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CLIENT ADVISORY

THE OFFICE OF FAIR TRADING RELEASES ITS REPORT INTO THE DISTRIBUTION OF PHARMACEUTICALS IN THE UK

The Office of Fair Trading (“OFT”) has published its report into the distribution of pharmaceuticals in the UK. In its recommendations for action, the OFT has preserved the right of all companies to select the distribution system, and the distributors, that suit its business. However, because of particular concerns in the pharmaceutical sector, the OFT has recommended that the Department of Health makes changes to the regulatory framework governing medicines prices and service levels for pharmacies and patients in the UK. These recommendations are intended to safeguard any adverse impact of “direct to pharmacy” distribution schemes on the interests of patients and the National Health Service (“NHS”). It has therefore recommended that the Department of Health implement a number of changes to the Pharmaceutical Price Regulation Scheme (“PPRS”) to ensure that changes in the structure of distribution of pharmaceuticals in the UK do not result in increased cost to the NHS or decreased service levels.

THE INVESTIGATION

A number of pharmaceutical manufacturers have, over the last several months, opted to simplify their supply chains. Many different schemes have been adopted, including: direct-to-pharmacy (DTP) schemes that replace wholesalers with logistics service providers (LSPs); a reduction in the number of wholesalers, mainly in favour of those that can provide for full national coverage; or exclusive distribution agreements with a single LSP.

One of the first to change was Pfizer, following an announcement in March 2007. Pfizer’s scheme involved the sale of prescription medicines directly to pharmacies and dispensing doctors, through Unichem—which was appointed as Pfizer’s sole LSP in the UK. This change, and the anticipation that other pharmaceutical manufacturers would follow suit, gave rise to a number of complaints being made to the OFT by pharmacies, dispensing doctors, wholesalers and smaller manufacturers. The British Association of Pharmaceutical Wholesalers brought an unsuccessful action to prevent Pfizer from implementing its plans.

The focus of the OFT’s investigation was whether changes to the traditional wholesale distribution of pharmaceuticals would have an adverse effect on

DECEMBER 14, 2007

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competition. Because of the widespread and diverse nature of the changes brought in by pharmaceutical manufacturers, the OFT determined to consider the effect of the changes on the competitiveness of the pharmaceutical distribution sector, rather than to investigate whether any of the manufacturers had infringed UK competition law. The OFT has broad powers to undertake these market studies. Having recently completed a significant study into the PPRS, the OFT has a close interest in the efficiency of the pharmaceutical sector in the UK. The current view of the OFT is that exclusive agreements for pharmaceutical distribution do not infringe UK competition law; nor do schemes under which the number of wholesalers is limited. But this view may change if its recommendations do not remove the competition concerns it identified.

The OFT identified three main concerns in relation to the introduction of DTP schemes or in the reduction in the number of wholesalers used by manufacturer:

A reduction in the discounts provided to pharmacies, leading to an increase in NHS costs.

Manufacturers have little incentive to grant pharmacists significant discounts to the list price. This is in contrast with the traditional distribution structure in which manufacturers sell to wholesalers who then compete on price to supply the branded products to the pharmacists. This could lead to higher NHS costs in order to guarantee pharmacy income.

A reduction in service levels to pharmacies and patients.

Under the traditional distribution model, wholesalers compete for the business for pharmacy business, based not only on price but also on standards of service. If manufacturers introduced DTP schemes—with distribution through one LSP or a limited number of providers—pharmacies will have no, or limited, choice on service levels offered by that provider. To guard against reduced service standards, pharmacies may have to increase stock levels to ensure prescription standards (which will be a cost to the NHS), and patients may have to wait longer to obtain their medicines

or search for available supplies. However, the OFT did acknowledge that DTP schemes could lead to efficiencies in distribution.

Increased concentration in the pharmaceutical wholesale distribution sector.

Should the use of exclusive distribution become more broadly adopted by pharmaceutical manufacturers, smaller wholesalers are likely to exit from the sector. This would lead to higher levels of concentration, assuming that manufacturers would appoint the same wholesalers as exclusive DTP providers, and assuming no new entry to the sector. These long term concerns were limited because there is currently no widespread adoption of the exclusive DTP model.

THE OFT'S RECOMMENDATIONS

The OFT has made recommendations that will affect the regulatory framework, in the context of the current renegotiation of the PPRS, rather than applying directly to the distribution models adopted by the manufacturers.

The first recommendation relates to the safeguarding of NHS costs. The second relates to the danger of service levels being eroded. The OFT made no recommendation on the possible adverse implications of the exclusive distribution model being adopted more broadly in the sector.

In relation to the safeguarding of NHS costs, the OFT has proposed two possible options for a modification to the PPRS framework:

■ **Option 1: a reduction in the list price for pharmaceuticals to reflect the removal of the discounts currently received by pharmacies.**

Under this option, the price agreed under the PPRS would effectively be the sale price *to pharmacies*, regardless of whether the sales were direct from manufacturers or indirect via wholesalers. Adjustments would be needed to the manner in which pharmacies are compensated in order to account for their lost purchasing profit. The 'clawback' mechanism that is currently part of the PPRS scheme might also be withdrawn. Option 1 is the preferred option for the OFT as it would result in greater transparency of prices paid by the NHS.

■ **Option 2: a requirement on pharmaceutical manufacturers to offer minimum list price discounts to pharmacies.**

This would be negotiated under the PPRS and would likely reflect the discounts generally available to pharmacies under the traditional wholesale arrangements. Option 2 would accommodate traditional and new distribution models, and would require fewer changes to the PPRS framework.

The OFT's second recommendation relates to its concerns about the deterioration in service standards. In order to safeguard against these, the OFT recommends that the NHS should determine the minimum service levels to pharmacies that are appropriate, and should require those levels to be required of manufacturers and their logistics service providers.

CONCLUSION

The general principle that all undertakings, even those in a dominant position, are entitled to select their own supply chain applies in the pharmaceutical sector as strongly as it does elsewhere. The OFT did not seek to impose a model for pharmaceutical distribution. It was "concerned to ensure that competition will remain in the wholesale sector so that each manufacturer will be able to select the method of distribution it would prefer, as well as the wholesalers and/or LSPs that it would prefer to use." As indicated above, the PPRS formed an important backdrop to the OFT's investigation because the PPRS was based in part on the traditional wholesale model. Rather than seek to limit the permissible types of distribution model, the OFT has suggested ways of adapting the PPRS pricing regime, and NHS requirements, so that it can accommodate the choices made by manufacturers on their distribution models.

The OFT did not make any specific recommendations in relation to the reduction in the number of wholesalers. However, if competition is significantly reduced in this sector in the future, this framework may require further investigation by the OFT. The OFT's rather unhelpful approach is to place responsibility back on the pharmaceutical sector as a whole. After pointing out that it is not in the interests of the manufacturing sector

for the intensity of distribution competition to decline, the OFT stated that it was "highlighting these findings to the industry in the expectation that manufacturers will take them on board. If more manufacturers do opt for exclusivity in distribution in such a way that competition in the sector is reduced significantly, future intervention by the OFT may be necessary." Having regard to the efficiencies that may be gained through exclusive arrangements, this need to balance collective concerns and individual benefits poses a real "prisoner's dilemma" for each pharmaceutical manufacturer in the UK. Although the non-interventionist approach of the OFT to the choices made by manufacturers is welcome, its ambiguous threats of future intervention will not ease the uncertainties faced by manufacturers in selecting long term changes in their supply chain models.

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