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MHRA
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16 February 2011

Dear Medicines and Healthcare Products Regulatory Agency,

Re: Review of Medicines Act 1968: informal consultation on issues relating to the PLR regime and homeopathy.

The Royal Pharmaceutical Society (RPS) is pleased to be able to comment on the informal consultation on issues relating to the product licences of right regime and homeopathy. The RPS is the professional body for pharmacists in Great Britain. We are the only body that represents all sectors of pharmacy in Great Britain. The RPS leads and supports the development of the pharmacy profession including the advancement of science, practice, education and knowledge of pharmacy. In addition, we promote the profession's policies and views to a range of external stakeholders in a number of different forums.

Response to Consultation

In responding to this informal consultation, RPS has provided some general comments together with more detailed comments on specific sections.

General Comments

The RPS believes that:-

- All products described as medicines should meet standards for quality, safety and efficacy to permit a Marketing Authorisation to be issued for the product; efficacy should be determined through randomised controlled trials.

- All products making any claims for efficacy through listing indications on the label should be required to demonstrate this through currently accepted methodologies.

- The extent of the evidence required to demonstrate efficacy should be the same for all types of products.

- If homeopathic products are not required to provide the same level of evidence for efficacy as conventional medicines, they should not be called medicines.

- Homeopathic products must only be used for the treatment of minor, self limiting conditions. Any indications for homeopathic products for serious conditions permitted through the PLR system must be removed.

- The MHRA should not continue to license homeopathic products. If homeopathic products continue to be licensed by the MHRA as a result of European Legislation, this should be done only on the basis of quality and safety i.e. the Simplified Scheme. Homeopathic products that wish to make claims for

indications should require the submission of applications for full Marketing Authorisations and the National Rules Scheme should be withdrawn.

Specific Comments

- Section 8 – RPS agrees that as it is 40 years since the Medicines Act (1971) was introduced, there is no longer any reason why PLRs should persist. Any products still licensed through the PLR scheme should either be removed from the market, or additional data provided to support a Marketing Authorisation.

- Section 11 – The legislation surrounding traditional herbal medicines allows minor indications to be based on evidence of traditional use. However, a registration would be refused if efficacy is not plausible. RPS believes that, if the licensing of homeopathic products is to continue, such an approach should also be applied to homeopathic products, and that registrations be refused if efficacy is not plausible.

- Section 14 – RPS does not believe the MHRA should license homeopathic products. While supporting MHRA's intention to end the PLR scheme by April 2013, if the licensing of homeopathic products is to continue, RPS disagrees with the suggestion that no fee should be charged when transferring homeopathic products to a new regulatory category. RPS considers that the companies involved should be required to pay the normal fees applicable, or at the very least meet the direct costs associated with any transfer to a new licensing scheme. As RPS does not believe the evidence exists to support indications for homeopathic products, it is our view that products should be transferred to the Simplified Scheme.

- Section 15 – RPS agrees that Bach flower remedies should no longer be regulated as medicines.

- Section 17 – It is the view of RPS that only efficacious medicines should be used to treat serious medical conditions. Assuming that the MHRA continues to license homeopathic products, RPS does accept the concept of injections (anthroposophic or otherwise) being licensed under any of the schemes proposed for homeopathic products. Parenteral products should be subject to full Marketing Authorisations.

- Section 21 – It is RPS's opinion that the concept that some products can avoid the various licensing processes (Marketing Authorisation; National Rules Scheme; Simplified Scheme) and be prescribed as a "Special" should not be adopted.

- Section 23 - RPS does not accept the idea of "efficacy accepted within homeopathic practice". There is no robust clinical trial evidence to support the clinical efficacy of homeopathy beyond the placebo effect.

- Sections 24, 25 and 26 – RPS believes that to be described as a medicine, a product must provide robust evidence of quality, safety and efficacy. RPS does not accept the idea of use within the homeopathic tradition or homeopathic provings as a means of demonstrating efficacy. In addition, describing a homeopathic product as a medicine may be viewed by a patient as providing efficacious medicinal actions which they clearly do not. If the MHRA is to continue to license homeopathic products, RPS would request that the term "medicinal" is removed from the wordings used on labels, patient information leaflets, and outer packaging that are described in 24, 25, and 26.

- Section 25 - RPS accepts that there needs to be greater clarity around the status of homeopathic products and their composition to enable patients to make informed choices about their healthcare. While the new more explicit form of wording given in the consultation paper is considered to be an improvement, RPS believes that if the licensing of homeopathic products is to continue patients

should also be informed that homeopathic products will contain no (30C products), or very few (6C products), molecules of active ingredient.

- Section 26 – In addition to the proposed wording, RPS believes patients should be informed of the lack of published data to support the efficacy of homeopathic products and to alert patients that an assessment of efficacy is not carried out in the same way as conventional medicines. If homeopathic products are to continue to be licensed by the MHRA, in RPS's opinion, labels on homeopathic products must make it explicit that there is no evidence beyond the placebo effect. RPS suggests wordings such as "There is no evidence to support the clinical efficacy of homeopathic products beyond a placebo effect" and "Any claims of efficacy made for homeopathic products are not based on the same stringent testing requirements applied to conventional medicines" are included on the labels of homeopathic products.

- Sections 27-33 – RPS supports the proposal that The Non-Orthodox Practitioner (NOP) scheme should be abolished. However, if any non-orthodox practitioners continue to manipulate medicinal products for administration to patients, controls must be put in place to ensure they have the necessary expertise and training. Even although the patient consents to the treatment and the medicines have general sales list status, this is a patient safety issue.

Yours sincerely

Catherine Duggan
Director of Professional Development and Support

Review of Medicines Act 1968: informal consultation on issues relating to the PLR regime and homeopathy

Introduction

1. The consolidation and review of the UK medicines legislation (including the Medicines Act 1968) provides an opportunity to address anomalous, outdated or unnecessarily complex elements of UK medicines legislation.

2. This informal consultation paper sets out MHRA's provisional ideas that particularly impact on the regulation of product licences of right (PLRs) and homeopathic medicines. In the light of responses received we will develop and adjust our proposals as necessary and then set out updated proposals in a formal public consultation.

3. This initial informal consultation will provide an opportunity for MHRA to have dialogue with those most affected in order to establish better information about likely regulatory impact and any implications not so far identified.

4. Our starting point is the Government's response in July 2010 to the report on homeopathy published earlier in that year by the House of Commons Science and Technology Select Committee. The Government made clear its obligations in European legislation to regulate homeopathic medicines; said that action to bring eligible homeopathic PLRs within one of the relevant regulatory schemes would continue; that outstanding issues concerning the future of PLRs would be addressed within the project to consolidate the Medicines Act; and undertook that the MHRA would further clarify the position as regards efficacy of homeopathic products licensed under the national rules scheme.

5. In commenting on the proposals, if possible, please include an estimate of any cost and administrative impact (whether negative or positive) that the proposals would have.

6. Comments should be sent either by post to Andrea Farmer in Area 5M, 151 Buckingham Palace Road, London, SW1W 9SZ or by email (andrea.farmer@mhra.gsi.gov.uk) to arrive by 18th February 2011.

7. To help informed debate on the issues raised by this consultation exercise, and within the terms of the Freedom of Information Act, the Agency intends to make copies of comments received publicly available. Unless you state otherwise we will assume that you have no objections to your comments being publicly available on the Agency's website.

MHRA's draft proposals

Product Licences of Right (PLRs)

8. PLRs were issued to all medicinal products, including homeopathics, on the market at the time the Medicines Act was implemented (1971). Most categories of medicine (but not homeopathic medicines) were subsequently reviewed by the early 1990s and products were granted a full product licence or the PLR was revoked.

9. In contrast to the position with other medicines, EU Member States are not legally required to ensure that certain homeopathic products conform to the requirements of the Directive 2001/83/EC – the principal European legislation regulating medicines placed on the market. This flexibility to maintain national arrangements applies only in limited circumstances: where products meet the European definition of a homeopathic medicinal product and were granted a registration or authorisation in accordance with national legislation before the end of 1993. For this purpose the definition of a homeopathic medicinal product set out in Directive 2001/83/EC is:

   "Any medicinal product prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopeia or, in the absence thereof, by the pharmacopoeias currently used officially in the Member States. A homeopathic medicinal product may contain a number of principles."

10. The number of PLRs has fallen over time and there are now somewhat under 500 remaining.

11. There are currently five forms of product authorisation potentially available to products under consideration:

    - Product licences of right (PLRs); these have indications, which in some cases are for serious conditions
    - Simplified scheme – this scheme, introduced in 1992, is required by European legislation. It is restricted to homeopathic products for oral or external use; under this scheme products are supplied without indications
    - National rules scheme (NRS) – this scheme was introduced in 2006 and allows homeopathic products to be indicated for the relief of mild, self-limiting conditions
    - Traditional herbal registration (THR) – this is open to traditional herbal medicines suitable for use without medical supervision. Minor indications are based on evidence of traditional use; registration should however be refused if efficacy is not plausible
    - Marketing authorisation (MA) – available to homeopathic and anthroposophic products on the same basis as for any other medicinal product, requiring evidence of safety, quality and efficacy of the product.

12. The MHRA considers that it would be undesirable to use the current review of the Medicines Act and associated legislation to further perpetuate the existence of PLRs. This kind of licence, by its nature is envisaged as a pragmatic, temporary arrangement until products are reviewed and, where appropriate, moved to an ongoing regulatory scheme where they meet the relevant standards. It is highly desirable that product licensing schemes

should reflect current regulatory standards and not represent a hangover provision from a number of decades ago. The review of the Medicines Act provides a suitable opportunity to bring the PLR arrangement to a close. This would also have the benefit for homeopathic products of achieving improved consistency of regulatory provision for labelling and advertising. This will better enable MHRA to regulate the market for these products. Improved patient information will benefit the consumer and facilitate informed choice.

13. Set out below are proposals for how the various products that currently hold PLRs might sit elsewhere in the regulatory framework.

Homeopathic medicines with PLRs

14. Many products with a PLR will fit into one or other of the two licensing schemes specifically intended for homeopathic products. As a result of earlier discussions, companies concerned are already expecting this transfer to occur. We propose that it would be realistic to complete this process by April 2013. Given that products are moving from one regulatory category to another the MHRA would propose not to charge the normal fees that would otherwise be payable for licensing applications under the NRS or the simplified scheme.

Flower remedies with PLRs

15. A number of PLRs are for Bach flower remedies. MHRA intends to take the position, against the criteria set down in European legislation, that such products should normally no longer be regulated as medicines. Indeed there are many Bach flower remedies on the UK market, (and we understand on the markets of other EU Member States) that are legally supplied under other regulatory categories, such as food supplements. This change would represent a useful simplification and create a more level playing field for suppliers of this kind of product.

Other medicines with PLRs (including anthroposophics)

16. There are likely to be a number of other PLRs that would not transfer readily to either of the existing homeopathic product licensing schemes. This is likely to be because either the product does not meet the 2001/83/EC Directive definition of a homeopathic product (see above) or it does meet that definition but does not come within the scope of the two existing homeopathic schemes. It is possible that other forms of product licence might be available, notably the option of a marketing authorisation based on demonstration of safety, quality and efficacy. However, if these options are not pursued there is the possibility of supply as an unlicensed medicine (see para 17 below) where a clinician judges that the patient has a special clinical need.

17. A particular issue with the outstanding PLRs is anthroposophic medicines. Some of these may well meet the definition of a homeopathic product but are injectable products, intended for use in serious conditions. The NRS does not require demonstration of efficacy to the normal standards required for a marketing authorisation, and it was not developed in order to licence products

intended for use in serious conditions - hence the current limitation of the scheme to minor indications. The current scheme is open in principle to all pharmaceutical dosage forms, but given the purpose of the scheme it is relatively unlikely that an application under the NRS for an injectable product would be successful.

18. Given the absence of a requirement to demonstrate efficacy to the normal standards the MHRA does not consider that it would be desirable to extend the scope of the NRS to cover products intended for use in serious conditions. For the same reason we do not favour an extension of the scheme to products known to be used in serious conditions but so that they were licensed without written indications. The original purpose of the NRS was for the regulation of homeopathic products intended for minor, self limiting conditions and we consider that the scheme should be limited to this type of product.

19. Anthroposophic products are typically prescribed by a number of doctors (which MHRA understands to be relatively few in number) who practise in the anthroposophic tradition. Existing UK regulatory arrangements already accommodate the situation whereby an independent prescriber (currently a doctor, dentist, nurse or pharmacist independent prescriber) or a supplementary prescriber acting within the terms of a clinical management plan takes the view that there is not a suitable licensed product available to meet their individual patient's special clinical needs. An unlicensed "special" can be commissioned. A key feature of this scheme is that the clinician takes personal responsibility for the suitability of the product for their individual patient. In the absence of a specific European regulatory scheme for anthroposophic products, this regulatory arrangement would seem suitable where an anthroposophic product is prescribed for an individual patient's use, to meet their special clinical needs, by an independent or supplementary prescriber. In effect, the normal arrangements would apply here as for other types of product supplied as "specials".

20. It should be noted that the UK does not have powers to create schemes of simplified/modified product licensing for medicines that come within the scope of the main European medicines Directive (2001/83/EC), except where specifically required or permitted in European legislation.

21. MHRA intends to have informal dialogue with individual companies affected. This should mean, if the proposals are pursued through subsequent formal consultation, that we should be able to give a broad indication of numbers: how many PLRs would be taken out of medicines regulation; how many would be eligible to transfer to one of the newer homeopathic schemes; and how many (in the absence of a marketing authorisation) could be supplied as unlicensed "specials" subject to a judgement by a doctor or other appropriately authorised healthcare professional that the medicine is necessary to meet the special clinical needs of their individual patients.

Information for patients under the national rules scheme

22. The report of the Science and Technology Select Committee raised a concern as to whether the product information under the NRS is sufficiently clear about the basis on which the product has been licensed.

23. In response the Government said:

"The MHRA will review the labelling requirements under the NRS to ensure that these deliver clarity as to the status of products and their composition.

MHRA registration of products under appropriate regulatory schemes does not imply that the regulator is endorsing homeopathic products. As stated above, the MHRA is reviewing product labelling requirements and elements of the guidance to ensure there is greater clarity on the position concerning efficacy as accepted within homeopathic practice."

24. The form of wording currently used on the labelling and in the accompanying patient information leaflet under the NRS is

"*A homeopathic medicinal product used within the homeopathic tradition for the symptomatic relief of ....*"

25. MHRA considers there is scope for this information to be made more specific, particularly for the benefit of those consumers who may be less familiar with the nature of homeopathy. We propose the following more explicit form of wording should be used, on the outer packaging and patient information leaflet:

"A homeopathic medicinal product licensed only on the basis of safety, quality and use within the homeopathic tradition"

26. Information about indications would read:

"A homeopathic medicinal product used within the homeopathic tradition for the symptomatic relief of..... "

The Non Orthodox Practitioner scheme

27. The requirements of the Non Orthodox Practitioners (NOPs) scheme are set out primarily in Article 2 of The Medicines (Exemptions from Licences) (Special and Transitional Cases) Order 1971 (SI 1971/1450). MHRA's Guidance Note 13 explains the arrangement.

28. In summary, a NOP may be anyone other than a registered doctor, dentist or pharmacist. The exemption permits the NOP to mix and assemble medicines without needing a product licence. The NOP must hold a manufacturer's licence authorising mix and assembly of medicinal products. The products mixed/assembled must be of general sales list status, (ie not a prescription only medicine or one restricted to pharmacy supply). The products used in mixing/assembly must be licensed or registered (unless themselves exempt). There is a requirement for a face to face consultation with the NOP and a

request for exercise of judgement as to the treatment needed. The product must not be advertised. Records have to be kept for 5 years. There is no requirement that the NOP has any particular skills or experience.

29. There are around 220 NOP licences. A licence application costs £457 and an associated inspection £287. Few new applications have been received for some years. No charged for inspections have been carried out under the scheme for some years and historically in practice no other checks have been carried out, either before or after a licence is granted, to check that the NOP meets the requirements of the scheme.

30. An MHRA survey of all NOPs licence holders in 2008, which elicited 30 substantive responses, suggested that the scheme is used predominantly by homeopaths. 16 respondents were homeopaths (half of whom also practised other therapies, whether in orthodox or complementary medicine). The next largest group were trichologists (5).

31. In the MHRA's view the NOP scheme serves little, if any, useful public health purpose. The virtual absence of any new licences granted in recent years suggests that the scheme is, for practical purpose, moribund. Our proposal therefore is that this scheme should be abolished, thereby achieving a useful simplification in regulation and legislation. Nonetheless, this informal consultation provides an opportunity to look at any implications arising.

32. Although the number of people actively using the NOP scheme may well be small it is important to consider the regulatory impact of abolition. The MHRA would particularly welcome input from anyone who actively uses the NOP scheme *and* who can describe their activity and in specific terms how it meets the requirements of the scheme, and what would be the consequence if the scheme were not to exist.

33. Potentially the NOP scheme would be ended at April 2012, but this would clearly depend on the outcome of consultation.

Summary of proposals

- Legislative provision for PLRs should be ended by April 2013

- Eligible PLRs should transfer to one of the newer regulatory schemes for homeopathic medicines; the MHRA would not charge for applications where this transfer was taking place

- Bach flower remedies should normally no longer be regulated as medicinal products

- Where a PLR was not eligible for any of the other forms of modified licensing regimes it would be open to independent and supplementary prescribers on their personal responsibility to commission an unlicensed "special" to meet the special clinical needs of a patient

- NRS products should include the following additional statement on outer packaging and the patient information leaflet: "*A homeopathic medicinal product licensed only on the basis of safety, quality and use within the homeopathic tradition*"

- The NOP scheme should be abolished, possibly by April 2012.

MHRA Policy Division
January 2011