

Call for evidence about the extemporaneous preparation of methadone

April 2011

Summary

This call for evidence asks for your experiences and views on the extemporaneous preparation of methadone liquid. The call for evidence will inform the way in which we (the General Pharmaceutical Council) develop our standards for pharmacy owners and superintendent pharmacists.

The call for evidence will run from 04 April 2011 to 24 June 2011. It is open to anyone with an interest who would like to respond.

Background

The GPhC is at the beginning of a twelve to eighteen month project to develop its approach to regulating retail pharmacy businesses. An essential part of the project is to develop the standards for pharmacy owners and superintendent pharmacists which will replace the *interim standards for pharmacy owners and superintendent pharmacists*.

The interim standards for pharmacy owners and superintendent pharmacists require pharmacists to supply a licensed medicine, where one exists, in preference to an unlicensed medicine. However there is an exemption from this standard which allows a pharmacist to prepare methadone liquid extemporaneously.¹

The Council agreed to this interim position on the understanding that a full review would be undertaken. Now that the project to develop the standards for pharmacy owners and superintendent pharmacists is underway, we want to have a fuller understanding of the practice and the impact of any changes to the current approach. In particular we are interested in hearing from pharmacy professionals who extemporaneously prepare methadone liquid and patients who receive extemporaneously prepared methadone liquid.

We want to hear about any positive aspects of this practice, as well as any concerns you may have or problems that you have encountered.

¹ Extemporaneous in this context would mean mixing the methadone powder and diluents at the time it is needed for a patient's prescription.

Methadone

There are two licensed formulations of methadone: a powder and a liquid.

Licensed liquid methadone comes in different strengths, and is ready to dispense.

Licensed methadone powder is weighed out and mixed with a suitable liquid, called a diluent, to make methadone liquid.

Methadone, in all formulations, is a schedule 2 controlled drug² that is subject to safe custody requirements. This means that it must be stored under secure conditions in a specially constructed cupboard called a controlled drugs cabinet. These cabinets are not usually very large.

Methadone powder takes up less storage space than methadone liquid.

Lack of storage capacity in the controlled drugs cabinet is often cited by pharmacies as the reason they prepare unlicensed methadone liquid rather than purchase licensed methadone liquid.

Evidence

It is important that any decisions we make are supported by appropriate evidence. Our initial search indicates that there is very little information or documented evidence available.

In coming to an agreed position on this issue, we would welcome feedback including any evidence in relation to a number of aspects of this practice, including but not limited to:

1. The reasons pharmacists prepare methadone in this way
2. The scale of this practice
3. The impact on the sector if methadone liquid could no longer be prepared in this way
4. Any complaints or concerns that have been raised about this practice.

² Controlled drugs are those that have additional legal restrictions placed on them to protect the public by reducing the risk of diversion and abuse. A Schedule 2 controlled drug is a drug listed as such in the Misuse of Drugs Regulations 2001. This class of drug has specific record keeping, storage and prescription requirements. There are also restrictions on who can possess this type of drug.

What the call does not cover

This call for evidence is very specific and is focused on the preparation of unlicensed methadone liquid. It does not cover the preparation and supply of other unlicensed medicines or 'specials'.

It is also not a substitute for the formal consultation on our standards for superintendent pharmacists and pharmacy owners, which we will hold towards the end of the year. At this stage we are specifically looking for evidence in relation to the extemporaneous preparation of methadone.

How to respond

You can respond to this call for evidence in a number of different ways:

1. You can view the questions online at:

<http://www.pharmacyregulation.org/getinvolved/consultations/currentconsultations/methodonecallforevidence/index.aspx>

2. By email by completing the form at the end of the document and sending it to:

consultationresponses@pharmacyregulation.org

3. By post, sending it to:

Extemporaneous Preparation of Methadone – a call for evidence, Consultation Response, GPhC, 129 Lambeth Road, London, SE1 7BT

This document is available in Welsh and in other languages and formats, such as large print, on request. If you would like to receive a copy of this document in an alternative format please contact us on 0203 365 3526 or communications@pharmacyregulation.org

Response to the call for evidence about the extemporaneous preparation of methadone

To complete the consultation response form online, go to our website

www.pharmacyregulation.org

Or you can use the response form at the end of this document. Please send your completed form to

email consultationresponses@pharmacyregulation.org

or

address Extemporaneous Preparation of Methadone – a call for evidence, Consultation Response, GPhC, 129 Lambeth Road, London, SE1 7BT

Name

Contact address

Postcode

Contact telephone

Email

Confidentiality

Information provided in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

The General Pharmaceutical Council will process your personal data in accordance with the DPA and, in the majority of circumstances; this will mean that your personal data will not be disclosed to third parties.

Please indicate all the countries to which your comments relate

- Great Britain
- England
- Scotland
- Wales
- Other (please give details)

Are you responding

As an individual

- as a pharmacy professional (please complete section A)
- as a member of the public
- as an allied health professional (please give details)

On behalf of an organisation

- on behalf of a pharmacy organisation (please complete section B)
- on behalf of a non-pharmacy organisation (please complete section C)

A. Pharmacy professionals

If you are responding as a pharmacy professional, please supply the following details

- Pharmacist
- Pharmacy technician

Area(s) of work

If you work in more than one area please tick all the relevant boxes that apply

- Community pharmacy
- Hospital pharmacy
- Primary care
- Pharmacy education and training
- Pharmaceutical industry
- Other (please give details)

B. Pharmacy organisations

If you are responding on behalf of a pharmacy organisation, please supply the following details

Type of organisation

- Professional body
- Regulatory body
- Education and training provider
- Employer
- Union
- Trade body
- Other (please give details)

Area(s) of work

If you work in more than one area please tick all the relevant boxes that apply

- Community pharmacy
- Hospital pharmacy
- Primary care
- Pharmacy education and training
- Pharmaceutical industry
- Other (please give details)

C. Non-pharmacy organisations

If you are responding on behalf of a non-pharmacy organisation, please supply the following details

Type of organisation

- Professional body
- Public/patient organisation
- Representative body
- Regulatory body
- Education and training provider
- Employer
- Union
- Trade body
- Other (please give details)

Questions for pharmacy professionals

We have set out below questions that we would particularly like to hear your views about. You don't have to answer all of the questions we have asked. You can also submit general comments at the end.

1. Scale and reasons for preparing methadone liquid extemporaneously

We would like to know more about the scale at which extemporaneous methadone liquid is prepared and the reasons why it is done.

- 1.1 What volumes of methadone liquid do you prepare extemporaneously each week, (or on each occasion if more or less frequently)?
- 1.2 Why do you choose to prepare methadone liquid extemporaneously rather than purchase the licensed product?
- 1.3 What would the impact be, if any, on the substance misuse services you provide if you stopped preparing methadone liquid?
- 1.4 What would the impact be on the pharmacy, including cost burden, if you stopped or were required to cease preparing methadone liquid?

2. Process and Records

If you have prepared methadone liquid extemporaneously we would like to hear about the process you followed.

- 2.1 Do you have a standard operating procedure, if so where did you get this from?
- 2.2 What records do you keep?
- 2.3 Do you tell your patients that you prepare the methadone liquid in this way?
- 2.4 Do you tell the drug misuse team and / or prescriber that you prepare the methadone liquid in this way?

3. Feedback, complaints or concerns

3.1 Please tell us about any feedback you have received, good or bad, about the preparation and supply of extemporaneously prepared methadone liquid. This feedback could be from patients, colleagues, regulators or members of the multi-disciplinary team.

Questions for other healthcare professionals, patients and other interested parties

4. Awareness

4.1 Did you know that pharmacists can supply either a licensed methadone liquid or a methadone liquid that they have prepared themselves?

4.2 If you are a patient that receives methadone liquid, do you know which preparation you receive? Does it matter to you which preparation you receive?

4.3 If you prescribe methadone liquid, or are involved in methadone treatment programmes, do you know which methadone liquid preparation your patients receive? Does it matter to you which preparation is supplied?

4.4 Do you have any concerns about the safety of extemporaneous preparation of methadone in pharmacy? If so, are you able to provide any evidence or specific examples where this practice has, or has had the potential, to put patients at risk?

5. Impact

5.1 Do you support or oppose the exemption in standards to allow extemporaneous preparation of methadone?

5.2 Do you believe that supplying methadone liquid prepared extemporaneously has a neutral, positive or negative effect on substance misuse services?

5.3 If methadone liquid could not be prepared extemporaneously, would this have a neutral, positive or negative effect on substance misuse services in particular the services to patients?

5.4 If methadone liquid could not be prepared extemporaneously, do you think this would have a neutral, positive or negative effect, including any additional financial or other burden, on the supplying pharmacy?

6. Feedback, complaints or concerns

6.1 Have you ever had a cause for concern or made a complaint about the methadone liquid that a pharmacist has supplied?