

# DTP and competition law

**Richard Hough**, a practitioner in pharmacy law, looks at legal issues surrounding the growing practice of pharmaceutical manufacturers to restrict distribution of their products

Prior to March, 2007, all prescription medicines in the UK were distributed through a number of competing wholesalers, at which point Pfizer Ltd commenced selling its medicines directly to pharmacies (DTP), with distribution solely through one wholesaler, UniChem Ltd, which is paid a set fee for delivering them. Pharmacy contractors were dismayed at the prospect of reduced discounts, increased administration costs and decreased service provision to patients. The British Association of Pharmaceutical Wholesalers mounted an unsuccessful legal challenge to the decision, based on its concerns over decreased competition and higher NHS costs. AstraZeneca, GlaxoSmithKline and Lilly UK have all since decided to adopt similar distribution models.

### Supply chain integrity

The manufacturers' commonly stated reason for adoption of the DTP model is that of attempting to regain control over the integrity of — and thereby preventing the entering of counterfeit medicines into — the supply chain. Some critics claim, however, that the manufacturers' real aim is to fight parallel trade, whereby medicines are legally imported for resale into one European country, in which prices are set at a certain level, from other European countries, where prices are lower.

The unpopularity of these decisions among pharmacy contractors has been compounded by the imposition of restrictive quotas by the manufacturers in question. Several complaints over shortages of supply have been made to the Office of Fair Trading (OFT), which, in response to those complaints, launched a market study in April, 2007, into the distribution of medicines in the UK, which looked at the motivation for exclusive arrangements and their long term impact on competition.

EC competition law is governed by legal principles stated in Articles 81 and 82 of the EC Treaty.

Article 81 prohibits, as incompatible with the common market, any agreements, decisions by associations of undertakings or concerted practices which may affect trade between Member States, and which have as their object or effect the prevention, restriction or distortion of competition within the common market.

Article 82 prohibits abuse of a dominant position by one or more undertakings within

the common market or a substantial part of it insofar as it may affect trade between Member States.

The equivalent UK competition law is contained within Chapters I and II of the Competition Act 1998 (CA 1998), which are closely based on Arts 81 and 82. Any agreements found to be in breach of Art 81 may be deemed void and unenforceable, may be terminated or amended to achieve compliance with UK competition law. Additional sanctions for breaches of Arts 81 and 82 include damages, injunctions and

“**The more companies that adopt the model the greater the likelihood of the OFT launching an investigation or making a referral**”

financial penalties (an infringing undertaking may be fined up to 10 per cent of the undertaking's group's annual worldwide turnover). Under the "consistency principle", the UK competition authorities and courts must ensure, as far as possible, that questions arising under CA 1998 are interpreted consistently with Arts 81 and 82.

### Anti-competitive practices

Classic anti-competitive practices include:

- Price fixing
- Export bans (direct or indirect)
- Customer restrictions (eg, restrictive quotas)
- Territorial restrictions (eg, exclusive and selective distribution agreements)

Distribution agreements containing territorial restrictions are potentially anti-competitive. An agreement between a UK manufacturer and a UK wholesaler, which gives the wholesaler "exclusive territory" (ie,



the wholesaler is the only authorised distributor of the manufacturer's product in the UK) could potentially infringe both Art 81 and Chapter I.

The agreement, a vertical restriction (ie, where two or more firms operate at different levels of the production and distribution chain), may affect trade and competition within the common

market and the UK if it makes it more difficult for other businesses to break into the UK market for the product in question, or it cuts down on the sources of supply for UK customers.

Vertical restrictions are regarded more favourably by the competition authorities than horizontal ones (those entered into between firms operating at the same level of trade), unless one party enjoys considerable market power or the agreement is one of a number of similar arrangements having a cumulative effect on the market. Subject to market share restrictions, an EC vertical agreement block exemption (and a parallel UK exemption) affords exemption to certain categories of vertical arrangements, which would otherwise be in breach of Art 81. Anti-competitive agreements may also be granted exemption if they either are of minor importance (based on market share of the product or products in question) or they give rise to benefits which outweigh their anti-competitive effects.

In its report published in December, 2007, the OFT made several recommendations to the government. Any future widespread use of exclusive distribution arrangements could lead to longer term competition concerns and it stated that it would monitor the situation with the prospect of future investigation, if appropriate, as reduced competition in the wholesale distribution sector could ultimately adversely affect manufacturers' ability to obtain competitive bids for distributing their medicines. However, it also acknowledged that "such schemes may also give rise to efficiencies in distribution". The OFT also recommended that pricing reductions be implemented in the form of changes to the Pharmaceutical Price Regulation Scheme and that manufacturers adopt minimum service standards.

### Government response

The government's response to the report stated that service quality had not been, nor was likely to be, adversely affected by the decision of some pharmaceutical manufacturers to bypass the conventional wholesale system and supply medicines direct to pharmacies. There were no plans to introduce legislation to protect standards of supply and it would keep the situation under review. The government does, however, admit that the new system

could significantly increase the price of NHS medicines, since it removes competition from the wholesale level of the supply chain.

In a case referred to the European Court of Justice (ECJ)<sup>1</sup>, the Greek subsidiary of GlaxoSmithKline (GSKg) was accused by a Greek pharmaceutical wholesaler, Sot Lelos kai Sia EE (Lelos), of breaching Art 82 in respect of GSK's refusal to meet the wholesaler's order for certain medicines. Lelos asserted that the refusal in 2001 of an undertaking holding a dominant position to meet fully orders for three of its products placed by Lelos and other Greek wholesalers, with the intention of limiting their export activity and, consequently, the harm caused to it by parallel trade, was abuse of a dominant position and in breach of Art 82. The ECJ ruled on September 16, 2008, that Art 82 must be interpreted as meaning that an undertaking occupying a dominant position on the relevant market for medicinal products, which, in order to stop parallel exports carried out by certain wholesalers from one Member State to other Member States, refuses to meet ordinary orders from those wholesalers, is abusing its dominant position. However, it is for the national court to ascertain whether the orders are ordinary in the light of both the size of those orders in relation to the requirements of the market in the first Member State and the previous business relations between that undertaking and the wholesalers concerned. The ECJ, in affirming the actions of GSKg, has ruled that pharmaceutical companies have the right to restrict volumes of sales to wholesalers to the boundaries of ordinary use.

The system of restrictive quotas imposed by some pharmaceutical manufacturers is, therefore, likely to continue. As long as it does not refuse to meet the ordinary volumes of orders, a pharmaceutical manufacturer will not be deemed to be acting anti-competitively and will not be in breach of Art 82 or Chapter II.

It will be interesting to see whether the OFT decides that further investigation is warranted in light of AstraZeneca's, GSK's and Lilly UK's subsequent announcements to adopt DTP models. The OFT has stated that any future widespread use of exclusive distribution arrangements by other pharmaceutical suppliers might lead to longer term competition concerns. The likelihood is that, the more pharmaceutical companies who decide to adopt this model, the greater the likelihood of competition concerns being raised and the greater the likelihood that the OFT will launch an investigation or make a referral to the Competition Commission.

## Reference

1. Sot Lelos kai Sia EE et al v GlaxoSmithKline AVEE Farmakeftikon Proionton, formerly Glaxowellcome AVEE (joined cases C-468/06 to C-478/06) (2008/C 301/11)

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