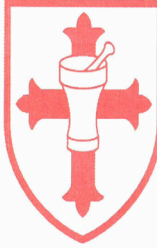

GHP

*Guild of
Healthcare
Pharmacists*



17th January 2012

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Medicines and Healthcare products Regulatory Agency
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Consolidation and review of UK medicines legislation (MLX375)

Response from the Guild of Healthcare Pharmacists

Thank you for the opportunity to respond to this consultation. The Guild of Healthcare Pharmacists (GHP) represents UK wide around 4,000 pharmacists including the majority of hospital pharmacists, pharmacists employed by Primary Care Trusts (PCTs) and pharmacists employed by other public bodies such as the Commission for Social Care Inspection and the Healthcare Commission. The Guild is part of the health sector of the union Unite.

Although we do not intend to respond to the specific questions listed in the consultation document we wish to raise the following issues and concerns:

GHP supports the need to consolidate and review the Medicines Act but it is our contention that this may be insufficient and it may be more appropriate to modernize the law as the original Act was designed for a very different era with very different pharmaceutical practice and with the intention that NHS hospitals would be unaffected due to Crown immunity.

We have specific concerns with the Medicines Act Consolidation that relate to removal of Section 10 subsection (7) the inappropriate repeal and review of which could cause major difficulties in the supply and distribution of medicines to

small NHS and charitable institutions from other NHS hospitals, who are part of a different corporate body as recognized in annex C.

We reserve the right to hold comments on the repeal of Section 10(7) until advice is available on how the MHRA and regulators will implement the changes and how they are expected by those organizations to impact on current and future practice. Until that advice is in provided we would prefer option 2. This area caused major problems due to the lack of fitness for purpose legislation during the implementation of the Responsible Pharmacist that had to be address by specific advice. We played a major part in that advice and we are willing to work with regulators again to deliver appropriate advice for our members to ensure confidence in any proposed changes.

Our other concerns relate to the strict liability and inappropriate application of section 64 in particular along with sections 58 and 85 and we remain unconvinced that this will be addressed by due diligence changes. Our preferred suggestion for Section 64 is either limiting it to adulteration as was intended in the source of the section in the 1955 Food Act or if not possible removing the section from the Act as part of this consolidation. The criminal law already prohibits acts that unlawfully and maliciously (intentionally or recklessly) cause someone to take a noxious thing thereby endangering their lives and this requires the burden of proof to be with the prosecutor not the defendant.

Other minor points we would raise would be

We support the proposal to remove the requirement to dispense certain medicinal products in fluted bottles.

We have no major concerns on the proposal to remove statutory warning from OTC products and rely on marketing authorizations provided consistency can be ensured through this route.

It is our view that the appropriate supply of medicines to research organizations can be left to professional discretion and control.

Many hospital pharmacists prefer the use of the term preparation for exemptions under section 10 and manufacturing for licensing activities we see no reason or advantages to remove the term preparation, which clarifies different activities

We support the clarification in relation to Adrenaline for the purposes of saving a life.

We would support and expand the options on water for injections for purposes other than parenteral administration to a wider range of diluents especially when required for the preparation and administration of a prescribed product.

We would wish to see the general structure and requirements of PGDs retained in their current form and the restriction of their use to registered health professionals. We would support amending the provisions to supply medicines to enable NHS bodies to supply medicines under directions written by nurse, pharmacist or optometrist independent prescribers and although we can see the advantage in terms of access by allowing dental practices and clinics to supply or administer medicines under PGDs but we are unconvinced on the need to extend the sales of medicines into these areas.

We fully support the change to improve the optimization of medicines by pharmacists as in practice this already routinely happens in hospital but we would seek to also enable the modification of the quantity to ensure appropriate treatment with appropriate information and updating of records.

We hope these comments are of assistance

Our reply may be made freely available.

Yours faithfully

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