

Trading Medicines for Human Use: Shortages and Supply Chain Obligations

Introduction

This paper sets out the key legal and ethical obligations on manufacturers, wholesalers, NHS Trusts, registered pharmacies and dispensing doctors in relation to the supply and trading of medicines. Recent increases in the export of medicines are a major contributor to supply problems and risk jeopardising patient care.

This guidance is relevant to market authorisation holders, manufacturers, pre-wholesalers, full-line wholesalers, short-line wholesalers, brokers, traders, dispensing doctors, registered pharmacies and NHS Trusts.

The Medicines Act 1968 and its supporting Statutory Instruments, provide that those who wholesale deal any medicinal product for human use are required to hold the necessary licence, unless an exemption applies. Conducting any of the specified activities listed in the Medicines Act, without the necessary licence or outside the conditions of an exemption, constitutes a criminal offence.

Article 81 of European Directive 2001/83, requires the maintenance of appropriate and continued supply of medicinal products by marketing authorisation holders and distributors. In 2005 two UK Statutory Instruments¹ were introduced which implemented this Article.

Manufacturers

Supplying Medicines: The legislation requires² that, where a manufacturer distributes by way of wholesale dealing any relevant medicinal product manufactured or assembled pursuant to his licence, they must comply with a number of requirements as if he was the holder of a wholesale dealer's licence. This includes the requirement to ensure, within the limits of his responsibility as a distributor of relevant medicinal products, the appropriate and continued supply of such relevant medicinal products to pharmacies and persons who may lawfully sell such products by retail or who may lawfully supply them in circumstances corresponding to retail sale so that the needs of patients in the United Kingdom are covered. A manufacturer that failed to comply with the requirements of the regulations could be subject to regulatory action by the MHRA.

Guidelines: The Department of Health has developed joint guidelines with both the ABPI and the BGMA. The guidelines "Notification and Management of Medicines Shortages"³ are designed to ensure best practice in the management of supply problems.

Wholesalers

Sourcing Medicines: 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 States.⁴ A licence holder obtaining products from outside of the regulated supply chain, including obtaining stock from a pharmacy

¹ SI 2005/2759 which amended the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994 (SI 1994/3144) and The Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 (SI 2005/2789).

² Regulation 2(3)(j) of The Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 No 2789

³ Available at www.dh.gov.uk/medicinesupply and www.abpi.org.uk

⁴ Regulation 9(1) of The Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 No 2789

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 by the RPSGB and also licensed as a wholesale dealer by the Medicines and Healthcare products Regulatory Agency (MHRA) would be legally required to comply with the legislation pertaining to both registration and licensing. It should ensure that its 'retail' and 'wholesale' transactions are clearly separated and fully documented. 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.

Supplying Medicines: The Regulations⁵ also require that a holder of a wholesale dealer's licence, insofar as that licence relates to relevant medicinal products, shall ensure, within the limits of his responsibility as a distributor of relevant medicinal products, the appropriate and continued supply of such relevant medicinal products to pharmacies and persons who may lawfully sell such products by retail or who may lawfully supply them in circumstances corresponding to retail sale so that the needs of patients in the United Kingdom are covered.

If a wholesaler chose to trade medicines for export that were in short supply in the UK and as a consequence the needs of patients in the UK were not met, the holder of a wholesale dealer's licence could be in breach of the Regulations, and could face regulatory action against his licence, and/or criminal prosecution. The requirements apply to all holders of a wholesale dealer's licence including pharmacists and pharmacy owners who hold a wholesale dealer's licence.

NHS Trusts

The Chief Pharmacist for England, Dr Keith Ridge, wrote to NHS Hospital Chief Pharmacists on 14th July 2009 about the exporting of medicines for short term financial gain. This letter set out that such activities were wholly unacceptable and contrary to acceptable professional behaviour as they threaten the medicines supply chain and therefore patient care. SHA pharmacy leads, working with the National Pharmaceutical Supplies Group, are asked to advise the Department if they become aware of such activities in hospital pharmacies.

Registered Pharmacies

The RPSGB states in its Law and Ethics Bulletin '*The Export of Medicines*' July 2009 that, the Code of Ethics requires pharmacists to make the care of patients their first concern and have advised that the export of medicines for commercial or financial gains could be considered a breach of Principle 2 of the Code of Ethics. This states that the pharmacist must exercise professional judgement in the interests of patients and the public and in doing so the pharmacist must be sure their professional judgement is not impaired by personal or commercial interests, incentives, targets or similar measures. The Code of Ethics requirement applies to all pharmacists.

Pharmacists exporting medicines or selling stock for exportation by others may be exacerbating existing supply problems or creating new supply problems. This is not in the best interests of patients or the public and pharmacists should carefully consider their ethical responsibilities to their patients and the public.

⁵ Regulation 8(1)(b) of The Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 No 2789

Pharmacists should also be aware that the holder of a wholesale dealer's licence may only legally obtain medicinal products for human use from licensed manufacturers or licensed wholesale dealers in the UK or other EEA Member States.⁶ It is, in the view of the RPSGB, unethical for a registered pharmacy to supply medicines to a wholesale dealer as they would be complicit in the breach of medicines legislation.

Dispensing Doctors

The General Practitioners' Committee (GPC) of the British Medical Association (BMA) and the Dispensing Doctors' Association have advised that in exporting medicines or selling stock for exportation by others, dispensing doctors should carefully consider their ethical responsibilities to their patients and the public. Patients' wellbeing must be Dispensing Doctors' overriding priority, followed by what is good for the wider NHS and what is good for the practice considered last. Patient care must never come second to business considerations.

The GPC and DDA have also reminded doctors that unless they have a wholesaler dealer's licence, it is a criminal offence under the terms of the Medicines Act 1968 for them to supply medicines otherwise than for the treatment of their own patients.

Conclusion

The various different parties in the supply chain are asked to bear in mind their obligations in respect of supply of medicines and to be aware of the consequences of exporting medicines for the supply of medicines to UK patients.

This document has been endorsed by the following organisations:

Association of the British Pharmaceutical Industry
British Association of Pharmaceutical Wholesalers
Department of Health
Dispensing Doctors' Association
Ethical Medicines Industry Group
General Practitioners Committee of the British Medical Association
Medicines and Healthcare products Regulatory Agency
National Pharmacy Association
Pharmaceutical Services Negotiating Committee
Royal Pharmaceutical Society of Great Britain

⁶ Regulation 9(1) of The Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 No 2789