Reforms of s12(1) of the Medicines Act 1968: safety issues

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. 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.

Current position

2. The lack of adequate safeguards for the patient is widely recognised as a weakness of the s12(1) provisions. The problems are fundamental:

   - anyone, irrespective of whether they have any relevant expertise or experience, can carry out a business in which they hold one to one consultations with patients, diagnose their condition, and make up and supply an unlicensed herbal medicine
   - there are no specific safeguards as to the quality of the medicine to be supplied, giving rise to the possibility of safety issues arising from low quality, such as contamination, adulteration or misidentification of ingredients
   - one of the main provisions for restricting/prohibiting use of specific herbal ingredients is weak. This is an Order dating from 1977 which lists ingredients that are restricted to use in one to one consultations. However, given the absence of any requirements as to the competence of the person carrying out the consultation, this legal instrument provides the public with little protection.

3. The concerns identified above are not simply theoretical. A persistent flow of incidents of poor practice continues to come to light, particularly from parts of the traditional Chinese medicine sector. These include:

   - practitioners holding limited or minimal consultations in which, for example, they fail to ask about other medication being taken
   - practitioners failing to respond appropriately when a patient has experienced a suspected adverse reaction

[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).

- practitioners found to be unable to communicate effectively with patients because of language difficulties
- practitioners sourcing poor quality and/or unsafe products from unreliable sources and supplying such products to the public. This practice continues despite the well publicised evidence of the risk that products drawn from the international trade in low grade products are prone to serious problems such as adulteration with potent pharmaceuticals. In parts of the herbal sector certain categories of products such as slimming aids and skins creams have a track record of adulteration
- clinics making unrealistic and unproven claims about the safety of herbal and traditional medicines supplied by practitioners/clinics
- clinics making unproven claims about efficacy of medicines and therapies for particular conditions; this poses a threat to safety, for example, it may encourage a patient to give up essential medication prescribed by a doctor or to take a variety of different medicines in an uncontrolled way without any form of adequate professional supervision.

4. The concerns above have variously been identified by practitioner organisations, by regulatory authorities such as MHRA and the Advertising Standards Authority, the health service, and by members of the public. The issue of standards followed by practitioners/clinics in the sector is also proving of continuing interest to the investigative media.

5. The MHRA's overall assessment is that, as compared to the early years of the operation of the s12(1) arrangements following the coming into force of the Medicines Act 1968, there is now wider, and growing, evidence of the risks posed to the public by poorly regulated practitioners/clinics supplying poorly regulated products. In part this may reflect advances in scientific understanding, results of increased international information sharing, and greater experience of identifying risk areas eg adulterated herbal medicines. However, it may well also be that, overall, there are more examples of bad practice to be found.

6. There is also now increasing awareness of the possibility of adverse reactions and herb drug interactions. Historically, levels of adverse drug reaction (ADR) reporting for herbal medicines have been low. This reflects many factors, not least that survey evidence shows that often patients do not tell their doctor that they are taking herbal medicines. Typically the MHRA has received about 60-70 ADR reports a year. However, the introduction of patient reporting via the yellow card scheme may well have a significant effect. Between 1 January and 30 September 2006 the MHRA received 63 reports, of which 36 were from health care professionals and 27 were from patients.

7. The reforms of s12(1) alongside the introduction of statutory regulation of the herbal medicine profession and the introduction of the traditional herbal registration (THR) scheme for manufactured OTC products could offer a major opportunity to introduce a more secure and systematic approach to safeguarding public health and promoting informed consumer choice.

Improving safety

8. By far the single most important step towards achieving systematic safety protection in s12(1) arrangements would be if the public could be assured that in future **only those who are recognised as professionally competent in the practice of herbal medicine and are subject to appropriate standards of statutory professional self regulation would be permitted to operate under s12(1**). For convenience, in this paper such practitioners are referred to as registered practitioners. In addition to registered herbal practitioners (ie assuming herbal practitioners are brought into statutory self regulation) this category could also include other statutorily regulated healthcare professionals recognised as competent in the practice of herbal medicine. The position of other operators who are not subject to statutory regulation needs careful consideration and is explored in a separate discussion paper.

The professionalism of the practitioner

9. If the public could be assured that s12(1) would be used only by a defined group of practitioners that was subject to systematic professional self regulation there would be a number of benefits. Depending on the requirements in place, the public should be assured that:

    - the professional competence of the registered practitioner had been assessed and found to be acceptable; a consistent approach would be taken to the acceptability of different qualifications
    - the professional competence of the registered practitioner would be subject to regular review
    - the registered practitioner should be aware of the limits of their own competence as well as having a duty not to act beyond the limits of their expertise
    - the ability of the practitioner to communicate would also have been assessed
    - the registered practitioner would be accountable for their actions within the context of a transparent complaints procedures
    - the registered practitioner would be required to keep their professional knowledge up to date on safety issues; this would include for example emerging information on interactions between herbal medicines and other medicines
    - codes of practice could, as necessary, address a range of important issues affecting safe and good professional practice, such as the conduct of consultations, patient record keeping and effective communication between the registered practitioner and other healthcare professionals.

Safety relating to quality of the product

10. This important issue is addressed in discussion paper No 4, on quality standards. A further discussion paper, No 6, addresses the issue of manufacturing and quality standards where a registered practitioner commissions the manufacture of an unlicensed herbal medicine from a 3rd party.

11. A key point is that it is not proposed to require a registered practitioner who makes up herbal medicines for use with their own patients to hold a Manufacturer's Licence. If that is the case there is a strong need for registered practitioners to follow a professional code of conduct and to be accountable for doing so.

Control of specific toxic or potent herbal ingredients

12. This analysis relates to the "steady state" situation assuming statutory regulation of the herbal medicine profession is fully in place *and* the transitional period under the THR scheme has ended. If use of s12(1) is restricted to registered practitioners it should be possible to achieve more systematic safeguards than is currently possible under either the s12(1) or s12(2) arrangements:

- registered practitioners would be professionally accountable for the safety of the unlicensed herbal medicines they supply
- manufactured herbal medicines which fall within Directive 2001/83/EC will require either a marketing authorisation (MA) or a THR (unless one of the exemptions in the Directive applies). Such products are assessed as to their safety before authorisation/registration; if safety issues emerge subsequently the authorisation/registration can be amended or withdrawn as appropriate.

13. There are various existing and possible future mechanisms for restricting or prohibiting the use of specific herbal ingredients in unlicensed medicines. Before firming up on proposals it would be necessary to clear on what were to be the arrangements for professional regulation of other statutorily regulated healthcare professionals who also wish to practise herbal medicine.

14. It would also be necessary to be clear on the **objectives,** eg is a restriction intended to to regulate the activity of registered practitioners or to regulate other activities, for example importation of an unlicensed herbal medicine by any member of the public for personal use.

15. Existing forms of restriction that could be applied to **unlicensed medicines**[2] containing named herbal ingredients include:

- **prescription only medicine (POM)**; this would generally have the practical effect of restricting legal sale and supply; it is unlikely in foreseeable circumstances that doctors/dentists or other healthcare

[2] For comparison it may be helpful to note the situation for herbal medicines with an MA or a THR:
- Herbal medicines with an MA may be either POM, P or General Sales List
- Herbal medicines with a THR are likely to mainly GSL; however a minority could be P

Following statutory regulation of the herbal medicine profession it might be feasible to create a category of registered herbal practitioner only.

professionals able to supply POMs would often wish to use this option to supply an unlicensed POM herbal medicine

- **pharmacy (P)**; supply from a registered pharmacy
- **agreement with the herbal medicine profession on restricting or avoiding the use of certain herbal ingredients in s12(1) medicines**; This option has been used in a limited way so far and has been subject to the weakness that it is not currently possible to reach a reliably comprehensive agreement covering all the ill defined and miscellaneous possible current users of s12(1). In future, if use of the s12(1) exemption is restricted to a defined body of registered practitioners, it may be altogether more feasible to reach agreement with the profession that, as a matter of good professional practice, on safety grounds various herbal ingredients should not be used in unlicensed herbal medicines supplied under s12(1); or only within certain restrictions, eg as to strength, dosage or method of preparation, or only if accompanied by particular warnings. Overall, there are considerable numbers of potent herbal ingredients, taking all the various herbal traditions represented in the UK, that either currently or historically have had some usage in herbal medicine. Potentially, agreement with the profession, which would be backed by the possibility of disciplinary action, could be a relatively flexible way of dealing with a range of the scenarios could arise. The feasibility of this option, as opposed to a legislative based solution, would depend on how robust statutory regulation is, and whether professional disciplinary sanctions are seen as sufficiently strong to be as persuasive as a legislative based restriction
- **prohibition of ingredient in unlicensed medicines**; Ministers can make an Order, subject to consultation, where it is considered in the interests of safety; this option could be useful, for example, where on public health grounds there is a particular need to prohibit personal importation by the public.

16. A further possibility that might be considered is:

    - (If s12(1) were to apply to non registered as well as registered practitioners), **restriction of certain ingredients in s12(1) to registered practitioners only;** This option might provide the public with certain limited safeguards in the event that unregistered practitioners were permitted continued use of s12(1). If, however, s12(1) were in any case to be restricted to registered practitioners the option would not add anything.

17. There may be *variants* of the above options or *additional* options. Also, if lists of herbal ingredients subject to various restrictions may be regularly evolving it would be necessary to ensure that the procedure was manageable. Irrespective of the arrangements it will be necessary to ensure that the approach taken is legally sound, the necessary scientific expertise is brought to bear, the approach taken is proportionate and that there is effective consultation.

    Herbal formulary/ materia medica

18. One other area of concern is that, taking all s12(1) practitioners together, a very wide range of herbal medicines are being supplied under s12(1). The full extent of this is not known and there is limited, if any, scrutiny or accountability. The position is unlikely to be static. For example, changes in fashion, increases in popularity of different herbal traditions, new research, advertising by suppliers, crop failures, rises in prices or numerous other factors could lead to changes in the herbal ingredients used by practitioners. On the other hand, some practitioners' usage of ingredients may not have changed for many years notwithstanding recognition elsewhere in the profession that safe practice of herbal medicine had moved on.

19. The MHRA's view is that there is a case for a profession led action to identify a formulary or materia medica of herbal ingredients that have an acceptable and safe place in the modern practice of herbal medicine. This is not to say that other herbal ingredients could not be used (unless there were specific restrictions) but rather that usage of other ingredients could trigger some form of assessment or review action. A formulary of this kind need not have a statutory basis.

20. If the profession were to establish a list of herbal ingredients currently in use:

    - the MHRA could identify a proportion, probably significant, on which no further action, other than keeping a watch, was necessary, eg ingredients that are GSL status, ingredients that are accepted as having safe food usage
    - the MHRA could provide a template for the information/analysis for the profession to supply
    - the Herbal Medicines Advisory Committee could be asked to review recommendations coming from the herbal medicine profession.

21. By way of a comparison in a different healthcare profession, it may be noted that from May 2006, the Nurse Prescribers' Extended Formulary was discontinued and qualified Nurse Independent Prescribers (formerly known as Extended Formulary Nurse Prescribers) are now able to prescribe any licensed medicine for any medical condition within their competence. The move took place within the context of careful training and accountability. Experience in this area has been that it can be a major undertaking to develop and maintain a potentially ever lengthening list of medicines suitable for use within a particular profession.

22. It should be noted, however, that there are significant differences:

    - herbal medicine practitioners will generally be using unlicensed herbal medicines, which will almost always have been subject to much less scrutiny eg as to safety and efficacy of the specific product and the information the patient needs for safe use. Licensed medicines in contrast are accompanied by authorized information concerning the safe usage of the product
    - the herbal medicine profession to date will have had very much less experience in operating under standards of professional scrutiny and accountability.

23. Factors such as these would argue that the scale and practical challenges of the task should not be used lightly as reasons for discarding the option of developing a herbal formulary.

Discussion points

24. Feedback on these issues would be welcome. In particular:

Overall assessment

- ***on the overall approach to safety and in particular the central importance that all practitioners operating under s12(1) should be subject to a strong framework of professional self regulation and accountability***

Control of toxic/potent ingredients

- ***on the relative merits of achieving controls on potent herbal ingredients in s12(1) products via agreement with the profession, via lists set out in legislation, or a mixture of both***

Formulary for herbalists

- ***on the merits and practicalities of the herbal medicine profession developing a formulary of herbal ingredients accepted as having a place within the safe practice of herbal medicine within the UK, with proposals for items to be included in the formulary subject to review by the Herbal Medicines Advisory Committee***

- ***if the above approach is considered undesirable or impracticable what alternative approach is proposed to give the public assurances that the safety of herbal medicine practice with regard to the extensive range of medicinal ingredients in use is subject to adequate scrutiny and accountability?***

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