Reforms of s12(1) of the Medicines Act 1968: who should be allowed to operate under s12(1)?

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 MHRA sees resolving the issue of who should be able to benefit from the s12(1) exemption as central if public health protection is to be improved. In a hitherto largely unregulated market a wide variety of practices have grown up and it may not be possible or desirable to reform arrangements in a way that accommodates all these practices. There are therefore significant issues of regulatory impact. 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 to pave the way for a subsequent formal public consultation.

Why is it significant who is permitted to use the provisions of s12(1)?

3. S12(1) of the Medicines Act 1968 exempts the sale, supply, manufacture and assembly of herbal remedies in the course of a business from the licensing provisions in the Act, provided that certain conditions are met. The first condition is that the remedy is manufactured or assembled on premises of which the person carrying on the business is the occupier and which he is able to close so as to exclude the public. The second condition is that the person carrying on the business sells or supplies the remedy for administration to a particular person after being requested by that person, and in that person's presence (i.e. in MHRA's view, following a face to face consultation) to use his own judgment as to the treatment required.

4. As set out above, it is important to remember that this provision has no effect on herbal medicinal products which fall within the scope of Directive 2001/83. For products within the scope of Directive 2001/83, the product must be authorised with a marketing authorisation (MA) or a traditional herbal registration (THR), unless one of the exemptions in the Directive applies.

[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).

5. For activity under s12(1) to be undertaken to acceptable levels of safety the public should be assured that:

- the practitioner has the expertise and competence necessary to identify what medicine the patient needs
- the practitioner is professionally accountable
- the practitioner has the expertise to safely make up unlicensed medicines.

6. There are various ways that public health risk can arise as a result of poor practice in consultations relating to herbal medicine. These include:

- failure to diagnose accurately
- failure to recognise the possibility of a serious condition that should be seen by a doctor
- failure to ask about or to take into account other medication being taken
- failure to understand the possibilities of side effects of medicines and interactions between medicines
- failure to respond effectively when adverse reactions occur
- discontinuity in treatment resulting from ineffective or lack of patient record keeping
- other failures resulting from ineffective communication with the patient
- failure to take precautions against other known safety issues with unlicensed herbal medicines, notably those resulting from poor quality, such as adulteration, contamination and misidentification of species
- encouragement of patients to reduce or give up prescribed medication without consulting their doctor (or other prescriber such as pharmacist or nurse) .

7. These issues illustrate the fundamental importance that the practitioner is trained and competent, accountable for their actions. It is also necessary, in relation to s12(1) that the practitioner has suitable expertise in manufacturing or assembling the unlicensed herbal medicines they use. The whole issue of professionalism needs to be considered in the round. Shortfalls on one issue could easily be indicative of problems elsewhere. For example, if a clinic advertises that its medicines have no side effects it may be doubtful whether practitioners in that clinic would take effective action when a patient experienced a possible adverse reaction.

<u>What are the consequences if the s12(1) exemption remains open to all, including practitioners who are not subject to statutory registration?</u>

8. The MHRA believes the main foreseeable consequences of this position to be:

- continuing risk to public health. The safety issues are set out more fully in discussion papers No 1, 3 and 4. There is continuing evidence

that a proportion of practitioners operating under s12(1) do not follow high standards. The MHRA doubts the issue of public safety can be addressed effectively if use of the s12(1) exemption remains open to all

- a reduction in the incentives for practitioners to join any statutory register and perpetuation of the current situation in which submitting to professional accountability is essentially a voluntary option for practitioners
- responsible practitioners could be undercut by practitioners offering lower prices or extravagant claims of the benefits they can deliver
- significant difficulties in successfully establishing statutory regulation of the herbal medicine profession. There are certain parts of the sector where voluntary professional self regulation currently may not be deeply rooted. Achieving statutory regulation in TCM, for example, will in any case represent a significant challenge to that sector; the challenge is likely to be considerably greater if anyone can still continue to practice under s12(1) whether or not they are on a statutory register
- if it is thought preferable that certain of the regulatory safeguards for the public under the reformed s12(1) regime would be achieved more effectively by agreement with the profession on codes of conduct rather than through detailed medicines legislation - this approach could not be followed if s12(1) remained open to anyone
- to leave the main safeguard for the public as the message "buyer beware". The MHRA doubts that this would promote public confidence in, and long term prosperity of, the sector.

<u>Categories of s12(1) users</u>

(i) herbal practitioners in good standing with the profession and planning for statutory regulation

9. The MHRA envisages that herbal practitioners on the proposed statutory register should be able to benefit from the s12(1) exemption in a reformed regime. The statutory regulation of herbal practitioners should be a major step forward in protecting public health in relation to consultations on herbal remedies. This would particularly be the case if:

- standards for practitioners joining and staying on the register were robust on all matters that affect the protection of public health
- any arrangements to "grandparent" existing practitioners onto the register did not over-emphasise the desire for inclusivity and comprehensive coverage of the register at the expense of maintaining standards that would protect public health
- professional standards were applied consistently, irrespective of the herbal tradition to which the practitioners belongs or whether the practitioner also practises other forms of complementary and alternative medicine (CAM).

(ii) members of other statutorily regulated healthcare profession who also practise herbal medicine

10. The MHRA envisages that members of other healthcare professions who are statutorily regulated and who are recognised within the framework of professional regulation as competent to practise herbal medicine should also be able to benefit from the s12(1) exemption (again, assuming the other conditions are met). Within other statutorily regulated healthcare professions there will be a number of practitioners who, in addition to being a registered nurse or pharmacist for example, have also trained as a herbalist. How professional recognition would be arranged (for example via dual registration) is one of the issues under consideration in the Joint Working Group that is preparing detailed proposals for the statutory regulation of the herbal medicine profession. As proposals relating to professional recognition and accountability are developed by the Joint Working Group it will be necessary to check that it is feasible to make consistent changes in s12(1).

11. The MHRA understands that a significant proportion of acupuncturists in the Chinese medicine tradition also use herbal medicine to varying degrees. It would be important that arrangements for statutory regulation were sufficiently robust as to give the public assurance that only those registered acupuncturists who have the necessary training and experience can potentially benefit from the s12(1) exemption.

(iii) others who currently benefit in practice from the exemption in s12(1)

12. MHRA's understanding from its knowledge of the sector and from a number of discussions and field visits over a period is that there are a wide range of categories of people who may currently make some use of the s12(1) exemption. This section focuses on some other s12(1) users *beyond* those already on a statutory register or those typical herbal practitioners who are in good standing with one of the existing self regulatory herbal practitioner bodies that are preparing for statutory regulation. This is a complex area in which there is a need for further detailed dialogue between MHRA and interested parties. **It is essential to bear in mind the point, emphasised at para 15 below, that it is likely that many CAM practitioners will be operating wholly or mainly without the need for the s12(1) exemption, notwithstanding their use of herbal products/ingredients.**

13. There will be people in these categories with considerable professional expertise in the practice in herbal medicine, those signally lacking in any such expertise and others falling at various points in between. There will be people who use s12(1) frequently and those who are only occasional users; there may be people who might be both willing and able to join a statutory register for herbal practitioners and others who might well not be able and willing to do so. In a hitherto largely unregulated market a whole range of miscellaneous practices has grown up. The following categories

probably does not cover all possible situations, but it does give an indication of the great variety:

- certain naturopaths, homoeopaths or others who mainly specialise in a specific CAM therapy other than herbal medicine
- certain aromatherapists who choose to present their activity of blending essential oils for external use as medicinal; any aromatherapists (possibly a tiny minority) that supply essential oils for internal use
- certain multi disciplinary CAM therapists who may offer a wide range of different therapies
- a limited number of shopkeepers in traditional herbal shops
- a small minority of retail staff, (eg trainee herbalists or shop assistants) working in the shop fronts of herbal clinics or in health food or similar shops. Certain of these staff may be advising the public and making up unlicensed herbal remedies for them. MHRA has seen examples where there may be some formal or informal supervision or advice from a herbalist and protocols for staff to follow
- people who may have only very limited training or expertise, eg a few weekend courses on herbal medicine, and have set themselves up as herbal practitioners
- herbal practitioners who are not in good standing with any of the current professional bodies working towards statutory registration, perhaps on account of previous poor professional practice or offences under medicines legislation
- certain herbal practitioners who may not have the appropriate language skills to communicate with patients
- herbal practitioners who are strongly individualist and uninterested in any involvement in collective activity.

14. It would be helpful to clarify with the Joint Working Group and other interested parties to what extent if any there may be CAM practitioners who do not regard themselves as herbal practitioners but may have a level of training and experience in the practice of herbal medicine that would be comparable to that of an orthodox herbalist.

<u>Is it possible to quantify the scale of activity under s12(1) of practitioners who fall into the categories described at section D(iii)?</u>

15. MHRA's field work suggests that it would be difficult to make reliable estimates of the numbers of practitioners in many of the above categories, that may from time to time currently make use of the s12(1) exemption. Among the reasons for this are:

- the very diverse and ill defined nature of such categories, and the fact that for many use of s12(1) may only form an occasional part of their activity; some of these categories are diverse people who simply happen to share one particular characteristic and are not part of any discrete group

- overall, on the basis of MHRA's experience, it is likely that many practitioners would find it difficult to identify with any accuracy (eg if asked in a survey) to what extent they used s12(1). The MHRA is aware, for example, of interested parties appearing to make an erroneous assumption that the giving of advice when supplying the public with a herbal product makes the activity fall within s12(1)
- **many herbal ingredients and herbal products would not be regarded as medicinal products under the Act** and therefore the s12(1) exemption is irrelevant to the regulation of such products; many could fall into more than one regulatory category (eg food, cosmetic, general consumer product), depending on the precise contents of the product and its presentation. The MHRA Borderline Section's list of herbal ingredients published on the Agency's website illustrates the variety of uses that different herbal ingredients have
- **various forms of CAM practice may use herbal ingredients or products for purposes such as promoting nutrition, maintaining health and well being, relaxation, or providing support in coping with the effects of unpleasant medical treatment. Unless the product itself is regarded as medicinal by virtue of its ingredients, with a suitable presentation it is unlikely that the product would be regarded by MHRA as a medicine. It is likely that many CAM practitioners will be operating wholly or mainly without the need for the s12(1) exemption, notwithstanding their use of herbal products/ingredients**
- in aromatherapy, typically the essential oils blended for external use will not be regarded by MHRA as a medicinal product; but the patient literature used in some clinics indicates that the activity is intended to be medicinal in nature. Fine distinctions in the wording of individual clinic literature may make the difference as to whether or not the activity taking place falls within the Medicines Act and thus requires a licence unless the s12(1) exemption applies.

<u>If the s12(1) exemption is limited to practitioners on a statutory register, what activities could be undertaken by practitioners who are not on this register?</u>

16. Practitioners in this position would be able to:

- supply manufactured GSL herbal medicines with an MA or a THR, subject to meeting the requirements applicable to sale and supply of GSL products
- make up and/or supply any herbal products that are not medicinal products, subject to meeting any regulatory rules applicable to that category of product. The MHRA's list on the website of herbal ingredients and their various uses illustrates some of the possibilities. Many herbal ingredients have recognised use for a range of non medicinal purposes such as improving nutrition, maintaining health and well being and promoting relaxation.

Are there options available that would permit persons other than those subject to statutory regulation to continue to benefit from the s12(1) exemption whilst providing satisfactory safeguards for the public?

(i) promote voluntary self regulation among users of s12(1) who are not on a statutory register while continuing to allow anyone to use s12(1)

17. Improved self regulation of CAM groups that are not heading for statutory regulation for the foreseeable future can offer a range of benefits for the public and practitioners and could be seen as worthwhile in its own right. In principle, information to the public could play a role, enabling identification of practitioners following particular self regulatory codes as well as practitioners who are subject to statutory regulation. However, this approach would still leave those practitioners who chose not to participate in schemes of statutory or voluntary self regulation free to operate to lower (and in some cases very low) standards.

18. In an earlier consultation, MLX 299, MHRA had considered the option of permitting practitioners not on a statutory register to continue to benefit from the s12(1) exemption while a further assessment was made of the possibilities for improving public health protection through voluntary self regulation. However, the continuing and significant evidence of poor practice, notably in parts of the TCM sector, has led the MHRA to the view that that this option would be very unlikely to tackle the most problematic issues of public protection. It is difficult to see that further initiatives in voluntary self regulation would have much if any impact on that segment of current operators under s12(1) who have not responded positively to existing self regulatory initiatives and who continue to pose a risk to public health. There is a clear risk that the opposite result could occur; the attempt to secure higher and more consistent standards of professional accountability through statutory self regulation could be undermined by continuing to permit lawful supply etc under s12(1) by those who declined to be part of the process.

19. Overall, the MHRA suggests that this option would neither protect public health sufficiently nor promote long term confidence in the sector.

(ii) identify a further group or groups that, while not subject to full statutory self regulation, could nonetheless be identified in law and continue to benefit from the s12(1) exemption

20. There are many and formidable difficulties arising with this option. Some of the most fundamental include:

- whether it would be legally feasible to recognise a body or bodies in legislation; if so what criteria should be used for identifying such a body or bodies
- there is currently a multiplicity of self regulatory bodies in the CAM sector

- any approach along these lines could cut across the thinking outlined in the Foster review of non medical regulation; why should a body be given recognition in law for its role in the professional regulation of healthcare professionals outside of the normal arrangements for managing statutory self regulation?
- there would need to be a very clear justification as to why it was desirable to recognise in law a body of people who would be acting as herbal practitioners while having more limited competence to the extent that they were not able to join the statutory register. How would that competence be defined in a way that did not undermine the process of statutory regulation or public health protection? For example, if a practitioner as part of reformed arrangements was entitled to supply GSL ingredients under s12(1), (s)he could be just as likely as a registered practitioner to come across a patient who had an underlying serious medical condition requiring referral to a doctor.

21. The MHRA's assessment is that this approach does not look at all realistic or achievable. It has, however, been included in this analysis so that all possible options can be considered.

(iii) permit statutorily registered herbalists to delegate the functions of holding consultations, identifying needs and making up unlicensed herbal medicines

22. One possibility which practitioner and other interests might consider investigating is the feasibility of arrangements under which a registered herbal practitioner maintained professional responsibility for the action of assistants working within agreed protocols. From visits undertaken by MHRA there is some evidence that a rudimentary and informal version of these arrangements may be operating in some clinics and shops. A herbalist is present on the premises for at least some of the time. Written or unwritten protocols are agreed which in effect also permit some other staff to see the patient at a counter and make up remedies for them.

23. There would be numerous issues to address, including:

- what training or qualifications would be necessary for someone safely to act as an assistant to a herbalist
- what arrangements would be needed to ensure safety if the assistant was involved in the manufacture/assembly of the remedy
- what are the various areas in which protocols would be required to deliver good practice and prevent the assistant straying beyond their competence
- what arrangements would be necessary for professional oversight of such assistants by the herbalist
- what oversight would be necessary of the registered herbalists themselves in setting up and operating such arrangements to ensure they were professionally acceptable
- what specific other restrictions would be necessary (eg use of GSL herbs only).

24. A wider issue is whether the herbal medicine profession itself would be sufficiently mature at this stage (in its operation of self regulation) to be able to operate such arrangements effectively.

25. The MHRA also has concerns about the rationale for the development of the practices described at para 22. It may be that some of these practices have arisen because some customers do not wish to pay for a consultation with a professional herbalist but in effect are looking for the services of an informed shop assistant to supply a herbalist's remedy. There is a risk here of confusion between professional consultation and retail activity.

26. Overall, if the profession wished to take this option forward it would be necessary to take full account of wider developments in the regulation of healthcare professionals, particularly when looking at issues such as accountability and the kind of safeguards needed to protect the public.

27. One relevant comparison is that pharmacists may delegate certain activities to appropriately trained members of staff. However, the pharmacist retains accountability for the provision of services by non-registered pharmacy staff and is required to ensure that if tasks are to be delegated they are delegated to persons competent to perform them. For example, any assistant who is given delegated authority to sell medicines under a protocol should have undertaken, or be undertaking, an accredited course relevant to their duties. There are certain activities that remain the direct responsibility of the pharmacist and cannot be delegated. For example, while a pharmacy technician may undertake the technical aspects of the dispensing process, the Code of Ethics requires that a pharmacist undertakes a clinical assessment of every prescription to determine its suitability for the patient. Additionally, there are requirements in the Medicines Act for sale and supply of POM and P medicines to be under the supervision of a pharmacist and a retail pharmacy business to be under the personal control of a pharmacist.

Implications of Analysis

28. In MHRA's view the discussion of options at paras 17 – 27 for allowing some of those who are not statutorily registered to operate under s12(1) underlines that there are major difficulties with going down these routes. It is unsurprising that in a hitherto largely unregulated sector a wide range of practices have grown up. While issues of regulatory impact are important, it would seem undesirable to build in to reformed s12(1) arrangements any ongoing features that are not objectively justifiable and may well not stand the test of time.

29. MHRA suggests there needs to be strong arguments for departing from the straightforward position that the when the public are supplied with herbal medicines one of the following two conditions should apply:

- the medicine should be an authorised/registered product made to assured standards and with authorised information about the indications of the product and its safe usage
- the medicine should be supplied by a practitioner who is subject to standards of professional accountability that are no less than apply to other healthcare professionals, and who is fully accountable for supplying the product to the patient.

30. It is MHRA's current assessment that the clearest and most defensible case can be made for providing that in future only those subject to statutory registration should benefit from the s12(1) exemption.

Transitional protection

31. It would be necessary to provide transitional protection if the use of s12(1) were to be restricted to practitioners subject to statutory regulation. The most obvious approach would be to say that usage of s12(1) should be restricted from the point that existing practitioners have had sufficient opportunity to apply for statutory registration (eg perhaps two years after the register was opened). This date would depend on the progress of the work on statutory regulation of the profession but it currently seems unlikely that this date would fall before 2010.

32. A separate discussion paper, no 8, considers a number of issues related to transitional protection.

Issues for discussion

33. The MHRA would welcome feedback on the issues discussed and in particular on the following points:

Issues for discussion

- ***Do you agree with the analysis of the central importance of giving the public assurance as to the professional expertise and accountability of the practitioner?***

- ***If the s12(1) exemption should remain available to all practitioners, irrespective of whether they are subject to statutory regulation, how would the public be protected against poor professional practice?***

- ***If, in addition to statutorily registered practitioners, the s12(1) exemption should remain open to some but not all practitioners who are not on a statutory register, how would the distinction be made in legislation?***

- ***What would the impact be on statutorily registered practitioners of permitting some or all non registered practitioners to continue to prepare herbal remedies without a licence under s12(1)?***

- ***What would the impact be of restricting s12(1) to practitioners on a statutory***

register? Is your organisation in a position to quantify how many actual s12(1) users there are (as opposed to the likely larger numbers that may make use of herbal products/herbal ingredients) in any of the categories identified at para 13. Are you aware of any other comparable categories of operators not covered at para 13, and the extent of their usage of s12(1)?

- ***Where there are trained and experienced practitioners from CAM therapies besides herbal medicine who regularly use s12(1) and operate to acceptable professional standards are there overriding reasons why they should not be expected to join the proposed statutory register if they wish to continue to operate under the s12(1) exemption?***

- ***Good regulatory systems should promote proportionality, accountability, consistency, transparency and targeting in regulation. What, overall, would the regulatory impact be of (a) restricting benefit of the s12(1) exemption to statutorily registered practitioners (b) of any alternative approach that you may advocate?***

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