proposals in relation to labelling were widely supported. A number of specific practical issues and concerns were raised, for example was it necessary to list ingredients in all cases (CMAS and a TCM company suggested company database of ingredient lists for standard formulas that could be requested by patients but not automatically given out with the remedy). The Royal College of Psychiatrists suggested that it was desirable to extend the labelling proposals to include side effects and interactions.

Third party Manufacture
There was wide support for the proposal to enable a registered herbalist to commission remedies made to the herbalist's specification from a holder of a Manufacturer's (Specials) Licence. However, some from orthodox medicine strongly opposed registered practitioners being regarded as authorised health care professionals (e.g. Royal College of Physicians (Edinburgh)). (In consultation the MHRA had noted that under European law, industrially produced medicines commissioned in these circumstances would require a full marketing authorisation or traditional use registration unless the practitioner commissioning them could be regarded as an authorised health care professional.) The General Naturopathic Council argued that naturopaths as well as registered herbalists should be able to use this provision.

Non-Herbal Ingredients
There was a varied response on the issue of whether the Section 12(1) regime should be extended to permit non-herbal ingredients. Some responses strongly emphasised the importance of non-herbal ingredients in the traditional Chinese and Ayurvedic medicines systems and welcomed an opportunity to extend the scheme. One respondent said that 17.2% of the ingredients in the Chinese Pharmacopoeia were of non-herbal origin. The Pan European Federation of TCM Societies said that their members used animal and human derived ingredients very infrequently. Some in the western herbal medicine tradition opposed such an extension. A range of respondents expressed particular opposition to the inclusion of parts of animal or human origin and/or emphasised the importance of applying rigorous standards to avoid public health risk from infective material.

There were several suggestions as to how categories of non-herbal ingredients for possible inclusion in Section 12(1) remedies might be defined. Several Ayurvedic groups suggested a foodstuff category i.e. milk, honey, ghee; a food supplement category. Several groups in TCM suggested an animal derived category and a mineral derived category. A number of respondents, including the RPSGB, the EHPA, the RCHM, the Herbal Forum, the Aromatherapy Trade Council, and the Ayurvedic Trade Association, suggested that there should be a positive list itemising permissible non-herbal ingredients and that such a list could be determined on the basis of expert advice. The Ayurvedic Trade Association argued that provided safety was acceptable it was not necessary for there to have been traditional usage of the non-herbal ingredient. There was a wide measure of agreement that any extension of the Section 12(1) to non-herbal ingredients should apply only to registered practitioners. A number of respondents stressed the importance of GMP standards applying to non-herbal ingredients, e.g. British Ayurvedic Medical Council.

Other Issues
There was general support for the proposals to review and rationalise two Statutory Instruments (dating from 1971 and 1977) and recognition that further consultation would be needed on more specific proposals.

Varied views were expressed on whether there was a case for permitting registered herbalists to combine licensed/registered herbal medicines. Among those against the possibility were the Herbal Forum and various pharmacist interests including the RPSGB.

MLX 299 raised the question - where it was proposed that certain activities be restricted to registered herbalists what should be the regulatory position of other professions that were subject to statutory regulation. Herbalist interests generally took the view either that only registered herbalists should be allowed to practice or that those from other professions should have to meet the same standards as herbalists if they were to be allowed to practise herbal medicine. A number of respondents, including the RPSGB, argued that pharmacists had suitable knowledge and experience. Several commentators suggested dual registration as a possibility; an alternative suggestion was that, where practitioners were on another statutory register, that regulatory body should liase with the Council that registered herbalists.

Several respondents (including NIMH) raised environmental issues relating to sustainability. A suggestion put forward was that herbalists should operate to a code of practice in this area. The Association of Chief Police Officers noted evidence of wildlife crime. They emphasised that plants as well as animals were subject to CITES controls and suggested that regulations should include reference to the CITES requirements.

Regulatory Impact

Most of the comments on regulatory impact were expressed in relatively general terms, reflecting the fact that the proposals were at a relatively early stage of development. As indicated above, different respondents argued from opposing standpoints that restricting activities to registered herbalists or permitting non registered herbalists to continue to operate under Section 12(1) would have an adverse regulatory impact. Likewise, while some argued that making a requirement to meet GMP standards compulsory would be over-regulatory others argued that not to do so would have an adverse regulatory impact, undermining of the position of those seeking to operate to acceptable standards.

One organisation representing traders submitted a survey of its members' use of Section 12(1).

Overall, a number of respondents said that it would be important to minimise costs, e.g. for suppliers complying with quality requirements. Several stressed that it would be important to look in the round at the overall impact of the emerging package, alongside that of the linked consultation on the statutory regulation of the herbal medicine profession. The British Association of Tibetan Medicine, while supporting the need for GMP, asked the MHRA to provide funding to help suppliers in developing countries to meet these standards.