Council meeting 16 June 2010

Public business

Extemporaneous preparation of methadone

Purpose
To consider an exemption to standard 4.10 of the standards for pharmacy owners, superintendent pharmacists and retail pharmacy premises.

Recommendations

The Council is asked to agree:

i. an exemption to standard 4.10 of the standards for pharmacy owners, superintendent pharmacists and pharmacy professionals in positions of authority to enable the extemporaneous preparation of methadone

ii. that consideration will be given to removing this exemption as part of the consultation on the future standards for pharmacy owners, superintendent pharmacists and retail pharmacy premises

1.0 Introduction

1.1 The GPhC standards for pharmacy owners, superintendent pharmacists and retail pharmacy premises are required to ensure that we are able to regulate retail pharmacies.

1.2 The Council agreed at their meeting in April that they intend to adopt interim standards which are largely based on the current Royal Pharmaceutical Standards of Great Britain professional standards documents.

1.3 The RPSGB professional standards currently require that:
a product with a marketing authorisation is supplied where such a product exists in a suitable formulation and is available, in preference to an unlicensed product or food supplement.

The RPSGB have issued an exemption to this standard to enable the extemporaneous preparation of methadone. They have issued specific standards, for those who prepare methadone exptemporaneously; these are detailed in Appendix 1.

1.4 The GPhC intends to undertake a standards development programme which will involve a work programme to develop the GPhC long term standards for pharmacy owners and superintendent pharmacists; required by Article 7 of the Pharmacy Order.

2.0 Extemporaneous preparation of methadone

2.1 Standard 4.10 of the GPhC interim standards for pharmacy owners, superintendent pharmacists and pharmacy professionals in positions of authority states that:

You must ensure a product with a marketing authorisation is supplied where such a product exists in a suitable form and is available, in preference to an unlicensed product or food supplement except where an exemption has been authorised.

2.2 Some pharmacies dispense methadone that they have extemporaneously prepared; this is done by mixing methadone powder with a diluent. Without a specific exemption for this process, pharmacies will not be able to prepare methadone in this way.

2.3 Methadone, in any formulation, is a schedule 2 controlled drug that is subject to safe custody requirements. This means that it must be stored in a controlled drugs cabinet. Methadone powder requires less storage space than methadone liquid.

2.4 Some pharmacies dispense high volumes of methadone on a daily basis; for these pharmacies storing methadone liquid rather than methadone powder would result in the need for larger CD cabinets and potentially a larger floor space.

2.5 The extemporaneous preparation of methadone is potentially a high risk activity where appropriate standards are not followed.
3.0 **Equality and diversity implications**

3.1 Removal of the methadone exemption, without proper consultation and an appropriate transition phase may have an effect on a specific group of patients; namely those who have a drug addiction.

4.0 **Communications implications**

4.1 Informing pharmacy professionals that the exemption to enable the extemporaneous preparation of methadone will remain can form part of the wider communications plan for launching the GPhC standards.

4.2 Consultation and communication with pharmacy professionals and others about the possible removal of the exemption will form part of the Council’s wider work when developing the long term standards for pharmacy owners, superintendents and retail pharmacy premises.

5.0 **Resource implications**

5.1 There is no resource implication associated with the first recommendation in this paper.

5.2 The resource implications associated with the second recommendation will be accounted for in the resource required for the standards development programme.

6.0 **Risk implications**

6.1 There are potential risks to patients if pharmacies that currently use the exemption to serve their community are unable too, and cannot store volumes of methadone they need for their patients.

6.2 A full assessment of the impact of the option of removing the exemption is indicated. This would involve evaluating the potentially negative impact of such a change in terms of convenience, practicality, cost and service, set against an assessment of public risk in terms of safety and quality if the exemption continues to be permitted in the medium to long term.

**Recommendations**

**The Council designate is asked to agree:**
i. an exemption to standard 4.10 of the standards for pharmacy owners, superintendent pharmacists and pharmacy professionals in positions of authority to enable the extemporaneous preparation of methadone.

ii. that consideration will be given to removing this exemption as part of the consultation on the future standards for pharmacy owners, superintendent pharmacists and retail pharmacy premises.

Priya Sejpal  
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RPSGB  

16 June 2010
Extemporaneous preparation of methadone mixture

You must supply a product with a marketing authorisation, where such a product exists in a suitable formulation and is available, in preference to an unlicensed product or food supplement. You must only prepare a product extemporaneously if there is no product with a marketing authorisation available and where you are able to prepare the product in compliance with accepted standards.

An exception to these requirements, to permit the extemporaneous preparation of methadone mixture in circumstances where a licensed product is available, will be granted provided the following requirements are adhered to:

STANDARDS

(a) If a licensed product is available, methadone mixture may only be prepared extemporaneously if the quantity of methadone dispensed on a regular basis is large enough to preclude storage of sufficient quantities of the licensed product within the pharmacy, in accordance with the safe custody requirements of the Misuse of Drugs legislation.

(b) In addition to the standard operating procedures (SOPs) required for dispensing, a SOP must be in place for the extemporaneous preparation of methadone. The SOP must ensure safe systems and provide a verifiable audit trail. Adherence to the SOP must be ensured.

(c) Extemporaneous preparation must only be carried out by persons who are appropriately trained and competent to do so.

(d) All quantities of methadone powder and diluent, and any colourings, flavourings and stabilisers, must be accurately measured. You must not rely on the accuracy of the quantities of powder, diluent etc stated on the manufacturers packs.

(e) The equipment used to measure and prepare extemporaneous methadone products must be appropriate and be maintained in good order to ensure that performance is unimpaired.

(f) Equipment must be properly cleaned between each batch of extemporaneously prepared product to ensure that no residue from previous batches remains.

(g) Visual checks must be made to ensure the methadone powder has fully dissolved in the diluent.
(h) Stock bottles must not be reused.

(i) The product must be labelled with the necessary particulars, including:

- The name and strength of the product
- The quantity of medicinal product in the container
- Any special handling and storage requirements (e.g., store in safe custody)
- The batch expiry date
- A batch reference number

(j) For each batch of extemporaneous methadone mixture prepared a record must be maintained for a minimum of two years of:

- The formula
- The ingredients and quantities used
- The source, batch number and expiry date of the ingredients
- The batch number and expiry date of the extemporaneously prepared mixture
- The persons involved in preparing the product, including the identity of the pharmacist assuming overall responsibility

(k) Extemporaneously prepared methadone mixture must be stored in a cabinet, cupboard or room that meets the requirements of the Misuse of Drugs (Safe Custody) Regulations 1973.

(l) Extemporaneous preparation of methadone mixture, when a licensed product is available, carries increased liability and must be covered by indemnity insurance arrangements.

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**GOOD PRACTICE GUIDANCE**

- Running balances of methadone powder and the resulting extemporaneously prepared methadone mixture should be maintained.
- The prescriber and the patient should be informed that the methadone product being supplied does not have a marketing authorisation.
- Wherever possible all measurements should be checked by a second person.