

To: Interested Organisations

Our reference: MLX MLX 383

Date: 19 November 2013

Dear Sir/Madam

PROPOSALS FOR AMENDMENTS TO THE HUMAN MEDICINES REGULATIONS 2012 TO ALLOW WIDER ACCESS TO NALOXONE FOR USE IN EMERGENCIES

Introduction

1. We are writing to consult you in accordance with section 129(6) of the Medicines Act 1968 about a proposal to allow wider access to naloxone for the purpose of saving life in an emergency. This would be achieved by an amendment of the Human Use Regulations 2012. The proposal is aimed at reducing deaths from heroin overdoses. The consultation document has been jointly produced by the UK Health Departments and the Medicines and Healthcare products Regulatory Agency (MHRA)

Application to England, Wales, Scotland and Northern Ireland

2. This consultation is also being made available in Wales, Scotland and Northern Ireland. The proposed changes to legislation would apply throughout the United Kingdom.

Current Legal Position

3. Under Regulation 214 of the Human Medicines Regulations 2012, the administration of parenteral (injectable) medicines is restricted. Unless self-administered they may only be administered by an appropriate practitioner or a person acting in accordance with the directions of an appropriate practitioner. Regulation 238 and Schedule 19 of the Human Medicines Regulations (copy at Annex A) provide an exemption from this restriction to enable the parenteral administration of a specified list of medicines by anyone where the administration is for the purpose of saving life in an emergency. The effect of the exemption is to allow administration at the time of an emergency if the person administering has access to the medicine. The type of setting where this is most likely to occur is in hospitals or ambulances. However, in other non-medical settings the availability of medicines listed in Schedule 19 is restricted as they cannot be supplied in advance to anyone who might need to use them in an emergency.

Background

4. Naloxone is a parenteral medicine used as an antidote in opioid overdose. It is on the Schedule 19 list of medicines which may be administered in an emergency. Naloxone is used in hospitals and carried routinely on ambulances to treat patients suffering from severe

respiratory depression following an opioid overdose but cannot currently be supplied in advance for use in other settings such as hostels and many drug treatment centres.

5. The Advisory Council on the Misuse of Drugs (ACMD) is an independent expert body that advises Government on drug-related issues in the UK. The ACMD has advised that naloxone should be made more widely available as a way of reducing deaths from heroin overdoses.

6. Following the ACMD recommendation, Aurum Pharmaceuticals Ltd sought a marketing authorisation from MHRA for a revised form of packaging with a view to making it easier for individuals who are not trained clinicians, e.g. hostel workers, to administer. The Commission for Human Medicines approved the variation to the marketing authorisation in December 2012 for the “community packs” indicated for emergency use in both health facilities and non-medical settings by appropriate individuals for the complete or partial reversal of respiratory depression induced by natural and synthetic opioids.

Proposals

7. Currently, drug treatment services are commissioned by the NHS and local authorities. In the light of both the ACMD recommendation and the CHM approval of community packs for use by people who are not clinicians, it is proposed to amend the Human Medicines Regulations 2012 to allow people providing drug treatment services to supply naloxone to anyone requiring access to it for use in an emergency. The amendment is aimed at making stocks of naloxone available in settings which drug users are likely to access, for example, hostels. It will also allow family members or carers to receive direct supplies of naloxone which they can administer in an emergency if needed. The proposal will apply to publicly commissioned and/or publicly provided drug treatment services. We welcome views on this proposal.

8. It is anticipated that organisations which intend to use these new provisions to widen the supply of naloxone would seek to ensure that people likely to be administering naloxone be trained in how to respond to an overdose, including when and how to use naloxone. Such training programmes could build on past and existing initiatives, including:

- the National Treatment Agency’s 2011 overdose and naloxone training programme for families and carers pilot: <http://www.nta.nhs.uk/uploads/naloxonereport2011.pdf>
- The Scottish Drugs Forum’s Take Home Naloxone Overdose Intervention Training: <http://www.sdf.org.uk/drug-related-deaths/take-home-naloxone-thn-overdose-intervention-training/>
- The Welsh Government’s take-home naloxone programme: <http://wales.gov.uk/topics/housingandcommunity/safety/substancemisuse/publications/naloxone/?lang=en>

Regulatory Impact Assessment

9. The proposal is intended to improve public health by widening access to naloxone. Whilst these proposals will not impose a cost compliance on business, charities or the voluntary sector or result in a cost saving, the proposed change to the legislation to relax the current restrictions is likely to have some impact on affected groups and manufacturer(s) of naloxone. In order to substantiate the anticipated impact and likely reaction to the proposals it would be helpful to obtain answers to the questions on proposed inclusion criteria and their impact listed in the reply slip attached.

Comments

10. You are invited to comment on the proposed changes set out at paragraph 7 above and their impact.

Circulation of Proposals

11. This consultation letter is being sent in hard copy to those organisations listed. Copies of the consultation are also available from our website - www.mhra.gov.uk and replies are welcome from all interested parties. A form is attached for your reply. Comments should be addressed to Judith Thompson, MHRA, 5th Floor, 151 Buckingham Palace Road, London SW8 5NQ (or e-mail to Judith.m.thompson@mhra.gsi.gov.uk) to arrive no later than 7 February 2014. Comments received after this date will not be taken into account. The DH/MHRA will not enter into any correspondence concerning these proposals.

12. The Commission on Human Medicines will be asked to consider the proposals in the light of comments received and their advice will be conveyed to Ministers. Subject to the agreement of Ministers, we plan to implement the changes by Statutory Instrument in XXX. Statutory Instruments are available from the Stationery Office and may also be viewed on their website <http://www.hms.o.gov.uk>

Making copies of the replies available to the public

13. To help informed debate on the issues raised by this consultation, and within the terms of the Code of Practice on Access to Government Information, the Agency intends to make publicly available copies of comments that it receives. Copies will be made available as soon as possible after the public consultation has ended.

14. The Agency's Information Centre at 151 Buckingham Palace Road will supply copies on request. An administrative charge, to cover the cost of photocopying and postage, may be applied. Alternatively, personal callers can inspect replies at the Information Centre by prior appointment (telephone 020 3080 6000).

15. It will be assumed that your comments can be made publicly available in this way, unless you indicate that you wish all or part of them to be treated as confidential and excluded from this arrangement.

Yours faithfully

Judith Thompson
Policy, Government and Corporate
MHRA

To : Judith Thompson
MHRA
5th Floor
151 Buckingham Palace Road
LONDON SW1W 9SZ

From : _____

CONSULTATION LETTER MLX : Amendments to the Human Medicines Regulations 2012 to widen access to naloxone for use in an emergency

A. Your response to the proposals

- * 1. I support the proposals contained in the MLX
- * 2. I have no comment to make on the proposals in the MLX
- * 3. My comments on the proposals in the MLX are below/attached.

Comments:

B. The relevance and impact of the criteria

If you are someone who:

- does not yet have access to naloxone
- interacts with opiate users on a regular basis
- can reasonably be expected to be present when a user experiences an overdose

please indicate in what capacity you have contact with users and answer questions i-vii below:

housemate of user parent of user outreach worker hostel staff/operator
friend of user other (please specify)

i) Do you currently have access to naloxone? If yes, through what mechanism?

ii) If you did not have access to naloxone before, would this proposal allow you to access/receive it?

iii) If you are eligible to access naloxone under the proposal, would you or your organisation consider stocking naloxone and completing (mandatory) training in administering it?

iiia) If you answered question iii) with yes, can you please indicate how many units you are expecting to request/buy and use in a twelve month period under this proposal (assuming that one unit of naloxone would treat one overdose)?

iv) Are you aware of any risks associated with the use of naloxone? Do you think there is potential for abuse in allowing wider access to naloxone?

v) Do you have regular contact with individuals who inject opiates such as heroin? How often do you see them?

vi) How many overdoses have you observed in the past 12 months?

vii) Where/in what setting have these overdoses occurred (e.g. hostel/private home of drug user etc.)?

C. Naloxone manufacturers

If you are a manufacturer of naloxone: Considering the likely demand for naloxone among the eligible groups under this proposal, how many additional units of naloxone might you expect to sell per year?

D. How we treat your response

* 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

SCHEDULE 19 Medicinal products for parenteral administration in an emergency

- Adrenaline 1:1000 up to 1mg for intramuscular use in anaphylaxis
- Atropine sulphate and obidoxime chloride injection
- Atropine sulphate and pralidoxime chloride injection
- Atropine sulphate injection
- Atropine sulphate, pralidoxime mesilate and avizafone injection
- Chlorphenamine injection
- Dicobalt edetate injection
- Glucagon injection
- Glucose injection
- Hydrocortisone injection
- Naloxone hydrochloride
- Pralidoxime chloride injection
- Pralidoxime mesilate injection
- Promethazine hydrochloride injection
- Snake venom antiserum
- Sodium nitrite injection
- Sodium thiosulphate injection
- Sterile pralidoxime

MLX xxx CONSULTATION LIST

NB: this list is not intended to be exhaustive. Copies of the consultation are also available from our website - www.mhra.gov.uk – and replies are welcome from all interested parties.

Advisory Council on the Misuse of Drugs
All Party Pharmaceutical Group
Ambulance Service Association
Ambulance Trusts in England, Wales, Scotland and Northern Ireland
Association of British Health Care Industries
Association of British Pharmaceutical Industries
Association of Independent Multiple Pharmacies
Association of Professional Ambulance Personnel
British Association of Pharmaceutical Wholesalers
British Dental Association
British Generic Manufacturers Association
British Institute of Regulatory Affairs
British Medical Association
British Pharmacological Society
Chemist & Druggist
College of Emergency Medicine
College of Paramedics
Community Pharmacy Northern Ireland
Company Chemists Association
Consumers Association
Co-operative Pharmacy Technical Panel
Dispensing Doctors Association
Drug & Therapeutics Bulletin
European Association of Hospital Pharmacists
General Dental Council
General Medical Council
General Pharmaceutical Council
General Practitioners Committee
Guild of Healthcare Pharmacists
Health & Safety Executive
Health Professions Council
Health Service Commissioner
Health and Social Care Board Northern Ireland
Public Health Agency Northern Ireland
Health Which?
Independent Healthcare Advisory Services
Independent Community Pharmacist
Information and Statistics Division Scotland
Joint Consultants Committee
Joint Formulary Committee
Joint Royal Colleges Ambulance Liaison Committee
Medical Defence Union
Medical Protection Society Ltd
Medical Research Council
MIMS Ltd
National Association of Private Ambulance Services

National Board for Nursing, Midwifery and Health Visiting
National Consumer Council
National Patient Safety Agency
National Pharmaceutical Association
National Voices
Neonatal and Paediatric Pharmacists Group
NHS Alliance
NHS Confederation
Northern Ireland Consumer Council
OTC Bulletin
Patients Association
Pharmaceutical Journal
Pharmaceutical Services Negotiating Committee
Pharmaceutical Society for Northern Ireland
Prescription Pricing Authority
Primary Care Pharmacists Association
Proprietary Association of Great Britain
Public Health England
Public Health Laboratory Service
Royal College of Anaesthetists
Royal College of General Practitioners
Royal College of Midwives
Royal College of Midwives (Scottish Board)
Royal College of Midwives (Northern Ireland Board)
Royal College of Nursing
Royal College of Nursing (Northern Ireland)
Royal College of Nursing (Scotland)
Royal College of Nursing (Wales)
Royal College of Obstetricians & Gynaecologists
Royal College of Ophthalmologists
Royal College of Paediatrics and Child Health
Royal College of Pathologists
Royal College of Physicians (Edinburgh)
Royal College of Physicians (London)
Royal College of Physicians & Surgeons (Glasgow)
Royal College of Psychiatrists
Royal College of Radiologists
Royal College of Speech & Language Therapists
Royal College of Surgeons (England)
Royal College of Surgeons (Edinburgh)
Royal College of Surgeons (Faculty of Dental Surgery)
Royal College of Surgeons of England (Faculty of General Dental Practitioners (UK))
Royal Colleges of Physicians: Faculty of Pharmaceutical Medicine
Royal Colleges of Physicians: Faculty of Public Health Medicine
Royal Pharmaceutical Society
Royal Pharmaceutical Society (Scottish Pharmacy Board)
Royal Pharmaceutical Society (Welsh Pharmacy Board)
Royal Society of Chemistry
Royal Society for the Promotion of Health
St John's Ambulance
Scrip Ltd
Small Business Service

Social Audit Unit
Specialist Advisory Committee on Antimicrobial Resistance
The Care Commission
UK Medicines Information Pharmacists Group
Unison
Welsh Scientific Advisory Committee
Welsh Pharmaceutical Committee
Welsh Medical Committee
Health Professions Wales