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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 Human Medicines Regulations 2012 (SI 2012/1916) ("the 2012 Regulations"), 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 Regulations, without the necessary licence or outside the conditions of an exemption, constitutes a criminal offence.

Article 81 of European Directive 2001/83/EC, requires the maintenance of appropriate and continued supply of medicinal products by marketing authorisation holders and distributors. In 2005 two UK Statutory Instruments were introduced which implemented this Article. These have been superseded by the 2012 Regulations.

Manufacturers

Supplying Medicines: The 2012 Regulations requires[1] that, where a manufacturer distributes by way of wholesale dealing any relevant medicinal product manufactured or assembled pursuant to his licence, he 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 Medicines and Healthcare products Regulatory Agency (MHRA).

Guidelines: The Department of Health has developed joint guidelines with both the Association of the British Pharmaceutical Industry (ABPI) and the British Generics Manufacturers Association (BGMA). The guidelines "Notification and Management of Medicines Shortages"[2] 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.[3] 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 by the General Pharmaceutical Council (GPhC) and also licensed as a wholesale dealer by the MHRA would be legally required to comply with the legislation pertaining to both registration and licensing.

The MHRA considers it to be best practice, for a registered pharmacy, that also holds a wholesale dealer's licence to ensure that its 'retail' and 'wholesale' transactions are clearly separated and fully documented. This is to help that:

- Medicinal products for wholesale supply are kept in the licensed distribution chain at all times, under a full quality system that is expected to be operated by licensed wholesale dealers and Good Distribution Practice controlled conditions before they are distributed for retail supply; and
- The obligation in Article 81 of European Directive 2001/83/EC, for the maintenance of an appropriate and continued supply of medicinal products detailed below is being met by licensed distributors; this is because those in the supply chain can be clearer as to which medicines are going to meet the needs of patients in the UK.

Supplying Medicines: The 2012 Regulations[4] 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

[1] 39(8) of The Human Medicines Regulations 2012 (SI 2012/1916)
[2] Available at www.dh.gov.uk and www.abpi.org.uk

[3] Regulation 44(1) of The Human Medicines Regulations 2012 (SI 2012/1916)
[4] Regulation 43(2) of The Human Medicines Regulations 2012 (SI 2012/1916)

such products by retail or who may lawfully supply them in circumstances corresponding to retail sale so that the needs of patients in the UK 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. Strategic Health Authority (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 GPhC - Standards of conduct, ethics and performance apply to all pharmacists in their day to day practice. The complete set of GPhC standards of conduct, ethics and performance can be found on the GPhC website www.pharmacyregulation.org

The following principles and standards may be of particular relevance:

Principle 1 – Make patients your first concern
Standard 1.2 – Take action to protect the well-being of patients and the public

Principle 2 – To use professional judgement in the interests of patients and the public

Standard 2.1 – Consider and act in the best interests of individual patients and the public

Standard 2.2 - Make sure that your professional judgement is not affected by personal or organisation interests, incentives, targets or similar measures.

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.[5]

[5] 44(1) of The Human Medicines Regulations 2012 (SI 2012/1916)

Dispensing Doctors

The General Practitioners' Committee (GPC) of the British Medical Association (BMA) and the Dispensing Doctors' Association (DDA) 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 2012 Regulations[6] 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 Pharmaceutical Council
General Practitioners Committee of the British Medical Association
Medicines and Healthcare products Regulatory Agency
National Pharmacy Association
Pharmaceutical Services Negotiating Committee
Royal Pharmaceutical Society

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[6] 34(1) of The Human Medicines Regulations 2012.