

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](http://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](mailto: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.hmso.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  
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From: \_\_\_\_\_  
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**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](http://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