

STATUS OF THIS DOCUMENT

This document provides information to pharmacists in Northern Ireland on both legal requirements and professional obligations that apply when trading medicines for human use.

1. BACKGROUND

Recent increases in the export of medicines have contributed to the experience of medicines supply problems, which have risked jeopardising patient care.

Therefore, in November 2009, the Pharmaceutical Society of Northern Ireland, in combination with the Medicines and Healthcare products Regulatory Agency (MHRA), the Association of the British Pharmaceutical Industry (ABPI), the British Association of Pharmaceutical Wholesalers (BAPW), the Department of Health, the Dispensing Doctors' Association, the Royal Pharmaceutical Society of Great Britain (RPSGB), the National Pharmacy Association, the Pharmaceutical Services Negotiating Committee, and other stakeholders, endorsed a joint guidance document: "*Trading Medicines for Human Use: Shortages and Supply Chain Obligations*".

The document is available from the MHRA website here:

<http://www.mhra.gov.uk/NewsCentre/CON062782>

2. LEGAL REQUIREMENTS FOR PHARMACISTS WITH AN MHRA WHOLESALE LICENCE

Owners of registered pharmacies in Northern Ireland wishing to engage in the wholesale of medicines must obtain a wholesale dealer's licence from the MHRA. The wholesale of medicines without such a licence is a criminal offence.

Furthermore, the holder of a wholesale dealer's licence may only legally obtain medicinal products from licensed manufacturers or licensed wholesale dealers in the UK or other EEA Member States¹. A licence holder obtaining products from outside of the regulated supply chain, **including obtaining stock from a pharmacy**, would be in breach of his licence and could face regulatory action against his licence and/or criminal prosecution.

A legal entity with premises registered as a pharmacy with the Pharmaceutical Society of Northern Ireland (PSNI) as well as being licensed as a wholesale dealer by the MHRA, is legally required to comply with legislation pertaining to **both** PSNI premises registration and MHRA licensing.

The legal entity should ensure that its 'retail' and 'wholesale' transactions are clearly separated and fully documented.

¹ Regulation 9 (1) of the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 No 2789

Businesses should not procure medicinal products from a wholesaler for pharmacy use and then transfer these products to the wholesale side of the business for supply by way of wholesale dealing.

3. ENSURING “THE NEEDS OF PATIENTS IN THE UK ARE COVERED”

Pharmacists with a wholesale dealer’s licence must be mindful of Regulation 8 (1) (b) of The Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005². This requires that the holder of a wholesale dealer’s licence shall ensure, insofar as that licence relates to relevant medicinal products and within the limits of their responsibility as a distributor of relevant medicinal products, “appropriate and continued supply” of such relevant medicinal products to pharmacies (and other persons who may lawfully sell such products by retail) **“so that the needs of patients in the United Kingdom are covered”**.

Therefore, in the scenario in which a wholesaler chose to trade medicines for export that were in short supply in the United Kingdom and as a consequence the needs of the patients in the UK were not met – the holder of the wholesale dealer’s licence could be deemed to have legally breached the Regulations. This could lead to removal of his licence, criminal prosecution and action against him by his professional regulatory body (with the ultimate sanction of removal from the pharmacist’s register). It could also threaten the continued registration of his pharmacy premises.

4. POTENTIAL ACTION BY YOUR PROFESSIONAL REGULATORY BODY IF FOUND EXPORTING MEDICINES IN SHORT SUPPLY IN THE UK FOR FINANCIAL GAIN

The exporting of medicines that are in short supply in the UK, for short term individual financial gain is seen by the Pharmaceutical Society of Northern Ireland as wholly unacceptable and contrary to professional behaviour as it threatens the medicines supply chain and therefore patient care.

Such activity could constitute a breach of the Code of Ethics for Pharmacists in Northern Ireland, the first principle of which is “*make the safety and welfare of your patients your prime concern*”, the fourth principle of which is “*exercise professional judgement in the interests of patients and the public*” and the seventh principle of which is “*act with honesty and integrity*”.

A registered pharmacist found to have exported medicines in short supply in the UK for financial gain may therefore be subject to a Statutory Committee hearing as to their fitness to be a registered pharmacist.

Further information, guidance or advice on the professional or legal obligations of the pharmacy profession in Northern Ireland can be obtained by contacting the Pharmaceutical Society of Northern Ireland on 028 9032 6927 or by e-mail info@psni.org.uk.

² <http://www.opsi.gov.uk/SI/si2005/20052789.htm>