

Dear Sir/Madam

17 August 2007

MLX 342: PROPOSALS TO AMEND SECTION 58 OF THE MEDICINES ACT 1968 TO ENABLE UK PHARMACISTS TO DISPENSE PRESCRIPTION ONLY MEDICINES PRESCRIBED BY DOCTORS AND DENTISTS REGISTERED IN EUROPEAN MEMBER STATES AND SWITZERLAND

Introduction

1. This letter seeks your views on proposals to amend section 58 of the Medicines Act 1968 and Article 2 of the Prescription Only Medicines Human Use Order 1997 (POM Order) to enable United Kingdom (UK) pharmacists to dispense prescription only medicines (POMs) lawfully prescribed by doctors and dentists in other EEA States and, possibly, Switzerland (EEA doctors and dentists).

2. This consultation abides by the six consultation criteria as set out in the revised Code of Practice on Consultation published by the Cabinet Office (www.cabinet-office.gov.uk/regulation/Consultation/Code.htm) and which are summarised at **Annex A**. As these proposals are required in relation to proposals to amend legislation for the purpose of complying with the views of the European Commission a period of consultation of 8 weeks, although shorter than usually expected, is appropriate. **Replies should therefore reach us by 12 October 2007.**

Application to Wales, Scotland and Northern Ireland

3. The proposed changes would be effected in regulations made under powers conferred by section 2(2) of the European Communities Act 1972 and have effect throughout the United Kingdom (UK).

Background

4. The current legal position as set out in **Annex B**. For the reasons explained below, the UK requirement for appropriate practitioners to be registered in the UK before a UK pharmacist can dispense their prescriptions has served to safeguard the health of patients and provides a means by which a pharmacist can fulfil his professional responsibilities.

5. Where a pharmacist in the UK is asked to supply against a prescription, he is under an obligation, pursuant to his professional Code of Ethics, to consider the welfare of the individual patient. He has a professional responsibility to exercise control over all medicinal products and related products which are purchased or supplied. A pharmacist who is presented with a prescription, completed by a doctor or dentist can, under the present system, if the practitioner is not known to him, easily access the relevant

professional register to check that the prescriber is on it and is qualified to prescribe that particular medicinal product. If there is no need for a prescriber to be on a register the pharmacist will have to use other means to satisfy himself of the authenticity of the prescriber. These other means may not be so straightforward or reliable as recourse to a register and so, if removal of the requirement for every prescriber of a POM medicine to be on a register means that a pharmacist will be unable to easily confirm the authenticity of the prescriber, the risk to public safety may be increased.

6. However, an effect of the requirement is that, in practice, prescriptions for POMs written by doctors and dentists in other Member States cannot be accepted for dispensing. This is because, although doctors and dentists can become registered on the appropriate UK register, they are unlikely to do so. Thus, by reason of the legislation a pharmacist in the UK cannot supply a POM against a prescription written in another Member State by a non UK registered practitioner, even if he knows that the prescription is genuine and has no concerns of a public health nature. Such a situation may arise where the patient and prescriber are known to the pharmacist, for example.

7. Against this background the European Commission have asserted that the provisions of section 58 of the Medicines Act 1968, Article 2 of the POM Order, the Medical Act 1983 and, by association, the Dental Act 1984 are contrary to the principle of the freedom to provide services enshrined in Article 49 of the EC Treaty. In the Commission's view the provisions may deter patients who live in other Member States from coming to the UK to seek services because of difficulties in obtaining their POMs whilst in the UK. It also considers that UK residents may be deterred from seeking medical services elsewhere in the Community because of the difficulty of getting their prescriptions honoured when they return to the UK.

8. The Commission does not consider that UK pharmacists must always dispense against a prescription written in another Member State by a non UK registered practitioner. Rather, the Commission's view is that, by imposing a complete prohibition of the supply of POMs against prescriptions written by non registered practitioners, the legislation goes beyond what is reasonably required for the purposes of ensuring public health and safety. The Commission considers that pharmacists, as highly trained professionals, can exercise proper judgement themselves, when deciding whether or not it is safe to supply a POM against a prescription given to them by a patient.

Situation in other Member States

9. The MHRA has canvassed practice in other Member States. It appears that most other EEA States do not have a registration system and leave it to pharmacists to decide whether and how to authenticate a prescription, and to refuse to dispense a prescription if they have doubts.

Reasons and Proposals for Change

10. Populations have become much more mobile over the last 20 years or so and with that mobility comes a demand for healthcare to be provided where most appropriate or convenient for the individual patient. A system of authentication which operates on such a case by case basis, relying on the judgement of individual pharmacists, is more flexible and less of a restriction than the existing prohibition on honouring prescriptions for POMs given by doctors and dentists who are not on the appropriate UK register. In view of the fact that to do so will assist people to move more easily and freely within the Community and bearing in mind that prescriptions for POMs written by non UK registered practitioners are likely to be presented by a relatively small number of people, the UK has decided that the exercise by pharmacists of their own professional skill and judgement in making a decision whether or not to dispense against such a prescription should, as appears to be the case in most other Member States, operate successfully and safely in the UK. Thus the UK agrees with the principle of the Commission's views that UK pharmacies should, subject to the professional judgement of individual pharmacists, be able to dispense POMs in accordance with a prescription written by an EEA doctor or dentist. The changes will be achieved through amendments to section 58 of the Medicines Act 1968 and Article 2 of the POM Order to make clear that it shall be lawful for a doctor or dentist who lawfully practices medicine or dentistry in another EEA State and who issues a prescription to a patient in that other Member State or Switzerland to have his prescription recognised in the UK.

11. At present no other Member State or Switzerland has legislative provision for independent prescribing by nurses, midwives or pharmacists. However it is proposed to amend section 58 of the Medicines Act 1968 so that if in the future they are lawfully permitted to write prescriptions by their Member State, they may be specified in the POM Order as "appropriate practitioners" and so have their prescriptions recognised in the UK, if Ministers think it is right to do so. **We would welcome views on the proposed "future proofing"**.

12. The changes outlined above will encompass prescriptions for all licensed POMs but, in agreement with the Home Office, will exclude all drugs that are subject to additional control under the misuse of drugs legislation.

Controlled Drugs

13. The amendments outlined above will not affect UK legislation relating to "controlled drugs" (i.e. medicinal products consisting of or containing narcotic or psychotropic substances). Dispensing and supply of such products is regulated under the Misuse of Drugs Act 1971, and associated regulations, which is the means by which the UK meets its international obligations as a signatory to the Single Convention on Narcotic Drugs 1961 and the Convention to Psychotropic Drugs 1971.

14. The UK has an established regime of control in relation to the prescribing, administration, supply, custody, auditing, destruction and disposal of such drugs. The single purpose of the regime is to prevent the diversion and misuse of such drugs in order to protect patients and the public. The Act and its Regulations have the effect that a pharmacist may dispense a controlled drug only against a prescription written by a practitioner registered in the UK. In addition, the ways in which controlled drugs are managed through this regime of control have recently been strengthened, to give effect to the recommendations of The Shipman Inquiry, a 4 year public inquiry into the activities of Dr Harold Shipman. It is essential to maintain strict controls on the supply of controlled drugs, so the proposed amendments will not enable doctors and dentists established in other Member States or Switzerland to have their prescriptions for controlled drugs recognised by a UK pharmacist. **We would welcome views on the exclusion of all drugs within Schedules 1 to 5 of the Misuse of Drugs Act 1971, and associated regulations, from the arrangements outlined in paragraph 10 above.**

Drugs that do not have a valid Marketing Authorisation in the UK

15. The Commission restricted its consideration to the requirements of section 58 of the Medicines Act 1968 and Article 2 of the POM Order and did not comment on other aspects of medicines legislation. In particular no reference was made to Section 10 of the Act whereby pharmacists can, in certain circumstances, prepare and dispense a medicinal product in accordance with a prescription given by a practitioner or to section 23 of the Act. Similarly no reference was given to the prescribing of medicinal products which do not have a Marketing Authorisation issued in accordance with the Directive, but which may be lawfully supplied by reason of Article 5 of Directive 2001/83 as implemented in the UK by Regulation 3(2) and Schedule 1 of the Marketing Authorisation Regulations 1994. We are of the provisional view that no amendments should be made to either section 10, section 23 or the 1994 Regulations to enable UK pharmacists to prepare or dispense an unlicensed drug in accordance with a prescription written by a doctor or dentist lawfully established to practice medicine or dentistry in another EEA State or Switzerland. However, it could be argued that this should also be a matter for the individual professional skill and judgement of an individual pharmacist. If a pharmacist is satisfied as to the authenticity of the prescriber and the prescription and has no concerns about the health and well-being of the patient, there seems little benefit in having to refuse to dispense against that prescription in the absence of a Marketing Authorisation. The MHRA therefore intends to give further consideration as to whether the legislation should also be changed so that patients who have prescriptions from doctors or dentists in other Member States or Switzerland for medicines which are not licensed within the UK may obtain them from UK pharmacists. **We would welcome views on this proposal.**

Charges for medicinal products dispensed in the UK

16. Any prescriptions dispensed by UK pharmacists in accordance with a prescription written by an EEA doctor or dentist will be subject to the commercial charge for the product in question.

Form of prescribing

17. Article 15 of the POM Order (extract at **Annex C**) specifies the conditions that must be fulfilled to enable the sale or supply of a POM. Communicating those requirements to all doctors and dentists in all Member States and Switzerland, in case they are required to write a prescription for a patient who will then have that prescription dispensed in the UK, is unlikely to be effective. Nor does it seem sensible to put a pharmacist in a position whereby the format of the prescription is the only barrier to dispensing the medicine prescribed. The proposal is therefore that a similar exemption to that already existing for hospitals (Article 12 of the POM Order) should be introduced. In other words, UK pharmacists will be able to dispense a POM in accordance with the written directions of a doctor or dentist lawfully established to practice medicine or dentistry in another Member State or Switzerland notwithstanding that those directions do not satisfy the conditions specified in Article 15 of the POM Order. **We would welcome views on this proposal.**

Exemption in cases involving another's default

18. In line with the existing provisions in Article 13 of the POM Order, the proposal is that the restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply to the sale or supply of a POM by a person who, having exercised all due diligence, believes on reasonable grounds that the product sold is not a POM. **We would welcome views on this proposal and whether a due diligence defence similar to that in Article 13A is necessary for prescriptions which are presented as being, but in fact are not, given by an EEA doctor or dentist.**

Exemption in the case of a forged prescription

19. In line with the existing provisions in Article 14 of the POM Order, the proposal is that the restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply to the sale or supply of a POM by a pharmacist in accordance with a forged prescription where the pharmacist having exercised all due diligence, believes on reasonable grounds that the prescription is genuine and has been written by an EEA doctor or dentist. **We would welcome views on this proposal.**

Professional guidance

20. As outlined above, the amendments to section 58 and Article 2 will not impose any obligation on a pharmacist to dispense a POM in response to a prescription from an EEA doctor or dentist. Pharmacists will be able to exercise their professional judgement and dispense a POM if they are satisfied that the prescription is genuine and that it is otherwise safe to do so, but need not do so if they have any concerns. Professional guidance will be crucial to help pharmacists decide when it is, or is not, appropriate to dispense against such a prescription. To this end, the DH/MHRA is already in contact with the Pharmaceutical Societies who will be responsible for developing and publishing such guidance. However, to encourage pharmacists to supply against such prescriptions, the

MHRA is canvassing views, via this consultation, on the topics for inclusion in such guidance.

21. We would not expect pharmacists to have to arrange for the translation of any prescriptions or to accept prescriptions where the product prescribed is in doubt. However possible topics for inclusion in the guidance could be methods for verifying the authenticity of the prescription (eg, details of registration bodies, including internet links, throughout the EEA and Switzerland, lists of the competent authorities for each Member State and Switzerland), the form of the prescription (see paragraph 17) and the arrangements for reporting any adverse drug reactions. **We would welcome views on the scope and content of the professional guidance.**

Timing of consultation

22. As these proposals are required in relation to proposals to amend legislation for the purpose of complying with the views of the European Commission a period of consultation of 8 weeks, although shorter than usually expected, is appropriate. **Replies should therefore reach us by 12 October 2007.**

Impact of Legislation on Business

23. The proposals will impose some burden on retail pharmacies in establishing, where necessary, that a prescription is genuine and has been written by a doctor or dentist lawfully established to practice medicine or dentistry in another Member State or Switzerland. However, we do not consider that this will result in a significant increase in the volume of transactions within a pharmacy and a number of pharmacies will not be affected by these proposals at all. Nor do we believe that the proposals impact in any way on equality, including gender, issues. However, **we would welcome views from the community pharmacies on the likely impact of these proposals and whether they have identified and quantified any additional direct or indirect costs (recurring and non-recurring) that may arise from the proposals.**

Circulation of Proposals

24. This consultation is being made available on the MHRA website – www.mhra.gov.uk - and replies are welcome from all interested parties.

How to Respond

25. Comments, using the attached response form (**Annex D**), as appropriate, can be e-mailed to: Part3@mhra.gsi.gov.uk or they may be addressed to: Roy Drepaal, 16/139, Medicines and Healthcare Products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ. **Comments must arrive no later than 12 October 2007.**

Responses: Confidentiality & Disclaimer

26. The information you send us may be passed to colleagues within the DH, Home Office, the Government or related agencies. Furthermore, 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. If you want the information that you provide to be treated as confidential, it would be helpful if you could explain why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on us. Your personal data will be processed in accordance with the DPA – in the majority of circumstances this will mean that your personal data will not be disclosed to third parties.

27. Please ensure that your response is marked clearly if you wish your response and name to be kept confidential. Confidential responses will be included in any statistical summary of numbers of comments received and summary of views expressed.

Making copies of the replies available to the public

28. A summary of the responses received will be published in accordance with the Cabinet Office Code of Practice on Consultation and will be published on the Agency's website. Copies will also be available on request from the MHRA.

Anne Thyer

Anne Thyer
MHRA
020 7084 2642

ANNEX A

This consultation follows the Cabinet Office Code of Practice on Consultation - the criteria for which are set below.

1. Consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of the policy [NB: see paragraph 2 of letter]
2. Be clear about what your proposals are, who may be affected, what questions are being asked and the timescale for responses.
3. Ensure that your consultation is clear, concise and widely accessible.
4. Give feedback regarding the responses received and how the consultation process influenced the policy.
5. Monitor your department's effectiveness at consultation, including through the use of a designated consultation co-ordinator.
6. Ensure your consultation follows better regulation best practice, including carrying out a Regulatory Impact Assessment if appropriate.

The full code of practice is available at: www.cabinet-office.gov.uk/regulation/Consultation

ANNEX B

CURRENT LEGAL POSITION

Article 70 of Directive 2001/83/EC on the Community Code for Medicinal Products for Human Use provides that Member States must classify certain products as subject to “medical prescription”. In order to be accepted by a United Kingdom pharmacist, a prescription for such a product must comply with the requirements of section 58 of the Medicines Act 1968. This section provides that medicines, within the scope of a specified order, cannot be sold by retail, or supplied in circumstances corresponding to a retail sale, except in accordance with a prescription given by an appropriate practitioner.

The specified order is the Prescription Only Medicines (Human Use) Order 1997 (SI 1997/1830). By Article 2 it specifies that doctors, dentists, veterinary surgeons and veterinary practitioners are appropriate practitioners for the purposes of section 58.

The Article also specifies nurses and pharmacists as appropriate practitioners for some medicines, subject to certain conditions. The medicines and relevant conditions are set out in Articles 3A and 3B and in the relevant Schedules to the Order. (Other Member States do not permit nurses and pharmacists to issue prescriptions and therefore the current proposals relate only to doctors and dentists.)

A doctor is defined as “a registered medical practitioner within the meaning of Schedule 1 of the Interpretation Act 1978”. This, in turn, means a fully registered person within the meaning of the Medical Act 1983. A dentist is defined as “a person registered under the Dentists Act 1984 or entered in the list of visiting EEA practitioners under Schedule 4 to that Act”.

A doctor or dentist who is an EEA national can apply to be registered in the UK and hence become an appropriate practitioner for the purposes of section 58. The procedure for registration does not require the doctor or dentist to be practising or established within the UK. So it is possible for a doctor or dentist who practises in another Member State to place their name on the relevant professional register in the UK and this will enable them to have their prescriptions dispensed by pharmacists in the UK.

ANNEX C

ARTICLE 15 OF THE POM ORDER

Prescriptions

15. (1) For the purposes of section 58(2)(a), and subject to paragraph (3), a prescription only medicine shall not be taken to be sold or supplied in accordance with a prescription given by an appropriate practitioner unless the conditions specified in paragraph (2) are fulfilled.

- (2) The conditions referred to in paragraph (1) are that the prescription—
- (a) shall be signed in ink with his own name by the appropriate practitioner giving it;
 - (b) shall, without prejudice to sub-paragraph (a), be written in ink or otherwise so as to be indelible, unless it is a health prescription which is not for a controlled drug specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations, in which case it may be written by means of carbon paper or similar material;
 - (c) shall contain the following particulars—
 - (i) the address of the appropriate practitioner giving it,
 - (ii) the appropriate date,
 - (iii) such particulars as indicate whether the appropriate practitioner giving it is a doctor, a dentist, a supplementary prescriber, a community practitioner nurse prescriber, a nurse independent prescriber, a pharmacist independent prescriber, a veterinary surgeon or a veterinary practitioner,
 - (iv) where the appropriate practitioner giving it is a doctor, dentist, a supplementary prescriber, a community practitioner nurse prescriber, a nurse independent prescriber or a pharmacist independent prescriber, the name, address and the age, if under 12, of the person for whose treatment it is given, and
 - (v) where the appropriate practitioner giving it is a veterinary surgeon or a veterinary practitioner, the name and the address of the person to whom the prescription only medicine is to be delivered and a declaration by the veterinary surgeon or veterinary practitioner giving it that the prescription only medicine is prescribed for an animal or herd under his care;
 - (d) shall not be dispensed after the end of the period of 6 months from the appropriate date, unless it is a repeatable prescription in which case it shall not be dispensed for the first time after the end of that period nor otherwise than in accordance with the directions contained in the repeatable prescription;
 - (e) in the case of a repeatable prescription which does not specify the number of times it may be dispensed, shall not be dispensed on more than two occasions unless it is a prescription for an oral contraceptive in which case it may be dispensed 6 times before the end of the period of 6 months from the appropriate date.

(3) For the purposes of paragraph (1) the prescription may, as an alternative to fulfilling the conditions specified in paragraph (2)(a) and (b), fulfil instead the conditions specified in paragraph (4), unless the prescription is a health prescription for a controlled drug specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations or is given by a veterinary surgeon or a veterinary practitioner.

(4) The conditions referred to in paragraph (3) are that the prescription shall be created in electronic form and signed with an advanced electronic signature and transferred to the person by whom it is dispensed as an electronic communication (including where it is so transferred through one or more intermediaries).

(5) The prohibition on sale or supply imposed by section 58(2)(a) shall not apply where a prescription only medicine is sold or supplied other than in accordance with a prescription given by an appropriate practitioner and —

- (a) the reason the sale or supply is not in accordance with such a prescription is that a condition specified in paragraph (2) or (4) is not fulfilled; and
- (b) the person selling or supplying the prescription only medicine has exercised all due diligence and believes on reasonable grounds that the condition is fulfilled.

(6) In paragraph (2) “appropriate date” means—

- (a) in the case of a health prescription, the date on which it was signed by the appropriate practitioner giving it or a date indicated by him as being the date before which it shall not be dispensed; and
 - (b) in every other case, the date on which the prescription was signed by the appropriate practitioner giving it,
- and, for the purposes of sub-paragraphs (d) and (e) of that paragraph, where the health prescription bears both the date on which it was signed and a date indicated as being that before which it shall not be dispensed, the appropriate date is the later of those dates.

(7) In this Article—

“advanced electronic signature” means an electronic signature which is—

- (a) uniquely linked to the signatory,
- (b) capable of identifying the signatory,
- (c) created using means that the signatory can maintain under his sole control, and
- (d) which is linked to the data to which it relates in such a manner that any subsequent change of data is detectable;

“electronic communication” means a communication transmitted (whether from one person to another, from one device to another or from a person to a device or vice versa)—

- (a) by means of a telecommunication system (within the meaning of the Telecommunications Act 1984, or
- (b) by other means but while in an electronic form; and

“signatory” means the appropriate practitioner giving the prescription.

ANNEX D

CONSULTATION RESPONSE:

Please write or (preferably) e-mail to:

Roy Drepaal,
16/139
Medicines and Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London, SW8 5NQ.

E-mail: Part3@mhra.gsi.gov.uk

From :

PROPOSALS TO AMEND SECTION 58 OF THE MEDICINES ACT 1968 AND ARTICLE 2 OF THE POM ORDER TO ENABLE UK PHARMACISTS TO DISPENSE PRESCRIPTION ONLY MEDICINES PRESCRIBED BY DOCTORS AND DENTISTS REGISTERED IN EUROPEAN MEMBER STATES AND SWITZERLAND

- * 1. I support the proposals
- * 2. I have no comment to make on the proposals
- * 3. My comments on the proposals are below/attached.
- * 4. My suggestions for inclusion in professional guidance are:

* *My reply may be made freely available.*

* *My reply is confidential.*

* *My reply is partially confidential (indicate clearly in the text any confidential elements)*

Signed: _____

* *Delete as appropriate*