

1st June 2009

**CONCEPT PAPER ON MHRA PROJECT TO CONSOLIDATE AND REVIEW
UK MEDICINES LEGISLATION**

Summary of the suggestions from stakeholders and note on next steps

We would like to thank our stakeholders for replying so constructively to our call for suggestions for the areas of legislation that require consideration as part of the MHRA's project to consolidate and review UK medicines legislation. A summary of the suggestions is below. We received 38 responses from a range of our stakeholders including: royal colleges, professional bodies, the pharmaceutical industry, NHS bodies and other organisations and individuals.

In the coming months we will explore the options for structuring the new legislation and will continue the process of consolidating current legislation. At the same time we will use your suggestions to develop our thinking around the areas of legislation to review in detail.

We intend to develop firm review proposals during the course of this year and will look to establish regular meetings with our key stakeholder groups in the Autumn to seek views on the issues subject to review. If you would be willing to be involved in further discussions about the proposals, please forward your contact details and area of interest to:

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We will consult again on any firm proposals to change the substance of current legislation. This is likely to take place in early 2010.

Summary of comments

There was widespread support for carrying out the consolidation and review exercise. Stakeholders agree that the current legislation is fragmented and complex and that bringing together the legislation in one place will significantly improve stakeholders' ability to access and understand regulatory requirements. There were some comments on the shape of the future legislation and support for illustrating – perhaps through a table – how current and future legislative provisions relate to one another. There was also support for detailed guidance to sit next to the future legislation.

The vast majority of comments were on the review aspect of the project. There was broad support for reviewing the areas of legislation that were described in Annex D to the Concept Paper. The following provides a flavour of the specific comments received:

Definitions and scope

- Support for reviewing the definitions in the legislation and for exploring whether additional definitions were needed in the legislation (for example, for 'prescription', 'patient specific direction', 'prescribing', 'supply', 'dispensing')

Pharmacy, prescribing and dispensing

- Support for reviewing the pharmacy exemptions in the Medicines Act to ensure they reflect current practice
- Support for reviewing the remote dispensing provisions in the Medicines Act
- Support for greater clarity in the exemption that permits pharmacies to trade stock with one another without a wholesale dealers licence (although concerns about the use of the exemption to undertake unregulated manufacture and onward sale of unlicensed products to other pharmacies)
- Need to ensure that wholesaler dealing arrangements take into account the various relationships under contracts and service level agreements within NHS structures
- Support for distinguishing between requirements for hospital and retail pharmacies
- Support for making dispensing in patient packs mandatory in all UK pharmacies except in exceptional circumstances and for reviewing the provisions around labelling of dispensed medicines
- General support for extending prescribing rights to non-medical professionals and revising restrictions that apply to supplementary prescribers

Legal classification of medicinal products

- Support for continuing the three levels of classification: Prescription Only Medicines (POM), Pharmacy (P) and General Sale List (GSL)

- Question whether POM, P General Sale Exemption Orders are needed and whether provisions could be included in individual marketing authorisations
- POM Order should not be included in the consolidation due to its size and the need for regular update

Herbal and homeopathic products

- Concerns about the impact on Product Licences of Right and the availability of anthroposophic medicines
- Sections 12(1) and 12(2) of the Medicines Act on herbal products are thought to be out of date and concerns that in 2011, when the Directive on Traditional Herbal Medicinal Products comes into force, many herbal products will disappear from the market

Sanctions and enforcement

- Sections 64 and 65 of the Medicines Act should be reviewed to exclude a simple dispensing error from being a criminal offence
- A review on sanctions for transparency, consistency, the terminology used and fitness for purpose
- Support for tightening of powers to permit random inspections and searches to tackle counterfeiting

Other

- Concerns about reliance on and management of Patient Group Directions
- The place of prisons within healthcare legislation should be formalised
- Need to align changes to UK legislation with the forthcoming changes as part of the EU pharmaceuticals package
- Current application of clinical trials legislation is overly bureaucratic
- Continued support for banning of direct to consumer advertising of POMs
- Pharmacovigilance obligations should be proportionate to the product's risk profile