Reforms of s12(1) of the Medicines Act 1968: issues concerning timing and transitional protection

Introduction

1. This informal discussion paper is one of a series prepared by the Medicines and Healthcare products Regulatory Agency (MHRA) which explores possible reforms of section 12(1) of the Medicines Act 1968 and its associated provisions. S12(1) is the legislative provision used by herbal practitioners, and some others, carrying out a business in which they prepare unlicensed herbal medicines to meet the individual needs of patients identified in consultation. The MHRA welcomes dialogue with interested parties on these ideas. The paper is intended to help focus such discussions. The MHRA's expectation is that this work will help prepare the way for a subsequent formal public consultation.

2. This paper raises several issues concerning timetable and transitional protection. At this stage only initial general pointers can be given. Further details will depend on:

   - the specific arrangements for statutory regulation of the herbal medicine profession, as these are further developed
   - further revision and working up of the proposals for reforms of s12(1), as set out in the other informal discussion papers in this series, in the light of dialogue with interested parties.

General principles

3. The MHRA suggests that the following approach for consideration:

   (a) where the s12(1) reform programme may enable registered practitioners to undertake activities not currently permitted under s12(1) and associated provisions:

   - it would be reasonable in principle to aim to introduce the changes in medicines legislation in time to apply either at the same time as the practitioner register opens, or as soon as practicable thereafter

   - it is necessary to bear in mind, however, the various practical considerations that will affect the timetable; there will be a need for consultation on detailed proposals – which in turn may need to await the final arrangements for statutory regulation of the profession; and, depending on the nature of the proposals, legislation and/or professional codes would need to be developed

   - if positive lists are required to be developed (eg of non herbal ingredients permissible for use by registered practitioners) such lists may need to be developed progressively over a period, depending on resources available

(b) if the s12(1) reform programme has the effect of preventing some practitioners undertaking some activities that they can currently legally undertake:

- unless the requirements for protection of public health are overriding it will be desirable to allow practitioners sufficient opportunity to apply to join the statutory regulation. It will therefore be necessary to ensure that the timetable for the s12(1) reforms take account of the timetable and arrangements for establishing the proposed register for herbal practitioners

- the MHRA does not presently consider that it would be realistic to give transitional protection to a limited subset of s12(1) operators, eg those already operating under s12(1) as at defined point in time. This would seem to pose formidable problems of definition and identification. As outlined in the informal discussion paper no 2, those who use the s12(1) exemption do not fall into easily identifiable or homogenous groups and many are likely to be unclear or indeed mistaken as to whether or not they have been using s12(1). Moreover, giving favourable transitional arrangements to existing practitioners could have undesirable consequences, eg in protecting the ability to use s12(1) of a practitioner who had for example been removed from one of the existing voluntary registers for reasons of lack of competence or unprofessional behaviour

- the MHRA is therefore minded to take the view that the timetable for any restrictions under s12(1) reforms should apply equally to existing and new operators

Issues for discussion

4. The MHRA intends to revisit the issue of transitional protection once discussions on both the statutory regulation of the herbal medicine profession and the s12(1) reforms are further advanced.

Issues for discussion

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

- ***Do you agree with the analysis in this paper? If not, what are your views and why?***

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