

Wholesale dealing and exporting medicines

Richard Hough, a practitioner in pharmacy law, examines the legal and ethical pitfalls surrounding the parallel exporting of medicines



Three theories have been suggested to explain the reasons for the recent shortages of proprietary medicines in the UK. The first potential cause is the direct-to-pharmacy supply arrangements made by certain drug manufacturers with selected wholesalers. The second is the quota system whereby the distributors of those medicines impose restricted quotas upon purchasers. (Both of these arrangements are deemed essential by the pharmaceutical industry to ensure the integrity of the supply chain.) The third cause is the relatively new phenomenon in the UK medicines market of parallel exporting.

Parallel trade within the EU is a well established practice that accords with the key EU principles of the free movement of goods and increased competition. For many years, due to the relative strength of sterling against the Euro, the prevailing flow of medicines was that of importation into the UK. Parallel trade occurs when a product placed on the market in one country is bought by an intermediary who exports it to a second country. The trader's profits have to be sufficiently large to be attractive and this occurs where significant price differences arise between countries.

The medicines market operates on a different basis from most other competitive markets. Instead of prices being set by pharmaceutical companies, individual governments often determine them. Most EU countries control pricing but the ways in which they do so result in wide price variations which can be exacerbated by currency fluctuations.

The current weakness of sterling means that, instead of the parallel importing which occurred when sterling was strong, parallel exporting of medicines has become sufficiently attractive for, according to The Association of the British Pharmaceutical Industry, up to 1 in 10 pharmacies to be involved in parallel exporting of medicines.

Wholesale dealing

The starting point for the law surrounding wholesale dealing and exportation of medicines is section 8(3) of the Medicines Act 1968,

which outlines a blanket prohibition for wholesale dealing of medicinal products in the course of business unless done so in accordance with a wholesale dealer's licence.

Distribution by way of "wholesale dealing" of a medicinal product is defined in section 8(7) of the Medicines Act as the "sale or supply to a person who, in the course of business carried on by that person, receives the product either for selling or supplying it or for administering it or causing it to be administered to one or more human beings".

“Pharmacists exporting medicines may be exacerbating existing supply problems or creating new problems”

However, section 10(7) of the Medicines Act carves out an exemption to the blanket prohibition by stating that "the restrictions imposed by section 8(3) of this Act do not apply to anything which is done in a registered pharmacy by or under the supervision of a pharmacist and amounts to wholesale dealing, where such dealing constitutes no more than an inconsiderable part of the business carried on by the pharmacist at that pharmacy".

Although the meaning of "inconsiderable" in this context has not been judicially scrutinised and is far from certain, a pharmacy which wholesales no more than 5 per cent of its total medicine trade would be likely to fall within this exemption, and may therefore engage in wholesale dealing of medicines without a wholesale dealer's licence.

Section 1.2 of the 'Medicines Ethics and Practice Guide' (33rd edition) gives guidance as to with which organisations and persons pharmacists may engage in wholesale medicines dealing. The non-exhaustive list

includes practitioners (doctors, dentists and veterinary practitioners), other registered pharmacies, hospitals, primary care trusts and health authorities, but not holders of wholesale dealer's licences, who may only obtain medicine from restricted sources.

Legislation regulating medicines wholesale dealing [Regulation 9 of the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005] states that the restricted sources from whom the holder of a wholesale dealer's licence may obtain supplies of medicines as being only either: a manufacturer's licence holder or wholesale dealer's licence holder; or a person authorised by another EEA State to manufacture or distribute medicines by way of wholesale dealing.

This, therefore, prevents a wholesale dealer from buying medicines by way of wholesale from a registered pharmacy. The corollary of this is that pharmacists wanting to take advantage of the S10(7) exemption may not sell medicines to the holder of a wholesale dealer's licence. Infringement can potentially lead to a fine or imprisonment for a term not exceeding two years or both.

Register entries

When a registered pharmacy makes a wholesale supply of a POM an entry must be made in the prescription only register (unless the pharmacist maintains a copy of the order or invoice, which must be kept for two years from the date of sale or supply), which may be written or recorded electronically. The entry must include:

- The date on which the POM was sold or supplied
- The name, quantity, form and strength of the medicine sold or supplied
- The name and address, trade business or profession of the person to whom the medicine is sold or supplied, and
- The purpose for which it is sold or supplied.

The record keeping requirements apply also to controlled drugs, with the additional requirement that controlled drugs in schedules 2, 3 and 4 require a Home Office licence before they may be exported. (For schedule 2 controlled drugs, an entry in the Controlled Drugs Register is also necessary).

Whether a pharmacist has applied for and is a holder of a wholesale dealer's licence or is exploiting the S10(7) Medicines Act exemption, he may not wish to confine himself to the domestic market and engage himself directly (as opposed to through intermediaries) in export activities.

The Medicines and Healthcare products Regulatory Agency (MHRA) is the governmental body that issues export

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certificates on request to assist exporters of medicinal products to satisfy the import requirements of other countries. The export certificate indicates whether the products or manufacturer to which the certificate applies has met statutory requirements. Whilst the issuing of export certificates is managed by the MHRA, the requirement for having one is not and is determined by the importing country. As such, the MHRA has no legislative authority over the requirement of the importing country and cannot specify whether or not such certificates are needed. If there is any doubt about whether or not the regulatory authorities in an importing country may require an export certificate the embassy for the country for which the importation is intended should be contacted. Pharmacists should also check whether any special labelling and packaging requirements are necessary for postage and customs purposes. Information may be obtained from carriers experienced in the export of medicines and from HM Revenue and Customs.

Ethics reminder

A recent Royal Pharmaceutical Society Law and Ethics Bulletin (www.rpsgb.org/pdfs/LEBexportmedicines.pdf) has addressed concerns that pharmacists involved in exporting medicines have contributed to the recent supply problems and has sought to remind pharmacists of their professional obligations. It states: "The Code of Ethics requires pharmacists to make the care of patients their first concern. Pharmacists are advised that the export of medicines for commercial or financial gain could be considered a breach of Principle 2 of the Code of Ethics. This states that you must 'exercise your professional judgement in the interests of patients and the public' and in doing so you must be sure your professional judgement is not impaired by personal or commercial interests, incentives, targets or similar measures'."

The Society opines that 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 as well as considering the legal constraints placed upon them, pharmacists should also carefully consider their ethical responsibilities to their patients and the public.

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