

MLex Ab Extra:

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THE INTERNAL MARKET FOR PHARMACEUTICAL GOODS

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In his report to the European Commission in May 2010, former EU commissioner Mario Monti noted that “a robust single market is key to the overall health of the European Union, because it represents the very foundation of the integration project.”¹ In the pharmaceutical sector, which is responsible for the very health of the EU, vile and highly questionable attempts to put in place measures affecting the free movement of pharmaceutical goods across the EU’s borders have left the EU’s internal pharmaceutical market in a less than healthy state. But why is this so?

The European Union was built on the principle of “free movement,” a principle that has been underpinned over the years by the creativity of entrepreneurs who have taken advantage of the wealth of opportunities generated by the internal market. However, market failures, commercial abuses and state interventions are today becoming a recurrent mantra of the EU market for medicines, undermining one of its major supporters: the parallel distribution industry.

Parallel distribution – using the internal market to offer savings

Parallel distribution, for those unfamiliar with the term, is the legal practice for authorised wholesalers buying medicines in one EU country, and selling them in another, generating savings for consumers, governments and health insurers alike. The practice is 100-percent legal in the EU, and is in fact encouraged by many enlightened governments to foster competition in the pharmaceutical sector and reduce their drug bills, particularly important at a time of economic austerity.

It also represents a significant component of the European medicinal supply chain, with a volume equating to roughly 3.5 billion euros² of the total EU pharmaceutical market per annum. Moreover, the German government estimated in a position paper to Günter Verheugen in 2008 that the cost savings for Germany through imports equated to 380 million euros annually.³

The practice also generates downward pressures on existing prices for medicines in the EU’s member states – the case of

Poland offers an example, where pressures on the imported price for a 21-pill pack of the contraceptive Cilest brought the regular price down from close to 20 zloty in November 2005 to close to 10 zloty in September 2009.

This concept of parallel distribution of medicines is therefore one of the success stories of the EU internal market, and it has been operating in Europe for more than 30 years now. The practice is highly sophisticated and tightly regulated, and has always functioned in a manner ensuring the safety and integrity of the supply chain.

Naturally, there are a number of leading pharmaceutical companies who abhor the practice. It eats away at their efforts to segment the EU into national markets, thereby extracting the highest possible price in each given market. Apparently they don’t like competition. Just like the recent case of the English pub landlady who bought a Greek TV card in order to show football games because it was three times cheaper than buying an equivalent card in the UK, parallel distributors work in the interests of the consumers – the buyers of medicines.

Recently some member states also seem to be forgetting about EU law in this area. So, while this is a success story, if the European Commission does not act to remind all players of their obligations under EU internal market and competition rules, drug bills will continue to spiral.

Internal market: obligations and threats

The free movement of goods within the EU is guaranteed by Articles 34 and 35 of the *Treaty on the Functioning of the European Union (TFEU)*, which clearly state that restrictions on imports and exports between member states are prohibited.⁴ Fair competition on the marketplace for all market actors is supposed to be upheld by Articles 101 and 102. All of these obligations should be policed by the European Commission. Whereas in the past the commission had a zero-tolerance approach to efforts to segment the EU market and was bold to take on big pharmaceutical interests in the name of the patient, their resolve has weakened in recent years.

As a result of this, an increasing number of measures have been enacted or are under consideration that represent a significant step towards reducing competition, and could set a dangerous precedent for the free movement of goods within the EU. These mechanisms aim in particular to directly or indirectly control distribution in the export countries to prevent resale in other member states. Typical measures include:

- Export bans
- Supply restrictions
- Sales conditions with different prices for national sales and exports – so-called dual pricing
- Notification systems

Export bans

This measure certainly constitutes the most obvious threat to the free movement of pharmaceuticals inside the EU. It is also perhaps the most draconian.

The most recent case can be found in Greece where, on 15 February this year,⁵ the national drug regulator (EOF) decided unilaterally to ban 28 medicines from export on public-health grounds. Explicitly described as a “temporary prohibition of parallel exports,” the decision was justified as a way to ensure that patients’ needs would be covered, pointing to shortages that have affected the market over the past years. A now recurring argument used by big pharmaceutical companies – the accusation has been flying for some time in the UK and has also recently appeared in France – to discredit the practice in the eyes of consumers, pharmacists and authorities alike.

Yet it simply lacks any evidence and fails to mention the root cause of the problem: supply restrictions that pharmaceutical manufacturers have increasingly employed in recent years.

Supply quotas

To counter the only competition for branded medicines existing on the market, numerous, and sometimes imaginative, strategies have been set up over the years: controlled supply of raw materials, product differentiation (various pack sizes and brand names), restrictive distribution agreements – or direct to pharmacy (DTP), and supply quotas, imposed on wholesalers who are suspected of supplying parallel importers. As the parallel distribution industry has the characteristics of a spot market and therefore tends to be limited by supply more than demand, it proves especially sensitive to such supply restrictions.

Today, wholesalers’ orders are more and more disregarded, with supply quotas for the major brands based on historical purchasing patterns. In some cases, wholesalers – including newly established ones – are not supplied at all. With no guarantee as to what the future supply situation will be, new

accounts cannot be sought and even existing ones may not be properly serviced in the event of a sudden surge in demand. The workload of the trade, as well as of pharmacists and doctors is increased, and anxiety is created amongst patients.

Restrictive supplies also contrast starkly with the instructions of the ECJ in the *Lelos* case, that manufacturers must supply “ordinary orders.”⁶

Furthermore, supply limitation by manufacturers is an artificial phenomenon, not designed to assist in their long-term planning and unrelated to temporary production difficulties. Based on unknown formulae set by companies’ head offices (often located outside the EU), it is inflexibly enforced. Their aim is primarily to reduce intra-brand competition, and lead to both a limitation of competition and to a foreclosure of national markets for the distribution of pharmaceuticals.

Another, stricter form of supply restriction that has appeared recently is the so-called DTP scheme, whereby only one, or a few wholesalers acting as logistics providers, ship medicines to pharmacies against a fee for the service. This model, established first in the UK, has eliminated regional wholesalers in the UK, undermined competition between wholesalers, and as a result brought higher prices for the NHS and a worse service to pharmacies.

These effects had been predicted in a previous analysis by the UK’s Office of Fair Trading, but the recommendations it made to the government were never taken up. That the DTP model has not spread wider geographically (with one exception, Poland) can largely be attributed to the fact that other restrictive modes, such as quota systems, have not been actively policed by competition authorities.⁷

Dual pricing

The logic of this system means that the same identical medicine would be priced differently depending on its final destination, generally with a lower price for medicines destined to the national market, and higher prices for medicines destined to another EU country. It is surely anathema to anyone who believes in the European project.

The most famous case which relates to such a measure is the *GlaxoSmithKline* case, whereby GSK, through its Spanish subsidiary GlaxoWellcome, introduced a so-called dual-pricing system in Spain in 1998. In 2001, following an investigation, the European Commission found that this scheme infringed EU competition law in a decision issued in May 2001 (2001/791). In October 2009, the European Court of Justice rendered a judgment recognising the anticompetitive nature of dual pricing, and at the same time encouraged the commission to re-examine the way it had addressed evidence provided in the GSK decision.⁸

We believe the commission must take the cue from the court, and push forward the market analysis to bring this case to fruition. It's a case which can have wide-reaching effects, and protect the ability of the commission to apply EU competition rules in other sectors too.

Notification systems

Most of the time dual-pricing systems go hand-in-hand with a system of notification. This is a unilateral measure imposed on wholesalers to inform the manufacturer of their sales data. It serves to identify on an ongoing basis whether wholesalers have in fact agreed to the manufacturer's demands and only supplied pharmacies within the 'national' market.

In June 2010, the Spanish government instigated Royal Decree 824/2010,⁹ imposing a duty on all actors exporting medicines to notify the national medicines agency of all their commercial export actions. A similar measure was also planned to be introduced in France in 2010, through an amendment to Article L-245-6 of the country's social security code, obliging wholesalers to inform original manufacturers of their sales from France to other EU member states, but it failed to receive sufficient support for its adoption.

Such measures create, de facto, a clear obstacle to exports, and therefore to the internal market as a whole, not to mention that the alleged objective of managing shortages could be easily achieved by far less restrictive means.

Does the EU believe in competition or not?

It is true that the pharmaceutical market is very complicated. Nevertheless, in the Lelos case, the ECJ noted that its specificities do not escape the application of EC competition law. Pharmaceutical distribution is important for the health systems to work, and it is a key component of this system, as are well-functioning wholesalers – big and small – responsive pharmacies and innovative pharmaceutical companies.

We are not asking for any special favours. All we are asking for is a level playing field. Once upon a time the commission seemed to believe in this.

With the plethora of threats to the smooth functioning of the internal market for medicines – dual pricing, supply restrictions, quotas, direct-to-pharmacy distribution schemes, export bans – it is time again for the commission to become active in this debate, and draw the conclusions from the pharmaceutical sector investigation further.

Otherwise, we will wake up in a few years to a market where big multinationals are able to exert full control over the distribution channels down to the pharmacy, at the expense of more affordable medicines for European patients and national governments. While illegal supply-management practices may help manufacturers increase profits in the short term, they are in the long run likely to be harmful to competition in the EU single market, and undermine the ability of the European pharmaceutical industry to compete globally. And most importantly, they will hurt national health services and patients by impeding cheaper access to innovative medicines provided by parallel distribution, and negatively impact on the final completion of a fully functioning EU internal market for pharmaceuticals.

If, as suggested by former commissioner Monti, a robust single market is the key to a healthy European Union, then the robustness of the very same single market needs to be upheld if it wants to provide its population with the health it deserves. The parallel distribution industry plays an important role in upholding the principle of the free movement of goods throughout the European Union. Let us hope that the message that competition is also good in the medicines market will finally come across. ■

Heinz Kobelt is secretary general of the European Association of Euro-Pharmaceutical Companies.

Footnotes

- 1 "A New Strategy for the Single Market" At the service of Europe's Economy & Society, Mario Monti, May 2010, p.12
- 2 Parallel Distribution – making modern medicines more affordable for European citizens, EAEP, 2010
- 3 Stellungnahme der Regierung der BRD Deutschland zur Konsultation der EU „Vorschlag zur Bekämpfung gefälschter Arzneimittel“ 9. Mai 2008
- 4 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2008:115:0047:0199:EN:PDF>
- 5 Hellenic Republic Ministry of Health & Social Solidarity National Organization for Medicines, Temporary prohibition of parallel exports, Reg. No.: 11962, 15/02/2011
- 6 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2008:301:0006:0007:EN:PDF>
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2008:301:0007:0008:EN:PDF>
- 7 A Critique of Direct to Pharmacy Distribution, Donald Macarthur, 2009, pp.4/5
- 8 Court of Justice of the European Communities, Press Release no 85/09, Luxembourg 6 October 2009, Judgement in in joined cases C-501/06P, <http://curia.europa.eu/jcms/upload/docs/application/pdf/2009-10/cp090085en.pdf>
- 9 Boletín, Official del Estado, Num 165, 08/07/2010, Num 165, <http://www.boe.es/boe/dias/2010/07/08/pdfs/BOE-A-2010-10827.pdf>