

To: **Interested Organisations**

Our ref: **MLX 386**

30 May 2014

Dear Sir/Madam.

PROPOSALS FOR AMENDMENTS TO THE HUMAN MEDICINES REGULATIONS 2012: SUPPLY AND ADMINISTRATION OF MEDICINES UNDER PATIENT GROUP DIRECTIONS BY PARAMEDICS INVOLVED IN MARITIME AND COASTGUARD AGENCY CONTRACTED HELICOPTER SEARCH AND RESCUE OPERATIONS

Introduction

1. We are writing to consult you in accordance with section 129(6) of the Medicines Act 1968 about proposals relating to supply and administration of medicines under patient group directions (PGDs) by registered paramedics involved in maritime and inland search and rescue (SAR) operations. The proposals would allow the paramedics to supply and administer medicines under PGDs and would be achieved by amendments to the Human Medicines Regulations. The consultation document has been jointly produced by the Maritime and Coastguard Agency (MCA) and the Medicines and Healthcare products Regulatory Agency (MHRA).
2. This consultation is being made available in Wales, Scotland and Northern Ireland. The proposed changes to medicines legislation would apply throughout the United Kingdom.

Current legal position

3. Under medicines legislation, all medicines are classified according to three legal categories – prescription only (POM), pharmacy (P) and general sale list (GSL). The general rule is that POM and P medicines can only be sold or supplied at registered pharmacy premises by or under the supervision of a pharmacist. POMs are subject to the additional requirement that they must be sold or supplied in accordance with an appropriate practitioner's independent prescriber's prescription. An 'appropriate practitioner' is a doctor, dentist, or other independent or supplementary prescriber. GSL medicines can be sold from a wider range of premises such as supermarkets, provided that those premises can be closed to exclude the public (i.e. they are lockable) and the medicines are pre-packed.
4. PGDs provide an exemption from these restrictions. A PGD is a written instruction for the supply or administration of medicines to groups of patients who meet the criteria specified in the PGD. Medicines legislation requires that a PGD must be authorised by a doctor (or, if appropriate, a dentist) and a pharmacist, both of whom should have been involved in developing the direction. Additionally, the PGD must be authorised by the relevant appropriate body and contain certain particulars, set out in legislation. PGDs can only be used by certain groups of registered and regulated health professionals such as nurses, pharmacists and paramedics. Organisations using PGDs should designate a senior person responsible for ensuring that only competent, qualified and trained health professionals work under PGDs. The National Institute for Health and Care Excellence (NICE) has published good practice guidance for organisations and individuals developing, authorizing and using PGDs.
5. Currently, PGDs can be used in the NHS, including private and voluntary sector activity funded by

the NHS, certain independent healthcare settings registered with the Care Quality Commission and the armed forces, police and prison services. They cannot be used in private SAR services.

6. A further exemption allows registered paramedics to administer a range of injectable medicines on their own initiative for the immediate necessary treatment of sick or injured persons.

Background

7. Provision for helicopter search and rescue services will move from a service provided by the armed forces and civilian operators under contract to the MCA to a wholly contracted service in 2016. Two companies currently provide a UK wide service (collectively referred to as UK SAR). This will reduce to one from 2017 for a subsequent ten years. Both companies employ registered paramedics and rescue crew always have one paramedic who is responsible for the administration of medicines. There is no legal provision for registered paramedics employed by the civilian operators to use PGDs. While all registered paramedics are able to administer a list of injectable medicines, lack of access to PGDs means that SAR paramedics cannot use exactly the same range of medicines as their counterparts in other settings specifically in the armed forces and the NHS. This applies particularly to injectable medicines which are not on the paramedic exemption list and new medicines. At present, this is only a small number of medicines but it is expected to increase with time. Due to the processes involved, medicines cannot be added quickly to the paramedic exemption list. Amending the list is not, therefore, a practical alternative to PGDs. However, there is an expectation that civilian SAR provides an equivalent service to the military provision.

Proposals

8. UK SAR requested a change to medicines legislation to ensure their registered paramedics were able to access the same range of medicines in line with the NHS and the armed forces. The proposals were supported by the MCA. UK SAR has subsequently worked with the Agency and MCA to develop the proposals.

9. UK SAR have advised the Agency that they have comprehensive clinical structures in place which can be mapped to the Care Quality Commission (CQC) standards and outcomes for quality and safety although they are not required to register with the Commission. Governance is provided through a Medical Steering Committee which includes independent health professionals with expertise recognized by peers in emergency care. UK SAR are confident that they are able to meet the legal criteria for PGDs and ensure only qualified, competent and trained registered health professionals are able to access them. All SAR paramedics are required to undergo regular CPD updates in excess of the minimum requirements of the Health and Care Professions Council (HCPC). Before any new technique or drug is introduced additional training is provided.

10. We propose to amend the Human Medicines Regulations 2012 to allow MCA contracted providers of SAR operations to use PGDs. This will enable them to offer the same level of care to patients that would be available in the NHS and armed forces. It will also enable the service to respond to developments in emergency care practice. We also propose that the PGDs are authorised by the Medical Director of the MCA contracted service provider.

Impact Assessment

11. No Impact Assessment has been produced. The costs to the providers of accessing PGDs are considered to be very low. The principal benefit of the proposals is to ensure that casualties involved in SAR incidents have the same access to medicines as would have been the case when operations were carried out by the armed forces.

Comments

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

Circulation of Proposals

13. 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 **Friday 22 July**. Comments received after this date will not be taken into account. The DH/MHRA will not enter into any correspondence concerning these proposals.

14. 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 later this year. 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

15. 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.

16. 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).

17. 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,

Anne Ryan
MHRA Policy Division

To: Judith Thompson
MHRA
5th Floor
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LONDON SW1W 9SZ

From: _____

CONSULTATION LETTER MLX 386: Amendments to the Human Medicines Regulations 2012 to allow supply and administration of medicines under patient group directions by MCA contracted helicopter search and rescue operations

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. 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

MLX 386 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.

Asthma UK
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
Northern Ireland Ambulance Service
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