Royal Pharmaceutical Society
of Great Britain

Helping pharmacists achieve excellence

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Dear Caroline

Re: Reforms of Section 12(1) of the Medicines Act

Please find attached the Royal Pharmaceutical Society of Great Britain (RPSGB) response to the above consultation.

The RPSGB is the professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians on a voluntary basis, a role that is expected to become statutory under new legislation soon. The primary objectives of the RPSGB are to lead, regulate, develop and represent the profession of pharmacy.

Should you require further clarification on any of the points raised in this response please do not hesitate to contact me.

Yours sincerely

Lynsey Balmer

Head of Professional Ethics

Reforms of section 12(1) of the Medicines Act –RPSGB Response to MHRA Discussion Papers

Introduction

The Royal Pharmaceutical Society of Great Britain (RPSGB) is the professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians on a voluntary basis, which is expected to become statutory under new legislation soon. The primary objectives of the RPSGB are to lead, regulate, develop and represent the profession of pharmacy.

The RPSGB has a long held view that there is an absolute need to ensure the quality and safety of herbal remedies and welcomes the opportunity to respond to the proposals outlined in the discussion papers. In the interests of patient safety, safeguards for herbal remedies should be comparable to the existing safeguards for allopathic medicines. It is our view that the preparation and supply of herbal remedies via the arrangements of Section 12(1) of the Medicines Act 1968 need to be under the control of statutory registered professionals. Pharmacists are currently permitted to supply unlicensed herbal remedies under s12(1), provided they have the necessary competence and expertise and comply with relevant professional requirements. As registered professionals, pharmacists are professionally accountable for their actions and are subject to the requirements of the RPSGB Code of Ethics and Standards. This code requires that pharmacists act in the interests of patients and the public at all times, that they have the necessary skills and competence for the tasks they undertake and that they ensure the medicines they supply are of an appropriate quality and suitable for the intended recipient. Failure to comply with the requirements of the Code of Ethics could form the basis of a complaint of professional misconduct and may put a pharmacist's registration at risk. In order to provide adequate public health protection, other practitioners operating under the s12(1) should be subject to comparable regulatory requirements. Robust quality and safety standards, applicable to all registered practitioners wishing to benefit from s12(1), should also be developed to ensure consistency of standards and protect public safety.

The RPSGB's views on the issues raised in the 8 discussion papers are detailed below.

Discussion Paper 1: Overview

What is your current assessment of the case for regulation?
The RPSGB agrees that there is a need to strengthen section 12(1) of the Medicines Act 1968 and its associated provisions. The public must be assured of the quality and safety of unlicensed herbal medicines prepared under s12(1) arrangements. Examples of the weaknesses in the current provisions and resulting risks to public health are clearly articulated in discussion paper 1. However, a consolidated body of evidence would further strengthen and substantiate the case for regulation.

In order to protect the public the RPSGB firmly believes this is a matter for statutory, not voluntary regulation. Individuals operating under s12(1) need to have the relevant qualifications or experience, have current competence, be professionally accountable for their actions and be required to adhere to robust quality and safety standards. Fundamental reform of the current regulatory framework is necessary to achieve this.

Do you agree on the central importance of requiring systematic professional accountability for those who wish to benefit from the exemption in s12(1)?
It is the view of the RPSGB that all those who wish to benefit from the exemption in s12(1) should be professionally accountable and subject to statutory regulation. As highlighted in

discussion paper 1, practitioners operating under s12(1) are exercising a judgement about the health needs of an individual patient and then preparing an unlicensed herbal medicine to meet those needs. The competence and professionalism of the practitioner is therefore as important as the quality and safety of the product they supply. It is essential that practitioners are aware of and work within the limits of their competence. It is also vital that practitioners give due consideration to whether the patient's condition may require treatment with an allopathic medicine and whether the herbal medicine they intend to supply could interact with any allopathic medicines the patient may be taking.

There needs to be an effective means of not only ensuring that practitioners have the necessary qualifications, adhere to required quality and safety standards and work within there sphere of competence, but also of ensuring that appropriate action is taken to protect the public if practitioners fall below the standards expected of them.

Do you agree that the best overall approach to improving s12(1) would be through a combination of updated legislation and agreement with professional codes of practice?
The RPSGB agrees that this combined approach is the most appropriate course of action if public health is to be adequately protected and consider such an approach to be in accordance with the principles of *Better Regulation*. The alternative approach outlined in discussion paper 1 (limited improvements to medicine legislation and voluntary arrangements to be regulated and comply to a code of practice) would not provide the necessary public health assurances that all those operating under s12(1) are professionally accountable and have the required qualifications and competence for the activities they undertake. Professional codes of practice would also provide a framework in which best practice improvements would be effectively disseminated.

Discussion Paper 2: Who should be allowed to operate under s12(1)

Do you agree with the central importance of giving the public assurance as to the professional expertise and accountability of the practitioner?
It is the RPSGB view that the public should be assured of the professional expertise and professional accountability of all practitioners who supply unlicensed herbal remedies under the s12(1) exemption. In order to adequately protect public health and ensure high standards of quality and safety, practitioners operating under s12(1) should be subject to statutory registration either as a registered herbal practitioner, or as a member of another statutory regulated healthcare profession (e.g. pharmacy), and should have the appropriate experience, training and competence for the tasks they undertake. It will be important to ensure consistency of standards between registered herbal practitioners and other regulated healthcare professionals operating under the s12(1) exemption and there will need to be adequate arrangements in place to ensure compliance with relevant codes of practice.

Registered pharmacists are currently permitted to supply unlicensed herbal remedies under s12(1), provided they have the necessary competence and expertise and comply with relevant professional requirements. The discussion paper suggests that dual registration could be one way of enabling members of other statutory regulated healthcare professions such as pharmacy, who also practise herbal medicine, to benefit from the s12(1) exemption. An alternative to this might be specialist annotation on an existing register. A requirement for dual registration would be of concern to the RPSGB. It is our opinion that pharmacists who have the necessary training and competence should be explicitly permitted to continue to operate under the reformed s12(1) provisions, without needing to also register as a herbal practitioner, and that any powers given to herbalists through proposed changes should also be given to pharmacists.

The recent Government White Paper on professional regulation *Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century*, warns against dual registration which would be costly and bureaucratic. The White Paper states that:

'Where a health professional joins a new regulated profession from within an existing regulated profession, it might be possible for them to remain registered with their existing regulator, in a system of distributed regulation, to avoid costly dual regulation.' **(Section 34, page 11)**

and that

'…the Government recognises that many professionals feel a degree of loyalty to the profession in which they were first regulated. The Government will therefore explore the practicality of a system of distributed regulation, including its relationship to revalidation, in which a lead regulator will regulate a new profession and register most of its practitioners, including direct entrants.' **(Section 7.18, page 86)**

The RPSGB therefore propose that future provisions for those who can operate under the s12(1) exemption should require individuals to be statutory registered practitioners, but not be restricted to statutory registered herbal practitioners.

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?
As stated above, the RPSGB believe that in order to adequately protect public health and ensure high standards of quality and safety, practitioners operating under s12(1) should be subject to statutory registration either as a registered herbal practitioner, or as a member of another statutory regulated healthcare profession (e.g. pharmacy), and should have appropriate experience and training for the tasks they undertake.

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?
The RPSGB does not support the view that practitioners who are not on a statutory register should be able to prepare unlicensed herbal remedies under the s12(1) exemption. It is difficult to justify from a public health protection perspective that practitioners who do not have the necessary qualifications or competence to join a statutory register should still be able to operate under the s12(1) exemption.

What would the impact be on statutory registered practitioners of permitting some or all non-registered practitioners to continue to prepare herbal remedies without a licence under s12(1)?
Allowing practitioners who are not statutorily registered to continue to prepare unlicensed herbal remedies under s12(1) will leave those individuals who chose not to, or are not able to, join a statutory register free to operate to lower standards with no form of redress. This risks undermining the steps being taken to secure higher standards, fails to assure adequate public health protection and may damage public confidence in all herbal practitioners.

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)?
As pharmacists are currently subject to statutory registration, requiring practitioners operating under s12(1) to be either a registered herbal practitioner, or a member of another statutory regulated healthcare profession would not have direct adverse implications for the pharmacy

profession. However, the RPSGB recognises that there will be far greater implications for other groups of practitioners and appropriate transitional arrangements will be required.

A requirement that existing registered healthcare professionals, such as pharmacists, would need to also be on a statutory register of herbal practitioners in order to benefit from the s12(1) exemption would impact on pharmacists who currently operate under this exemption. The full impact of such a requirement is difficult to determine without further information about the intended proposals for statutory registration of the herbal medicine profession. As stated earlier, the RPSGB would not support a move towards dual registration and find this inconsistent with the conclusions of the recent White Paper on healthcare professional regulation.

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?
As stated previously the RPSGB supports the view that practitioners who are not subject to some form of statutory registration should not be able to prepare unlicensed herbal remedies under the s12(1) exemption. Dual registration should not be required if a CAM register with specialist annotation already exists.

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?
The RPSGB considers the proposed approach for reforming s12(1) to be in accordance with the principles of *Better Regulation*. However, there will need to be appropriate transitional arrangements in place and the regulatory systems for herbal practitioners and other statutory registered health professional operating under the s12(1) will need to be consistent.

Discussion Paper 3: Safety issues
Overall assessment- feedback 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
The RPSGB supports the overall approach to safety and believes, for the reasons outlined in the discussion paper, that requiring all practitioners operating under s12(1) to be registered and professionally accountable is of central importance to improving safety.

Control of toxic/potent ingredients- feedback 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
In order to assure public health protection it is essential that there are robust mechanisms for controlling the use of specific toxic, or potent herbal ingredients. As the type and range of restrictions will be constantly evolving, the process needs to be manageable and the procedures for identifying which ingredients are to be restricted or avoided needs to be evidence based. Furthermore, due consideration should be given to sale of herbal ingredients to athletes which could compromise test results in competitive sport.

Agreements with the herbal medicine profession, and other professions recognised as competent in the practice of herbal medicine, has the potential to provide a more flexible basis for identifying and keeping up to date the range of herbal ingredients whose use should be restricted or avoided. However, robust statutory regulation and disciplinary sanctions will be essential if this option is to ensure the same safeguards as legislative based restrictions. A mixture of both legislative restrictions and professional guidance is likely to be the most

effective long term option, but there may need to be a greater reliance on legislative restrictions initially while systems for registering and regulating herbal practitioners are developed and refined.

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*

There are merits in developing a formulary of herbal ingredients for the reasons identified in the discussion paper, especially during the development stages of regulating herbal medicine practitioners. However, procedures would need to ensure any such formulary was relevant, comprehensive and regularly reviewed. *The British Pharmacopoeia* has a historical background in herbal monographs and this is an important resource to build on. Developing a formulary would be a good mechanism by which a new regulatory body might demonstrate its authority and expertise.

Discussion Paper 4- Quality Standards

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

The RPSGB supports the need to introduce specific quality requirements for the preparation of unlicensed herbal medicines under s12(1) and believes that this is key to ensuring consistency of standards and providing public health protection. As highlighted in the discussion document, the current RPSGB Code of Ethics and Standards details specific professional requirements for pharmacists who engage in extemporaneous preparation or compounding of medicines under s10 of the Medicines Act 1698. The RPSGB is currently in the process of developing a new standards document for pharmacists undertaking s10 activities and proposes that comparable standards for the preparation of unlicensed herbal remedies should be developed. It will be essential that registered herbal practitioners and other statutorily registered healthcare professionals operating under s12(1) work to equivalent standards.

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?

Setting out quality requirements in a code of practice will enable specific areas of concern to be addressed in greater depth than can be effectively managed in legislation. It will also provide a more flexible basis for updating requirements in response to changing practices or new concerns. However, in order to ensure public health protection, there will need to be robust and consistent means of monitoring compliance with the code and of imposing appropriate sanctions where there is a failure to comply. The code of practice will need to be applicable to all registered practitioners involved in s12(1) activities and will need to be developed in conjunction with all the relevant regulatory organisations.

The RPSGB propose that the most appropriate course of action would be a combined approach. There should be an overarching legislative requirement to ensure safe, effective systems and comply with relevant quality standards when preparing unlicensed herbal remedies. The details of these quality requirements could then be detailed in a code of practice which all practitioners operating under s12(1) have a professional responsibility to comply with.

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?
The RPSGB does not support s12(1) remaining open to some or all practitioners who are not subject to statutory regulation (see response to discussion paper 2).

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?
The RPSGB agrees that processed ingredients used in the preparation on s12(1) herbal medicines should meet GMP standards. The purpose of these reforms is to protect the public and an effective quality assurance scheme for ingredients is central to ensuring the quality of herbal products. The GMP scheme for herbal ingredients should be developed through discussions with relevant stakeholders. The requirement for ingredients to meet GMP standards should be a legislative requirement.

Discussion Paper 5: The requirement for face-to-face consultation
The way in which patients access and receive healthcare is continually evolving. In response to this, both the medical and pharmacy professions have developed robust guidance for the remote prescribing and supply of medicines in order to ensure that patients receive the same high standards of care and advice that they would during a face-to-face consultation.

The on-line supply of allopathic medicines has been a particular area of growth in recent years. While the on-line supply of medicines can offer a number of benefits to patients, particularly in terms of convenience, there are also risks which need to be addressed. For example, the large number of illegal internet suppliers and the difficulty members of the public have identifying whether they are obtaining services from a bona fide health professional or an unqualified commercial operator are specific concerns for the RPSGB.

Similar issues would arise if the current requirement for face-to-face consultation when preparing supplying unlicensed medicines under s12(1) were to be removed. All practitioners operating under this exemption would need to be subject to robust professional requirements that are comparable to those currently in place for the medical and pharmacy professions. Consideration would also need to be given to how illegal operators looking to bypass regulatory requirements would be managed. The RPSGB notes the concerns about removing the current requirement for face-to-face consultations and agrees that it would be prudent to proceed with caution in this matter until a registered herbal medicine profession is better established.

Discussion Paper 6- The regulation of unlicensed herbal medicines commissioned by a registered practitioner from a third party to meet the needs of individual patient.
The RPSGB agrees that the commissioning of unlicensed herbal remedies from a third party by a registered practitioner, to meet the needs of individual patients, should be appropriately regulated in order to ensure that the commissioned product meets the necessary quality standards and does not present a risk to patient safety. A system comparable to the existing 'specials' scheme for allopathic medicines should be considered. The ideas presented in the discussion paper should act as the basis of future discussions on arrangements for registered herbalists, and other appropriately competent registered healthcare professionals, to commission herbal medicines from a 3rd party. To ensure overall coherence of regulatory arrangements, requirements
will need to take account of the existing specials scheme and the developments on professional regulation. The RPSGB would wish to be involved in future discussions about these arrangements.

Discussion Paper 7- Possible extension to non-herbal ingredients

For the reasons of public health protection identified in the discussion paper, the RPSGB has some doubts about authorising registered practitioners to provide non-herbal traditional medicines under a s12(1) arrangement. Further to our point on safety issues (Discussion Paper 3), practitioners should be aware of the consequences of providing remedies to athletes participating in competitive sports. We would however, see merit in involving an advisory professional group to look at some remedies on a case-by-case basis and give more detailed consideration to how the principles outlined in the discussion document could be implemented in practice whilst adequately protecting public health. This group should include herbalists, pharmacists and lay persons.

Discussion Paper 8- Timing and transitional protection

Are there additional issues concerning transitional protection that the MHRA should bear in mind?

The RPSGB suggests that the issue of transitional protection should be revisited once discussions on the statutory regulation of the herbal medicine profession and the s12(1) reforms are further advanced. Prior to statutory regulation, transitional arrangements should require professionals to observe existing regulatory standards.

Do you agree with the anaylsis of this paper? If not, what are your views and why?

The RPSGB agrees that the timetable for the s12(1) reforms should take account of the timetable and arrangements for the proposed register of herbal practitioners. The changes should be introduced at the same time as the herbal practitioner register opens and transitional arrangements should be in place to allow practitioners sufficient opportunity to join statutory regulation.

Do you agree that if there are to be restrictions under s12(1) reforms they would need to apply equally to new and existing operators?

The RPSGB agrees that the restrictions under s12(1) reform should apply to all new and existing statutory registered practitioners.