Reforms of s12(1) of the Medicines Act 1968: possible extension to non herbal ingredients

Introduction

1. This informal discussion paper is one of a series prepared by the Medicines and Healthcare products Regulatory Agency (MHRA) which explores possible reforms of section 12(1) of the Medicines Act 1968[1] and its associated provisions. S12(1) is the legislative provision used by herbal practitioners, and some others, carrying out a business in which they prepare unlicensed herbal medicines to meet the individual needs of patients identified in consultation.

2. The paper is drafted on the assumption that work on the statutory regulation of the herbal medicine profession will lead in due course to the creation of a defined body of herbal practitioners that can be identified in law. In the text we have sought to indicate those areas where there are particular legal constraints on the direction of reform.

3. As indicated below, a possible extension of the s12(1) regime to certain non herbal ingredients would raise significant public health issues. In the event that these cannot be resolved satisfactorily the conclusion to this paper identifies for consideration a more limited way forward on the issue. In this context the paper should also be viewed alongside the separate informal discussion paper, no 6, which sets out MHRA's latest thinking on the regulation of unlicensed herbal medicines made up by a 3rd party for practitioner use.

4. The MHRA welcomes dialogue with interested parties on these ideas. The paper is intended to help focus such discussions. The MHRA's expectation is that this work will help prepare the way for a subsequent formal public consultation.

Background

5. A herbal remedy is defined in s132 of the Medicines Act as "*a medicinal product consisting of a substance produced by subjecting a plant or plants to drying, crushing or any other process, or a mixture whose sole ingredients are two or more substances so produced, or a mixture whose sole ingredients are one or more substances so produced and water or some other inert substance*."

6. The MHRA is aware that in a number of traditions, notably traditional Chinese and Ayurvedic medicines, significant use is made of non herbal ingredients,

[1] Section 12 is an exemption from the licensing provisions in the Medicines Act 1968, and is only relevant to medicinal products which in the first place fall outside the scope of Directive 2001/83/EC (eg products which are neither prepared industrially nor prepared using an industrial process).

and this was also reflected in the responses to the earlier public consultation, MLX 299 (the consultation and a summary of responses are available on the MHRA website). The case for permitting some non herbal ingredients was supported by a number of respondents, while others expressed strong opposition and/or considerable concerns about potential risks to public health.

7. Suggestions made in response to MLX 299 for non herbal ingredients included a number of foodstuffs, minerals or animal parts.

Objectives

8. The MHRA considers that any updated arrangements must:

- provide necessary public health protection in an area of known risk
- be legally robust
- give due regard to issues of regulatory impact.

9. Where products are within the scope of Directive 2001/83/EC, the default position both on public health and legal grounds is that where medicines are to be placed on the market a marketing authorisation (MA) is required, based on demonstration of safety, quality and efficacy. There is, however, recent recognition in European legislation (Directive 2004/24/EC on traditional herbal medicinal products) that in certain circumstances a simplified registration procedure (instead of a MA) is suitable for manufactured over-the-counter traditional herbal medicines. The Directive recognises that in principle it is possible to include within the simplified traditional herbal registration (THR) scheme certain other categories of ingredients. Accordingly, the Directive permits medicines with a THR also to include ancillary vitamins and minerals.

10. The MHRA's view is that the position in relation to the UK s12(1) regime (which only applies to products outside the scope of the Directive) is broadly analogous. In principle it is feasible to have a modified form of regulatory regime for herbal medicines made up by herbal practitioners to meet the needs of individual patients identified in consultation. The s12(1) regime, with suitable strengthening to improve public health protection, (eg on the basis of the ideas set out in these discussion documents) could serve this purpose. Certain traditional medicine systems, while making substantial use of herbal ingredients, also make significant use of non herbal ingredients in their medicines. This applies for example to TCM and Ayurveda. It may be that there are certain non herbal ingredients for which the regulatory controls in a strengthened s12(1) scheme would provide sufficient public health protection.

Public Health issues

11. The MHRA is concerned that in recent times when unlicensed medicines supplied by herbal/traditional medicine practitioners have been identified on the UK market illegally containing non herbal ingredients, the practice has often been associated with a clear public health risk. This is the case in relation to adulteration with pharmaceuticals, the inclusion of heavy metals,

and materials of human or animal origin such as human placenta or animal excreta. The existence of such products on the market emphasises the need for the regulatory system to be very robust.

12. Public health concerns relating to non herbal ingredients could arise in a number of different ways, and all would need to be taken into account. They include:

    - inherent toxicity of the ingredient
    - risks, eg contamination or infection, arising from manufacture, distribution and storage
    - TSE issues
    - other practical considerations surrounding safe manufacture, for example whether it is realistic for herbalists to weigh out very small amounts of certain substances (eg certain vitamins and minerals
    - openness of the regime to abuse
    - risks of misunderstanding arising from cultural difference, eg there are parts of the world where the practice of including heavy metals within traditional remedies is acceptable.

13. All ingredients should meet acceptable quality standards. Where possible currently authorised or registered ingredients with Drug Master Files or Certificates of Suitability should be used.

    Legal parameters

14. Only if products supplied under s12(1) are outside the scope of the Directive will they fall outside the requirements of Directive 2001/83/EC as amended. (If products fall within the scope of the Directive they would be required either to have a MA or a THR unless the requirements of any applicable "specials" scheme were met.)

15. Products that are produced industrially or manufactured by a method involving an industrial process cannot come within the s12(1) scheme.

Ideas for discussion on the extension of S12(1) to certain non herbal ingredients

16. The following ideas are put forward for consideration.

A. Overall

- ***The possibility should be available of creating a positive list of specific non herbal ingredients, permitted to be supplied under S12(1) where these ingredients meet certain criteria.***

- ***Any extension of the s12(1) scheme in this way should not take place unless and until there is a statutory scheme for the regulation of herbal practitioners, and should be limited to practitioners subject to statutory regulation.***

- ***The list should not include any ingredients where, for reasons of practicality or safety, it would be necessary for the practitioner to use industrial processes in preparing the medicine. (A medicine made using industrial processes could not come within the scope of the s12(1) exemption.).***

- ***The MHRA envisages that possible candidates for inclusion on the positive list could include some food stuffs, certain minerals and certain ingredients that would be acceptable as excipients in licensed or registered medicines.***

- ***Where a non herbal ingredient was included on the positive list there would be no equivalent restriction to that in the THR scheme under which non herbal ingredients (specifically vitamins and minerals) are only permitted for inclusion in a product where they are ancillary to the traditional herbal medicine.***

B. Criteria for considering inclusion of ingredients in positive list

- ***Is it necessary as a pre-condition for possible inclusion on the positive list to demonstrate that the ingredient has traditional use in herbal/traditional medicines system(s) used by practitioners subject to statutory regulation? This should be determined as follows:***

    - ***where an ingredient, if supplied on its own without medicinal claims, would not normally be regarded by MHRA as medicinal[2] it would not be necessary to demonstrate traditional usage of that ingredient***

    - ***where an ingredient, if supplied on its own, would normally be regarded as medicinal by the MHRA it would be necessary to demonstrate traditional usage. This is necessary to ensure that the s12(1) is not opened up to supply types of medicinal product in which registered practitioners have little or no expertise.***

- ***Conventional active ingredients used in medicines should not be considered for inclusion on the positive list other than where they have a tradition of use in traditional/herbal medicines.***

- ***Each ingredient for consideration for inclusion on the positive list should be assessed for safety to determine whether it could be safely used in medicines supplied under s12(1) by a registered practitioner.***

- ***The safety assessment should include:***

    - ***inherent safety of the ingredient***
    - ***possibility of interactions with other ingredients***
    - ***safety issues arising from quality. This will include, for example, issues relating to GMP and specifically for example to risks of transmission of infectious agents and of TSE and the feasibility of practitioners operating the necessary quality controls.***

[2] ie in accordance with the definition in Article 1(2)(b) of Directive 2001/83/EC

C. Process

- ***Herbal practitioner organisation(s) that are actively participating in preparations for statutory regulation of the profession should be invited to identify non herbal ingredients/category of ingredients and complete a template to enable assessment of suitability for possible inclusion within the s12(1) scheme.***

- ***The template requirements would be targeted, with fuller information and assessment required depending on the nature of the substance and possible risks.***

- ***The MHRA would review submissions received and seek the advice of the Herbal Medicines Advisory Committee on the suitability of the list.***

- ***Following this process any specific proposals would be subject to public consultation.***

- ***The list would be kept under review.***

Conclusion

17. This paper has covered the possibility of permitting the inclusion of certain non herbal ingredients within the s12(1) regime (which only applies to products which are outside the scope of Directive 2001/83/EC). It may be, however, that while the possibility may be acceptable *in principle*, further detailed consideration may question whether such a move *in practice* could occur whilst adequately protecting public health.

18. One option could be that any extension permitting inclusion of non herbal ingredients should be wholly or mainly limited to a regime whereby a registered herbalist commissions an unlicensed herbal medicine from a third party to meet the needs of individual patients. The possibility of including some non herbal ingredients within such a regime is discussed in discussion paper no 6.

19. The MHRA will consider these issues carefully in the light of further discussion with, and feedback from, interested parties.

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