

Tuesday, 15 May 2012

Dear colleague

Repeal of Section 10(7) of the Medicines Act 1968 – supplying medicines within healthcare services

I am writing to draw your attention to the imminent repeal of this provision, as part of the exercise to consolidate all UK medicines legislation into a single set of regulations. The repeal is necessary as the provision is incompatible with EU legislation.

Section 10(7) provided an exemption in UK law from the requirement for pharmacists who purchased medicines for supply other than direct to a patient or the public to hold a Wholesale Dealer's licence in certain circumstances. This allowed pharmacists to obtain medicines for supply to a range of organisations that need to hold stocks for later dispensing to patients.

The Medicines and Healthcare products Regulatory Agency (MHRA) is concerned to ensure that the necessary repeal of Section 10(7) does not adversely impact on the current arrangements for supply of medicines in these circumstances, and has drawn up the attached statement which provides an explanation to pharmacy on the MHRA's position on enforcement of the legislation after this repeal. This has been published on the MHRA's website.

In summary, the MHRA takes the view that the supply of medicines by community and hospital pharmacies to other healthcare providers in the UK who need to hold stocks for treatment of, or onward supply to their patients represents an important and appropriate part of the professional practice of both community and hospital pharmacy, and falls within the definition of provision of healthcare services. In such circumstances the MHRA will not deem such transactions as commercial dealing and pharmacies will not be required to hold a Wholesale Dealer's Licence.

The MHRA expects that this clarification will ensure that the range of organisations currently supplied with medicines under the Section 10(7)



exemption will be able to continue to receive them, and that the repeal of the exemption will not adversely impact on supply arrangements. If you would like to discuss the implications of this change for your own organisation please contact MHRA Customer Services on 020 3080 6000 who will be pleased to discuss this with you, or email info@mhra.gsi.gov.uk

Yours sincerely

A handwritten signature in black ink, appearing to read 'M. Jackman', is written over a light grey rectangular background.

Margaret Jackman
Head of EU and International Policy and Strategy
MHRA

SUPPLY OF MEDICINES BY PHARMACY TO HEALTHCARE PROFESSIONALS

Introduction

1. With effect from July 2012 Section 10(7) of the Medicines Act 1968 will be repealed. Section 10(7) currently provides an exemption in UK law from the requirement for a pharmacist to hold a Wholesale Dealer's Licence if they trade in medicines in certain circumstances. Its repeal is necessary in order to comply with EU legislation, in particular, Articles 77(1) and 77(2) of Directive 2001/83/EC which require anyone undertaking wholesale dealing activities to hold a Wholesale Dealer's Licence.
2. This note provides guidance for pharmacists working in registered pharmacies and in hospitals on how the MHRA, as the regulator responsible for the enforcement of EU legislation, proposes to address the implications of the necessary repeal of Section 10(7) for the supply of licensed medicines by pharmacy other than direct to the public.

The legislation governing supply of medicines

3. The legislation and underpinning guidance requires persons trading in medicines to hold a Wholesale Dealer's Licence and to apply Good Distribution Practice (GDP) standards and have a suitably experienced "Responsible Person" named on the licence to ensure that medicines are procured, stored and distributed appropriately. The legislation also ensures that medicines can only be supplied to other wholesale dealers, pharmacists or other persons authorised or entitled to supply medicines to the public. These rules also serve to provide confidence in the medicines supply chain by regulating the transit of medicines from manufacturer to patient.

How this applies to supply of medicines by pharmacy in the UK

4. The MHRA is concerned to ensure that the repeal of the Section 10(7) exemption does not adversely impact on arrangements for supply of medicines in the UK. In determining how to address this issue, the MHRA has taken careful account of the particular arrangements for delivery of healthcare in the UK which involve a wide range of individuals and in a diverse range of locations. In particular:

- Many healthcare professionals and others authorised or entitled to supply medicines to the public in the UK and others authorised to receive medicines, need to hold stocks of medicines for a range of purposes including local healthcare provision and look to a local community or hospital pharmacy to supply them as part of their professional practice.
- In contrast, some pharmacies engage in commercial trade in medicines, not solely as part of their professional practice within the UK healthcare system.
- Pharmacists may also occasionally need to obtain small quantities of a particular medicine or medicines from another pharmacist in order to meet the needs of individual patients.

MHRA enforcement

5. The MHRA takes the view that the supply of medicines by community and hospital pharmacies to other healthcare providers in the UK who need to hold medicines for treatment of or onward supply to their patients represents an important and appropriate part of the professional practice of both community and hospital pharmacy and falls within the definition of provision of healthcare services. In such circumstances, the MHRA will not deem such transactions as commercial dealing and pharmacies will not be required to hold a Wholesale Dealer's Licence.
6. Conversely, pharmacists who wish to engage in commercial trading in medicines are entitled to do so only if they hold a Wholesale Dealer's Licence and comply with all the relevant requirements. As the authority responsible for enforcement the MHRA will take appropriate action to enforce the requirement of the legislation and will require any commercial trade in medicines to be undertaken only by holders of a Wholesale Dealer's Licence.
7. Pharmacists needing to obtain small quantities of a medicine from another pharmacist to meet a patient's individual needs may do so without the need for the supplying pharmacy to hold a Wholesale Dealer's Licence only if the transaction meets all of the following criteria:
 - It takes place on an occasional basis and

- The quantity of medicines supplied is small and intended to meet the needs of an individual patient and
 - The supply is made on a not for profit basis.
8. This restriction does not apply to exchange of stock between pharmacies that are part of the same legal entity.
9. Guidance on Wholesale Dealer's Licences, the application process and a downloadable application form are available on the MHRA website at:
- <http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Informationforlicenceapplicants/Licenceapplicationforms/Wholesaledealerslicencesapplicationforms/index.htm>