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MHRA
Medicines legislation consolidation and review project
Informal consultation: streamlining and reducing regulatory burdens
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22 December 2010

Royal Pharmaceutical Society Response

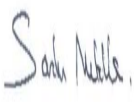
Thank you for asking the Royal Pharmaceutical Society (RPS) to comment on the informal consultation: **Streamlining and reducing regulatory burdens**
The Royal Pharmaceutical Society (RPS) is the new professional body for every pharmacist in Great Britain. We are the only body that represents all sectors of pharmacy in Great Britain.
The RPS leads and supports the development of the pharmacy profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

Its functions and services include:

Leadership, representation and advocacy: promoting the status of the pharmacy profession and ensuring that pharmacy's voice is heard by governments, the media and the public.
Professional development, education and support: helping pharmacists to advance their careers through professional advancement, career advice and guidance on good practice.
Professional networking and publications: creating a series of communication channels to enable pharmacists to discuss areas of common interest.

This section of the response was produced by the Royal Pharmaceutical Society's National Pharmacy Boards (NPBs) for England, Scotland and Wales, and it focuses on professional leadership issues. The NPBs in each country are made up of representatives from all sectors of pharmacy practice, and this response reflects that broad voice.

Yours sincerely,



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The RPS's vision for pharmacy is that pharmacists should be the universally accessible frontline clinical provider of all aspects of pharmaceutical care and be responsible for all aspects of medicines use. Pharmacists aim to be the healthcare professional entrusted by patients to take care of their every pharmaceutical need.

Pharmacists are the experts in medicines – their management, their usage and information about them. Pharmacists can impact at different points on the patient pathway and lead to a reduction in medicines waste, a reduction in unplanned hospital admissions and better medicines adherence resulting in better patient outcomes.

General comments including the response to the proposals in Annex A

Manufacturing and wholesale dealing

1. ***Variations to wholesale dealing and manufacturing licences that could be made without full MHRA consideration***

We believe there is currently an unacceptable administrative burden to the wholesaler dealer and therefore support the suggested changes.

We would further suggest that this change is extended to include minor amendments to Product licences supported by an annual notification system for minor amendments as is currently operated in the USA.

2. Changes to the process of applying for a manufacturing and wholesale dealing licence

No comment

3. Appointing responsible persons- agree with change to align with procedure for varying a licence

No comment

4. Review of licence exemptions for pharmacists under section 10 of the Medicines Act 1968

We would strongly recommend that the section 10 exception for pharmacists, from the need to hold a wholesale dealers licence, is retained. Its inclusion is continually justifiable as it allows for a degree of operational freedom to enable the many small transactions in medicine supply that occur within the course of operating a pharmacy, but retains the overarching legal framework. The prospect of pharmacies routinely having to pay for and comply with the conditions of a wholesale dealing licence would be disproportionate to its safeguarding benefits , and would effectively increase the regulatory burden to pharmacies at a time when Government policy intent is about right touch regulation.

We would however suggest that this review takes the opportunity to clarify the terminology within the exception namely:-

- "The sale constitutes no more than an inconsiderable part of the business." The term is widely interpreted as being no more than 5% of its total medicine trade but this has never been subject to judicial interpretation and a more specific phrase should now be inserted into the legislation.

Proportionate enforcement provisions

5. More flexible administrative penalties for breaches of borderline and advertising provisions, with appeal mechanisms where necessary

The move to a more flexible and proportionate system of sanctions for breaches of borderline and advertising provisions seems appropriate. This must incorporate a formal appeals procedure with appropriate provisions for the offending activity to be prohibited until the outcome of the appeal has been determined. Any sanctions should be suitably punitive in nature to deter the offender from committing the offence or re-offending, with harsher penalties being enforceable for serial transgressions.
In respect to administrative penalties for advertising any proposed changes to the current system should ensure there is a strengthening of arrangements to prevent the misleading of the public taking into account all methods of communications including the, internet, mobile phones, kiosks etc.

6. Proportionate prosecution of dispensing errors

We would strongly ask that the MHRA takes the opportunity of this informal consultation to redress the anomaly that pharmacists face by being the only professionals to be prosecuted for a single dispensing error under the Medicine Act legislation. We would ask that rather than redress this position by amendments to the Act, the Section should be removed in relation to the individual pharmacists.

A single dispensing error being a criminal offence acts as a disincentive to report the error. This leads to a lack of opportunity to collate those errors and feedback common themes to the profession.

The most important aspect of the practice of dispensing errors is for healthcare professionals to learn how such errors occur and how to stop them in future. Learning from errors and being able to put in place such matters as to reduce those errors, leads to an increase in patient safety. Everything should therefore be done to encourage error reporting in the same way that the aircraft industry does this constructively to increase safety.

Only in cases where there is prima facie evidence of criminal negligence manslaughter, as assessed by the police, the HSE and the CPS should criminal action be taken. If there is no such evidence the case should then revert to the General Pharmaceutical Council as the professional regulator

It is imperative that a proportionate response be developed to deal with what are often minor incidents. Where minor errors have occured healthcare professions should be investigated by a body that has the relevant expertise and experience required to understand issues relating to dispensing process .We believe that the public would be better served by genuine errors being managed by the professional regulator who would have the experience to deal proportionately and in the public interest.

A proportionate response from the police and regulator must be introduced to ensure that healthcare professionals are not automatically treated as criminals – until either intent or willful negligence can be proved.

Streamlined administrative processes
7. Streamline panels for reviewing licensing decisions

No comment

8. Dispensing with requirement for Commission for Human Medicines (CHM) advice to refuse marketing authorisation holder initiated variations

No comment

Simplified processes in relation to herbal medicines
9. Medicines not requiring a marketing authorisation

We recognise there is currently a need for interim reforms but believe that this reform should only be viewed as a very short term measure and a decision on regulation of herbal practitioners is sought as a matter of priority.

We would ask that clarity is given on whether homeopathic products and other alternative therapies are included in the advertising sections on the medicine Act .There is a need for adequate control the advertising of herbal and fringe medicines to protect consumers.

10. Aligning the domestic definition of herbal medicine with the definition in Directive 2001/83/EC that was introduced by the Directive on traditional herbal medicinal products (Directive 2004/24/EC)

As per answer to question 9

Labels and leaflets

11. Streamlining statutory warnings for labels and leaflets

We would support any move to simplify, rationalise and standardise warnings and wordings on labels and leaflets. We fully support the need for standardisation of statutory warnings to ensure that consumers are receive a consistent , easy to understand message every time the receive the same product and we would thus oppose to only controlling warnings for labels and leaflets in individual product licences.
Any changes to legislation pertinent to statutory warning labels will have a considerable impact on pharmacies in terms of implementation and thus any changes must have demonstrable safety benefit for patients. It would be advisable to seek advice from health literacy experts prior to legislative change to ensure medicine safety is not compromised.

We would ask for consideration of an exception "*for all dispensed medicines to be accompanied by a patient information leaflet " ,* for certain dispensing situations. Whilst this requirement is appropriate for most of the European countries that supply medicines in original packs/ patient packs, as prepared by the manufacturer, it is difficult to comply with in the UK, where there is no requirement for original pack dispensing. There are many legitimate occasions when non original pack dispensing occurs for instance when medicines are supplied in monitored dosage systems and other patient-specific presentations, daily/ weekly instalment dispensing of drugs likely to be abused eg methadone or for supply of quantities as stated by a practioner which cannot be met from a single patient pack. On these occasions the supply of a PIL is not adding to patient safety but imposing an additional bureaucratic burden on pharmacies.

Prescribing, sale and supply

12. Sale, supply and administration of medicines

Please refer to separate response submitted previously

13. Patient Group Directions

Please refer to separate response submitted previously