

Guidance for pharmacists on the repeal of Section 10(7) of the Medicines Act 1968

With effect from 14 August 2012, Section 10(7) of the Medicines Act 1968 has been repealed. Section 10(7) provided an exemption in UK law from the requirement for a pharmacist to hold a Wholesale Dealer's Licence (WDA(H)) if they trade in medicines in certain circumstances. Its repeal was 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 an authorisation.

This note provides guidance for pharmacists working in registered pharmacies and in hospitals on how MHRA, as the regulator responsible for the enforcement of EU legislation, will 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

The legislation and underpinning guidance requires persons trading in medicines to hold a WDA(H) 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

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, 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 need to hold small quantities of medicines for 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

MHRA takes the view that the supply of medicines by community and hospital pharmacies to other healthcare professionals in the UK who need to hold small quantities of 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. Also community and hospital pharmacies may need to obtain small quantities of a medicine from other pharmacies to meet a patient's individual needs. Both these activities are considered by MHRA to fall within the definition of provision of healthcare services. In such circumstances, provided the transaction meets all of the following criteria MHRA will not deem such transactions as commercial dealing and pharmacies will not be required to hold a WDA(H):

- it takes place on an occasional basis
- the quantity of medicines supplied is small
- the supply is made on a not for profit basis
- the supply is not for onward wholesale distribution.

Conversely, pharmacies who wish to engage in commercial trading in medicines are entitled to do so only if they hold a WDA(H) and comply with all the relevant requirements. As the authority responsible for enforcement 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 WDA(H).

These restrictions do not apply to the exchange of stock between pharmacies that are part of the same legal entity, although where a legal entity holds a WDA(H) as one (or more) of its pharmacies is involved in the commercial trade of medicines, the supplying pharmacy must also be named on the WDA(H) if the stock supplied is for the purposes of wholesale.

Guidance on the need for a WDA(H), the application process and a downloadable application form are available on MHRA's website.

<http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Manufacturersandwholesaledealerslicences/index.htm> (applications)

<http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Informationforlicenceapplicants/Licenceapplicationforms/Wholesaledealerslicencesapplicationforms/index.htm> (forms and guidance)

<http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Feespayablefortheregulationofmedicines/Feesforwholesaledealer'slicences/index.htm> (fees)

<http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodDistributionPractice/Theinspectionprocess/index.htm> (the inspection process)

<http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:343:0001:0014:EN:PDF> (Good Distribution Practice)