Medicines and Healthcare products Regulatory Agency

Safeguarding public health

Our reference: **MLX 329**
Date: 30 September 2005

Dear Sir/Madam

PROPOSALS FOR AMENDMENTS TO THE MEDICINES (ADMINISTRATION OF RADIOACTIVE SUBSTANCES) REGULATIONS 1978 (MARS) AND THE PRESCRIPTION ONLY MEDICINES (HUMAN USE) ORDER 1997

Introduction

1. We are writing to consult you, in accordance with section 129(6) of the Medicines Act 1968, on proposals relating to aspects of the administration of radioactive medicinal products (RMPs) by suitably trained operators. The proposals in this letter would ensure that such operators are acting within the law. This would be achieved by amendments to the Medicines (Administration of Radioactive Substances) Regulations 1978 (the MARS Regulations) and the Prescription Only Medicines (Human Use) Order 1997 (the POM Order).

Application to England, Wales, Scotland and Northern Ireland

2. This consultation letter has been produced jointly by the Medicines and Healthcare products Regulatory Agency (MHRA) and the Department of Health. The proposed changes to the legislation would apply throughout the United Kingdom.

Background

3. The MARS Regulations 1978 implement a system of prior authorisation for clinicians wishing to administer radioactive medicinal products (RMPs). The MARS Regulations 1978 also established an expert advisory committee – the Administration of Radioactive Substances Advisory Committee (ARSAC) - to advise Ministers on the granting, revocation etc. of these prior authorisation certificates. These certificates list the RMPs that the clinician is authorised to administer and the purpose for which they may be used – diagnosis, therapy or research. The certificates are granted for five years (in the case of diagnosis and therapy) and two years for research.

4. The MARS Regulations, made under section 60 of the Medicines Act 1968 and enforced by the MHRA, require the administration of an RMP to be made by a doctor or dentist or a person acting in accordance with the directions of a doctor or dentist. The MARS Amendment Regulations 1995 require that these are written directions. Section 58 of the

Medicines Act restricts administration of prescription only medicines (which includes all RMPs) in similar terms (ie by a doctor, dentist or person acting in accordance with their directions). The Agency's view, confirmed by legal advice, is that to meet the requirements of the legislation, these directions have to be patient specific and that the same interpretation would apply to section 60 and the MARS Regulations 1978. The term "patient specific" refers to the direction being made for an individual, named patient (and not, for example, a general direction that would apply to any patient that has an appointment on any particular day).

5. The Ionising Radiation (Medical Exposure) Regulations 2000 (IR(ME) Regulations) implement EC Directive 1997/43/Euratom and lay down measures on health protection of individuals against the dangers of ionising radiation in relation to medical exposure. Under the Regulations, a suitably trained operator may undertake practical aspects of medical exposures and may authorise the decision to undertake an exposure to ionising radiation. The Regulations are not made under the Medicines Act and, in relation to administration of a RMP, the additional requirements of the MARS Regulations 1978 must still be met.

PROPOSALS

6. It has recently come to light that in nuclear medical services RMPs are widely administered in accordance with IR(ME)R procedures. These are implemented in practice by written protocols and guidelines provided by the ARSAC certificate holder. However, these protocols and guidelines are being used instead of rather than in addition to the requirements for written patient specific directions under the MARS regulations. We have received legal advice that under these arrangements, criminal offences may be committed if no change to the legislation is made.

7. There are practical difficulties for requiring the ARSAC certificate holder to write patient specific directions for each administration of a RMP. Many nuclear medicine procedures are carried out at locations remote from the specialist. At a number of locations, there is only one certificate holder and patients may not be treated if, for example, the certificate holder is on holiday or working remotely from the treatment site. This has the potential to impact adversely on the provision of patient care. There have been no reports of patient safety being compromised under the current procedures. Therefore**, we propose** to amend medicines legislation to bring existing practice within the scope of the law and allow RMPs to be administered by operators under protocols and guidance provided by the ARSAC certificate holder. The present provisions for administration in accordance with the patient specific directions of the certificate holder will remain as an alternative. **We would welcome views on these proposals.**

REGULATORY IMPACT ASSESSMENT

8. A Regulatory Impact Assessment is not required for these proposals because they will not impose a cost compliance on business, charities or the voluntary sector or result in a cost saving.

COMMENTS

9. You are invited to comment on the proposed changes to medicines legislation in relation to allowing the administration of RMPs by operators in accordance with protocols and guidelines provided by the ARSAC certificate holder.

CIRCULATION OF PROPOSALS

10. 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 Mrs Anne Ryan, MHRA, 16-142, Market Towers, 1, Nine Elms Lane, London SW8 5NQ (or e-mail to** anne.ryan@mhra.gsi.gov.uk **to arrive no later than 11 November 2005.** Ministers have agreed this consultation period should be less than the usual 12 weeks in view of the specialist nature of the proposals. Comments received after this date will not be taken into account. The DH/MHRA will not enter into any correspondence concerning these proposals.

11. The Commission for 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 by the end of the year. Statutory Instruments are available from the Stationary Office and may also be viewed on their website http://www.hmso.gov.uk

Making copies of the replies available to the public

12. 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.

13. The Agency's Information Centre at Market Towers 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 020-7 084 2351).

14. 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

Patricia Brown
DH

To: Anne Ryan
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LONDON SW8 5NQ

From : _____

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CONSULTATION LETTER MLX 329: PROPOSALS FOR AMENDMENTS TO THE MEDICINES (ADMINISTRATION OF RADIOACTIVE SUBSTANCES) REGULATIONS 1978 (MARS) AND THE PRESCRIPTION ONLY MEDICINES (HUMAN USE) ORDER 1997

* 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.

** 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 329: HARD COPY CONSULTATION LIST

Copies of the consultation are also available from our website - www.mhra.gov.uk

British Institute of Radiology
British Nuclear Medicine Society
British Medical Association
Institute of Physics and Engineering and Medicine,
Royal College of Physicians (Edinburgh)
Royal College of Physicians (London)
Royal College of Physicians & Surgeons (Glasgow)
Royal College of Radiologists
Royal College of Surgeons (England)
Royal College of Surgeons (Edinburgh)
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Royal Pharmaceutical Society of Great Britain (Scottish Department)
Royal Pharmaceutical Society of Great Britain (Welsh Department)
Society and College of Radiographers