



22nd November 2010

Anne Ryan
MHRA Policy Division

Dear Mrs Ryan

**REVIEW OF MEDICINES LEGISLATION: INFORMAL
CONSULTATION ON THE PROVISIONS FOR PATIENT GROUP
DIRECTIONS AND OTHER MATTERS**

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.

Our response to main questions are listed as follows:

We would be interested in your views on the positive and negative aspects of PGDs generally and whether they are worth retaining in their present form. If there is evidence to suggest that PGDs may be a bar to health professionals developing further skills, we also welcome suggestions for addressing this.

We feel that although the development of PGDs can be time consuming and may be perceived as bureaucratic by some people who are required to write them or by those individuals who use them for the supply and administration of medicines, they have greatly improved patient care in the limited situations in which they are used. PGDs are now so well established, particularly in the hospital setting, that this continued advantage for patient care would be removed in their absence.

Although we have not observed PGDs being a direct obstacle to non-medical prescribers attaining independent prescribing qualifications, some organizations may view PGDs as a 'short-cut' for providing services providing the supply and administration of medicines as the costs involved for PGDs would be far less than costs involved in training independent prescribers. This may therefore hold back the development of services involving independent prescribers and therefore ultimately be detrimental to patient care.

We agree with the proposal that there is a case for stating more strongly that PGDs are not intended to be a general substitute for the provision of clinical care on an individual, patient specific basis. We also agree that PGDs are not intended to substitute or replace the Medicines Act exemptions that allow some

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registered health professionals to sell, supply and administer on their own initiative. In the hospital setting, it is made clear to all individual healthcare professionals who wish to use a PGD that they can only supply or administer medicines in specific areas of practice and competence once authorised to do so by their line manager.

Article 12 to 12E of the POM Order and corresponding provisions in the Pharmacy and General Sale (Exemption) Order

Elsewhere in legislation reference is made to “the course of a business of a hospital or health centre”. The reference to a “health centre” appears in the original provision in the Medicines Act 1968. However, we do not think there should be potential for the exemption to apply to health centres in their broadest sense. We therefore propose to retain this exemption but consider whether the references to health centres, which appear here and elsewhere in the legislation, should be removed. We would welcome views.

We agree that the exemption should be retained but that reference to ‘health centres’ should be removed. In the past, Health centres were in fact an extension of secondary care provision but over time they have eventually evolved into providing more primary care based services and do not therefore meet the original provision of the Medicines Act 1968.

9. We are aware that there is some confusion around Article 12, the requirements for a prescription, an understanding of what is meant by a PSD and the mechanisms for giving directions for the administration of POMs. We aim to clarify this area in guidance and would welcome any views.

We feel that the current legislation is sufficiently clear and that from the secondary care perspective there is no need to clarify the guidance within Article 12.

Article 12A

10. This Article provides exemptions for supply and administration of medicines by NHS bodies such as, currently, Trusts and PCTs. With the organisational changes being proposed for the NHS, we have concerns that, without amendment, the legislation will not support the use of PGDs in future. We welcome suggestions on how this might be best addressed. We also invite views on who should be required to authorise PGDs.

We suggest that the legislation - Prescription Only Medicines (Human Use) Order 1997 the Medicines (Pharmacy and General Sale - Exemption Order) 1980 and the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 - should be amended to support the use of PGDs in the new structures.

We feel that the commissioning bodies, rather than the ‘provider’ of the service, should authorize the use of PGDs as they will be monitoring the services provided. This process would then be analogous to NHS hospitals where medicines management committees monitor the use of PGDs.

10. We are also considering amending the exemption to allow supply for the purposes of administration in accordance with the written directions of other independent non-medical prescribers. We invite views on retaining and amending this provision.

We would support this proposal for retaining and amending this provision. Currently, PGDs are written and signed off by a doctor and a pharmacist (as required under the current legislation) and usually by a senior nurse or head of service in which the PGD to be used, before being

finally signed by senior representatives of the organisation. If the legislation was changed to allow a non-medical prescriber to provide the written instructions we do not see that this would be detrimental to patient care under the current system.

Article 12B

13. Article 12B provides exemptions for groups of health professionals. We propose to retain the current list of registered health professionals who are able to use PGDs. We also propose that the requirement that only registered health professionals can supply or administer medicines under PGDs will remain.

We support this proposal and have no further comments on this issue.

Article 12C

15. Article 12C provides an exemption for persons conducting a retail pharmacy business. We invite views on whether the law should be amended so that an independent provider entering into arrangements with a pharmacy must be registered in the country where that pharmacy is registered and where those services are offered.

Although we feel that a pharmacy should be registered in the country where those services are provided our concern here is that this may be viewed as being restrictive, unjustified and disproportionate for the purpose of maintaining public health in the same way as identified in MLX 370: Medicines for Human Use/Prescribing by EEA practitioners Regulations 2008, which called for recognition of EEA prescriptions for certain drugs.

Article 12D

16. Article 12D provides exemptions which allow independent hospitals, clinics and medical agencies registered with the Care Quality Commission (CQC) to develop and authorise their own PGDs. The implementation of the Health and Social Care Act 2008 means that providers of health and social care across the NHS and independent sectors will be registered by the CQC. We propose to retain Article 12D. However, we welcome views on whether 12D should be expanded to include other providers who will be registering with the CQC such as GP and dental surgeries. Pharmacists will not, we understand, be required to register with the CQC. They will continue to be able to enter into arrangements with NHS and independent providers to sell, supply and administer medicines under a PGD.

We support this proposal and have no further comments on this issue.

Article 12E

17. Article 12E provides an exemption for prisons, police and armed forces. We are not aware of any issues relating to use of PGDs in the armed forces. We would be interested in views.

We have no comments on this issue.

19. For prisons, we propose to clarify the law so that in circumstances where healthcare in the prison is provided under PGDs which have been developed and authorised by an NHS body, there will be no requirement for the prison governor to sign it as well. We would welcome views.

We have no comments on this issue.

Particulars required to be contained in PGDs

20. These are listed in Annex A. We propose to retain these requirements. We also seek views on whether there is a need for any further particulars to be included in a PGD. For example, should there be a definite requirement for a review date?

We agree with the proposal to retain the requirements listed in Annex A, but feel that it is essential that the following requirements are included in the list:

- (a) A review date. There could be changes in medicines legislation, national guidance or changes in clinical or best practice that need to be incorporated or would require an amendment of the wording in a PGD. These necessary changes could otherwise be missed if a review date is not stipulated.
- (b) A statement on the necessary training that is required before an individual may authorized to use the PGD.

Unlicensed medicines

21. We do not consider that PGDs should include unrestricted use of unlicensed medicines. However, we welcome your views on allowing unlicensed medicines to be included under PGDs where there is a nationally identified need to use a specific unlicensed product. We would also welcome views on the types of situations where the inclusion of unlicensed medicines under PGDs would be of benefit to patient care.

We agree that PGDs should not include unrestricted use of unlicensed medicines. In our experience, situations have not arisen where an unlicensed product has been needed under PGD. To allow a specific unlicensed product under a PGD, in our view, would not be beneficial to patient care and that if such a product was needed for a specific patient then the a prescription must be written by the patient's doctor for subsequent dispensing of the medicine by a pharmacist.

22. Schedule 5 to the Marketing Authorisation Regulations SI 1994/3144 (as amended) contains the requirements for labelling of dispensed relevant medicinal products. Although prescription only medicines supplied under a PGD do not fall within the definition of a dispensed medical product, the Agency has advised that it is good practice to label them in accordance with the Schedule 5 provisions. We therefore propose to amend the Marketing Authorisation regulations to extend the labelling requirements for dispensed medicinal products to prescription only medicines supplied under a PGD.

We agree with this proposal. Many organizations over-label original packs of medicines so that these may be used by e.g. a nurse to supply or administer the medicine under a PGD. The label allows for the patients' name date of supply, name and address of the Pharmacy, product name, directions for use and any precautions to be shown. However, such over-labeling is done in a way that does not obscure the important details provided by the manufacturer of the pack as this would otherwise render the product as an unlicensed medicine and therefore not be permissible under a PGD.

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

Yours faithfully

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