Reforms of s12(1) of the Medicines Act 1968: quality standards where a practitioner prepares unlicensed herbal medicines

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 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. 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.

The current position and the need for reform

2. S12 of the Medicines Act 1968 exempts herbal remedies, under certain conditions, from the requirement for a product licence and various other provisions of the Medicines Act[1]. The provisions are used by practitioners to prepare and supply unlicensed herbal remedies to meet the needs of individual patients identified in consultation.

3. Currently there are no specific requirements as to the quality standards which have to be met by products sold under this exemption. For example there is nothing that indicates what standards should be met or that requires practitioners to follow safe procedures. There are some relevant general provisions in medicines legislation. For example s64(1) of the Medicines Act provides that "*no person shall, to the prejudice of the purchaser, sell any medicinal product which is not of the nature of quality demanded by the purchaser.*" Likewise there are provisions in general consumer legislation[2].

4. The absence of specific quality requirements relating to products sold under the s12 exemption has for some years been widely recognised as a weakness in regulatory protection. There is evidence that in the UK unlicensed herbal sector a significant proportion of safety issues result from poor standards in manufacture or sourcing of ingredients rather than to the inherent safety of the intended product. This is a situation which is not unique to the UK and it is recognised that there is an international trade in poorly regulated low grade herbal products and 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).

[2] See, for example, the General Product Safety Regulations (SI 2005/1803)

5. The importance of accurate and reliable identification of species, and the safety concerns where things go wrong, has been highlighted internationally by a number of incidents concerning toxic *Aristolochia* species. These have been associated with kidney failure and cancer. Work in the UK and elsewhere demonstrated that there is a persistent risk of accidental or deliberate confusion of species. Problems have included the same common (or pin yin) name used in traditional Chinese medicine to cover a number of different species. This has led to the accidental inclusion of toxic species. The problem is exacerbated in some cases by different toxic/non toxic species having a very similar appearance, so that only experts can tell them apart.

6. During its investigation of incidents involving use of *Aristolochia* species the former Medicines Control Agency identified that the inclusion of the wrong herb was not restricted to manufactured products but included material intended for use by herbalists.

7. The worldwide growth in popularity of herbal medicines has placed heavy demands on the supply of some herbal ingredients. Shortage of supply with associated price rises means that there can be a clear incentive for less scrupulous operators to substitute species, or to bulk up supply with low grade materials.

8. In an earlier consultation of the reform of the s12(1) exemption there was wide agreement that the present arrangements are unsatisfactory and that in the interests of safety the public should be able to expect regulatory arrangements to provide more systematic assurance of the quality of products than is currently the case.

<u>Alternative approaches to improving regulation</u>

9. The MHRA considers that there are three broad approaches to giving the public improved assurances as to the quality of unlicensed herbal medicines prepared by practitioners:

- requirements set out in medicines legislation
- requirements set out in a herbal practitioners' code
- a combination of both.

10. Where a herbalist prepares an unlicensed medicine to meet the needs of an individual patient (s)he is undertaking an activity comparable to that of a pharmacist who engages in extemporaneous preparation or compounding.

11. The Royal Pharmaceutical Society of Great Britain has a code "*Medicines, Ethics and Practice*" July 2006 which addresses the issues of standards in this area. A section of the code covers extemporaneous preparation/compounding. This includes a range of issues such as:

- use of accepted standards

- maintenance of equipment
- sourcing of ingredients
- checking of calculations
- handling of hazardous substances
- labelling
- record keeping

12. The MHRA considers that the detailed requirements for quality standards to be met by herbal practitioners in their preparation of unlicensed medicines would most appropriately be met by use of a comparable code, tailored as necessary to reflect the responsible practice of herbal medicine. Such a code would be able to set out a systematic approach to quality issues and would also be able to cover in greater depth the various areas of concern, ranging from correct identification of species and use of reputable suppliers to storage conditions, hygiene, and weights and measures. A code could incorporate the best practice already advocated for use by some practitioner professional organisations.

13. The Agency considers that use of a herbal practitioner's professional code as the principle means of giving the pubic assurance as to quality would accord with the principles of better regulation. In particular, this approach could potentially score well as regards consistency of approach (with the regulation of the activities of other health care professionals) targeting, proportionality and accountability within the regulatory arrangements. A code would also be more flexible than legislation and more readily adaptable in the face of new information and concerns.

14. However, this approach could only be applied effectively if it is possible to identify in law which practitioners are allowed to operate under s12(1); and if these practitioners are required to be held accountable for meeting the required standards by a body that has the capability of operating this oversight. Effective arrangements for enforcement of the code would be an important consideration. **Therefore this is one of a number of areas of s12(1) reform where it would be necessary to review provisional ideas for reform once the proposals for the statutory regulation of the herbal medicine profession are clearer.**

15. There is one area where the use of legislation alongside a professional code could be considered. This is where practitioners buy in processed ingredients, eg bulk tinctures, which they then use (eg by combining a number of different tinctures) to prepare individualised medicines for their patients. The MHRA understands this is a widespread practice.

16. On grounds of public health it is desirable that such processed ingredients should meet standards of Good Manufacturing Practice (GMP). If this is not the case there is a risk of double standards with the tinctures used by some herbalists being of a lower standard than those that are used in herbal medicines with a traditional herbal registration (THR) or marketing authorisation (MA). A regime where this is possible could create adverse

incentives for companies that are investing to reach the level of standards required for the THR scheme.

17. One option to address this situation would be to introduce a specific legislative requirement relating to the need for processed ingredients used by herbalists to meet GMP standards. An alternative approach would be to ensure that the practitioners' code covered this issue with advice that good professional practice would require that, wherever the option existed, processed active ingredients should be sourced from suppliers who had demonstrably met GMP standards, eg through their participation in the supply chain for licensed/registered products and or holding a relevant GMP certificate. The MHRA is currently minded to favour the latter approach but would welcome views.

18. By the time any new s12(1) arrangements are introduced it is likely that there will be an extended range of suppliers able to provide processed ingredients made to assured standards.

Issues for discussion

- ***Do you agree on the need to introduce specific quality requirements relating to the preparation by practitioners of unlicensed herbal medicines under s12(1)?***

- ***On the assumption that there is to be statutory regulation of the herbal medicines profession, do you agree that the relevant quality requirements should be set out in a professional code of practice and that practitioners should be professionally accountable for compliance?***

- ***If you favour s12(1) remaining open to some or all practitioners who are not subject to statutory regulation (see discussion paper No2) how would you propose that relevant quality standards could be required and compliance ensured?***

- ***Do you agree that where practitioners buy in processed ingredients to use in preparing their s12(1) medicines, it is desirable that these should meet GMP standards? If so, do you consider this should be covered by legislation or by the proposed herbal practitioner's code?***

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