

Introduction

Is Pfizer's policy of charging Spanish wholesalers a higher price for products which they export than for products which they resell for consumption purely in Spain a breach of EU rules? The European parallel traders association EAEPC thinks it is, as it recently lodged a competition (Articles 81 & 82 EC) complaint with the European Commission. Pfizer rebukes the allegation, saying it is fully in compliance with Spanish and EU law.

Rather optimistically, EAEPC describes the matter as a 'simple open and shut case', but a decision from the Commission is unlikely to come soon. A similar EAEPC complaint against Pfizer is still pending after four years, as is an appeal by GlaxoSmithKline (GSK) to the European Court of First Instance (CFI) to annul a 2001 Commission decision against dual pricing, also in Spain, by the former Glaxo Wellcome (GW).

The GW case has already been running since 1998, and it has some way to go yet before the matter is resolved. Despite the appeal (case T-168/01) being made back in July 2001, an oral hearing at the CFI is not yet scheduled. Even if a decision does come this year, it is likely that the losing party will take it to the full European Court of Justice (ECJ), adding another two to three years before all appeal rights are exhausted.

At the heart of the matter lies parallel trade. In appealing to the CFI, GSK cited the Commission's failure 'to make a proper analysis of all the relevant factors because of its blind and mistaken commitment to parallel trade for prescription medicines as a vehicle to achieve market integration'. GSK and other manufacturers say this trade hits profits in destination countries and leads to product shortages in source countries. Spain is a major parallel exporter, especially to the UK and Germany. Three separate reductions in the Spanish wholesale margin have encouraged almost all wholesalers to export, either directly or through co-operatives such as Unycop, Edifa and Satel/Ofsa. Manufacturer attempts to curb the flow of parallel exports have therefore led to strong confrontation with wholesalers.

Pfizer's Trading Policy

In making changes to its distribution terms in Spain in 2005, Pfizer's declared aim has been to provide 'enhanced access, traceability, accountability and safety advantages' to patients and pharmacists. Pfizer SA is the leading pharmaceutical company on the Spanish market, with a 9.7% market share.

Pfizer SA first incurred EAEPC wrath in 2001, with a forerunner to its current scheme. Rather than getting wholesalers to sign a contract in advance, as GW did, declaring the goods were for use under the local healthcare system and to be marketed only through Spanish pharmacies and wholesalers, Pfizer's approach was to seek confirmation after the sale was undertaken that goods supplied at a 'provisional discount' to Pfizer's 'freely fixed' prices were dispensed in Spain. If this confirmation – in the form of invoice copies – was not forthcoming within six months of the sale, another invoice to recover the difference from the wholesaler would be raised by Pfizer. The parallel traders were especially annoyed that Pfizer announced its 2001 scheme just 13 days after the Commission's unequivocal decision against GW.

Two changes to Pfizer policy have taken place since 2004 and today a mixed system ensures adequacy of supply to all retailers. Direct sales to pharmacies are made through depositaries (prewholesalers) using logistical service providers. In response to protests from wholesalers and 'serious doubts' expressed by the health ministry that service levels to all 20,000 pharmacies could be maintained by direct distribution, Pfizer has also signed supply contracts with 16 wholesalers, cutting out 29 of the smaller players. The manufacturer requires proof each month that sales from contracted wholesalers are made within Spain in order to refund the difference between the price initially charged and the price for the national health service. Differences between the two are often large; several are over 100% and some (e.g. with Zarator [atorvastatin] 80mg) are more than 200%. The measure seems to have worked. According to EAEPC, 'there are virtually no Pfizer products leaving Spain'.

Inspiration for the latest measure came from Royal Decree 725/2003. This obliges wholesalers to implement batch tracking controls. They are required to inform their regional health authorities of the quantities, batch numbers and final destination of all sales. Manufacturers can then request these details on their own products from the same authorities.

Aseprofar, a grouping of some of the larger exporting wholesalers, has had its attempt to quash Law 725/2003 as a breach of Article 29 EC (barrier to exports) thrown out by the European Commission, and like GW it has an appeal pending with the CFI (case T-247/04).

In point of fact, most parties agree the government's

batch tracking Decree cannot work for technical reasons in its current format, but this did not deter Pfizer. The company devised and implemented its own traceability plan. It checks the sales by auditing each wholesaler and cross-referencing with data provided by the General Council of Pharmacists. Significantly, the Ministry of Health has signed an agreement with the General Council to allow pharmacists to provide the data required by Pfizer, and to certify the sales inside and outside Spain.

Does this Amount to Dual Pricing?

GW, Pfizer, and a third manufacturer (Lilly) – which in 2003 announced but does not seem to have enacted a similar price policy - argued their schemes did not represent dual pricing. This would only exist if the supplier was free to determine both prices, and this was not the case as domestic prices were fixed by the Spanish government.

In the case of the Pfizer and Lilly schemes, Article 100(2) of the Spanish Medicines Act 25/1990 (as amended by Law 55/99) provided further legitimacy. This states that price intervention only applies if products are dispensed inside national territory. This amendment was only enacted at the end of 1999 and was therefore unavailable to GW to use in its initial defence.

To qualify for the lower price, GW required wholesalers to declare in advance that goods were to be resold only for use in the Spanish healthcare system, while Pfizer's approach is to rebate the difference between the 'Pfizer price' and the 'regulated price' after it verified the sale was undertaken in Spain.

Model for Europe?

Openly advertising two prices for a single product to the same customer is only found in Spain. Elsewhere in Europe, industry-led discussions have centred on maintaining the separation of differentially priced national markets.

One solution considered jointly with the Commission was to have a higher 'official' price, freely set by the manufacturer in line with prices in other EU countries or in a narrow price band to restrict parallel trade and international price referencing, and lower actual price created by periodic rebates to poorer countries or those only willing to pay lower prices. Though employed in France with some success (parallel exports from there have been greatly curtailed), industry has gone cool on the idea of wider adoption of free pricing with rebates.

Implications for Strategy Development

Legal examination of Pfizer's scheme will have to wait until the GW case is resolved, and the prospects for over-turning the Commission's strongly-worded and detailed 2001 decision on this are not considered good. The CFI may only review the inferences drawn from the

facts and not the facts themselves.

Even if the eventual result is favourable to industry, the form of dual pricing used in Spain may not be capable of wider application. Few EU governments have tackled parallel trade with legal instruments as vigorously as Spain's.

The GW case has, however, importance beyond dual pricing. Some of the arguments made by the company against parallel trade, and originally refuted by the Commission – reduction in R&D budget and delayed market entry of new drugs in low-price countries - were similar to those of ECJ Advocate General Jacobs in his October 2004 opinion in Syfait vs GSK Greece (case C-53/03). Unfortunately, the ECJ did not consider this matter further, ruling that it had no jurisdiction to answer the questions referred to it. Therefore, the appeal by GSK to the CFI might be the next opportunity to test judicial response to industry's contention that parallel trade is economically harmful.

Restricting supplies in the source markets for parallel trade remains the most effective counterstrategy, though schemes must be carefully designed and implemented for both legal and practical reasons.

Quotas should not be overly-restrictive as it is vital the domestic market is adequately supplied at all times. A manufacturer without a dominant position can unilaterally implement measures to impede parallel trade without breaching Article 81 EC (ECJ linked cases C-2/01P & C-3/01P), but there must be no mention of an export ban, no monitoring of final destination and no threat of sanctions if the products are exported. Any form of an agreement with wholesalers must be avoided, emphasising instead that this is a non-negotiable decision solely by the manufacturer. The failure of the ECJ to rule in Syfait means there is no jurisprudence yet on whether impeding parallel trade with a dominant product amounts to abuse, breaching Article 82 EC.

PriceSpective is an international firm of pricing strategy experts, focused on providing strategic guidance in pricing and reimbursement to the pharmaceutical and biotechnology industries and has specific expertise in price and non-price measures to tackle parallel trade, including development and implementation of an effective methodology for supply allocation.

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