



22nd December 2010

Natasha Barnes
MHRA,
151 Buckingham Palace Road,
London
SW1W 9SZ

Dear Ms Barnes

**Medicines legislation consolidation and review project
Informal consultation, 24 Nov – 22 Dec 2010: streamlining and reducing Regulatory burdens**

Response from the Guild of Healthcare Pharmacists

Thank you for the opportunity to respond to this consultation. The Guild of Healthcare Pharmacists represents UK wide around 4,000 pharmacists including the majority of hospital pharmacists, pharmacists employed by NHS Primary Care organisations and pharmacists employed by other public bodies such as Prisons and the Care Quality Commission. The Guild is part of the health sector of the union Unite. We will formally respond in more detail to the full consultation in spring 2011 but have taken this opportunity to outline our comments on the general direction.

We specifically wish to respond to the issues raised in Question 3:

Manufacturing and wholesale dealing

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

We would support these proposals, as they should reduce the regulatory burden on licence holders. However, we would propose that by undertaking these minor amendments there should be a reduction the fee.

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

We have no comments on this issue

3. Appointing responsible persons

We would support this proposal but would wish to see improvements to the vetting and approval of

President: David Miller

Professional Secretary: Barry Corbett

Email: barry_corbett@hotmail.com

Website: www.ghp.org.uk

Responsible Persons with a view to having a formal register of Responsible Persons similar to that held for Qualified Persons.

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

We believe that any changes to the current regulations would have to have very careful consideration. Many NHS hospital Pharmacy departments provide services for patients that involve the preparation and supply of a range of certain medicinal products, which utilise the provisions of section 10 of the medicines act 1968. Thus, any major changes could have profound affects on these services, which could ultimately affect patient care. The major danger is that excessive legislation and control could lead to increased medicines preparation outside the pharmacy at ward level.

Proportionate enforcement provisions

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

We have no comments on this issue

6. Proportionate prosecution of dispensing errors

We fully support the proposal to only have a proportionate response to pharmacists or other health professionals who have been involved in a dispensing error. This is an urgently required amendment. We feel that the Medicines Act has no connection with wilful intent or negligence and pursuance to criminalise pharmacists, who have made dispensing errors through human error, is totally unreasonable. In our view the relevant sections of the legislation largely taken from previous Food Acts is about deliberate adulteration of medicinal products and/or clear misrepresentation of those products to the public and it should have no connections with the dispensing process. If a health professional commits a deliberate or wilful act of negligence there is sufficient existing law dealing with health and safety and/or criminal negligence to address this aspect of human behaviour. We know from the evidence that most prescribing, dispensing and administration errors are due to inappropriate systems and in our view the inappropriate use of these provisions has the danger of destabilising currently established systems for error reporting and learning lessons arising from the use of these systems In addition as most of our members have a contractual requirement to report errors this may be in breach of their basic human rights. Our view is that it would be inappropriate to continue to seek to prosecute those pharmacists who have committed an offence under Sections 64 and/or 65 of the Medicines Act, as acts of wilful intent or through negligence are already covered by other legislation, although we would accept this is an improvement of the current in our view total misapplication of the current act with its strict liability provisions.

Streamlined administrative processes

7. Streamline panels for reviewing licensing decisions

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

We have no comments on these issues

Simplified processes in relation to herbal medicines

9. We believe that there is scope to simplify the provisions which exempt herbal remedies (subject to certain conditions) from the provisions relating to the sale of pharmacy and general sales list products

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)

We have no comments on these issues

Labels and leaflets

11. Streamlining statutory warnings for labels and leaflets

We are considering how to simplify and rationalise the number of statutory warnings and to standardise wordings on labels and leaflets where possible

Although we support these proposals we feel that the changes should be done with due regard to the standard cautionary and advisory details for dispensed medicines outlined in the British National Formulary. If this was not undertaken there could be a potential difference in the information provided or the information may not be readily available to patients to read, leading to patient safety concerns. It is important that leaflets and labels are about the core patient information to improve their care and safety and less about protecting the manufacturer of the medicinal products.

Prescribing, sale and supply

12. Sale, supply and administration of medicines

We have already responded to these proposals in a previous informal consultation

13. Patient Group Directions

We have already responded to these proposals in a previous informal consultation

We hope these comments are of assistance. Our reply may be made freely available.

Yours faithfully

Barry Corbett
Professional Secretary
Guild of Healthcare Pharmacists

Graeme Richardson
Chair of Practice
Guild of Healthcare Pharmacists