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17 January 2012

Dear Mr Fawbert

**Response to the MHRA's consultation on the Consolidation and review of UK medicines legislation (MLX 375).**

The General Pharmaceutical Council is the regulator for pharmacists, pharmacy technicians and registered pharmacy premises in Great Britain. It is our job to protect, promote and maintain the health, safety and wellbeing of patients and the public who use pharmaceutical services in England, Scotland and Wales.

We welcome the opportunity to respond to your consultation on the consolidation and review of UK human medicines legislation.

Whilst the consultation as a whole, and your wider proposals, are of interest to us, we have limited our responses and only provided comments where we feel we have a direct interest in the proposals or where any change may require us to reflect changes in our own regulatory standards or policies. We are happy to continue to contribute to future work in this area.

One of the areas that you have expressed an interest in hearing views on, is whether the draft consolidated regulations are full, accurate and workable.

We broadly support the proposed changes which seek to clarify current legislation and remove obsolete medicines legislation. We also support the incorporation of the majority of medicines legislation into one comprehensive legal instrument, making it easier to refer to, and comply with. This change should be beneficial for healthcare professionals, members of the public and other interested parties who wish, or need, to access medicines legislation.

We note that, in general, the consolidated Regulations are written in plain English, as far as is possible for a medical and technical document. We can see that there has been an increased use of tables within the Regulations which are much more user friendly, clear and understandable than simple text.

Another area that you asked for views on was whether the draft Regulations would introduce any unintended changes

We have not identified any areas, that we are involved in, that have been changed unintentionally and are inconsistent with your stated proposals.

You have also invited comment on whether there were any views on the policy changes outlined

### **Wholesale dealing**

One of the key policy changes contained in this consultation is the repeal of Section 10(7) of the Medicines Act. This part of legislation is currently used by registered pharmacy premises to wholesale stock of licensed medicinal products. This is currently carried out for a variety of reasons which includes providing stock to other healthcare professionals, hospitals, or other pharmacies to meet the needs of patients. The proposed change to repeal section 10(7) therefore has an impact on our work as a regulator of registered pharmacy premises.

As the current provision is not compatible with EU law we understand that you intend to remove this exemption from the legislation. The changes will mean that pharmacies that intend to commercially trade by wholesale, will need to obtain an appropriate licence to allow them to do so.

We support your practical proposals which will maintain patients' access to the medicines they require by allowing the small scale transfer (wholesale) of stock between registered pharmacies and between pharmacies and healthcare professionals in order to directly meet the needs of individual patients and allow healthcare professionals to obtain stock to treat their patients.

As a regulator our primary concern is patient safety. We believe that the wholesale of medicines should be undertaken to an equal and consistent standard, whether by way of an exemption as prescribed by the MHRA, or having obtained an MHRA licence.

We support your proposals to produce guidance and clarify the position in relation to wholesale dealing and to allow particular supplies to be made where this type of supply only occurs occasionally and not for profit, and we look forward to being involved in producing this guidance.

### **Optimisation**

Another significant change is to allow pharmacists to make minor changes to a prescription, (relating primarily to the directions for use), without having to contact the prescriber. Any changes made to the prescription will not go outside the overall timeframe and intention of the original prescription.

We recognise that pharmacists are well placed to use their pharmaceutical knowledge and clinical skills, and exercise their professional judgement, to ensure that the patient receives the best possible outcome from their prescribed medication. Pharmacists will still need to ensure that they only practise within their competence and would need to take our standards into account when providing a professional service such as this.

## Section 64

With respect to Section 64 and the continuing criminal liability for dispensing errors by pharmacists and pharmacy technicians, we thought it may be useful if we set out our position, (whilst we note that this Section is not being amended or consolidated as part of this process).

We believe that the current legal position which criminalises dispensing errors by pharmacy professionals should be reviewed. We are particularly keen to ensure that any clarification supports a culture of openness including a drive to promote reporting of errors so that there is learning and information which can support developments of system and practice. We are prepared to help find an appropriate and workable solution to this important issue.

Our Council has made clear that it is committed to being a modern and proportionate regulator. We have taken significant steps to explain what we mean by this. This includes making it clear that we do not see a single dispensing error as a fitness to practise matter, without any significant aggravating factors (for example an error being part of a trend, or any evidence of intent etc). Underpinning this work are our standards of conduct, ethics and performance as well our [threshold criteria](#) for decision making at the investigating stage.

Yours sincerely



Duncan Rudkin  
Chief Executive & Registrar