E A E P C

European Association of Euro-Pharmaceutical Companies

The safety of parallel distribution of medicines in Europe

EAEPC Handout to MEPs – March 2008

About parallel trade in medicines

Parallel distribution - the only form of intra-brand price competition in the European pharmaceutical market - makes expensive, innovative medicines more affordable for patients and governments. Direct savings to patients and health insurers in just four countries – Denmark, Germany, Sweden and the United Kingdom – amounted to €441.5 million in 2004.

Most importantly, parallel distribution delivers these benefits without compromising patient safety. Our industry is fully committed to continue working with pharmaceutical companies, governments and regulators to ensure the European supply chain remains safe.

Parallel trade is a uniquely European feature resulting from the principle from free movement of goods and the regional exhaustion of IP rights. Parallel trade takes place only within the European Economic Area.

Parallel trade delivers savings through price competition

Parallel distribution makes expensive, innovative medicines more affordable for patients and governments.

A 2006 study carried out by the University of Southern Denmark confirms earlier research findings that parallel trade generates significant savings for consumers. It is estimated that direct savings to patients and health insurers in just four countries – Denmark, Germany, Sweden and the United Kingdom – amounted to €441.5 million in 2004.

Parallel distribution generates savings directly for the patient when medicines are partially or fully paid for by the patient. In these cases, the patient profits directly from parallel distribution by paying less for medicines at the pharmacy. Parallel distribution also generates savings for national social security systems, enabling governments to contain rapidly rising social security costs. Since parallel distribution delivers considerable savings, many governments consider parallel import as an integral part of their national healthcare systems.

Parallel trade is safe

Parallel distribution of medicines in Europe is safe.

In 2007, in Germany alone some 40 million packages of parallel imported medicines were sold via pharmacies without any safety problem and at an average of 10 percent lower cost than the original.

All parallel imported (PI) products are subject to a marketing authorisation (MA) that the importer/distributor must obtain either from the national regulator or, in the case of centrally approved medicines, the EMEA. This implies a second level of regulatory control, the first being the original marketing authorisation issued to the brand owner. Any repackaging or relabelling carried out by the importer is therefore performed at the behest of and under the supervision of the national regulator. Further, in the alternative, to suggest that imported medicines should be presented to patients in their original form (i.e. in foreign language packaging) would clearly be misguided.

In addition, after having received the marketing authorisation, under trademark rules the PI must inform the TM holder (the original manufacturer) in the importing state of the intention to market the product sourced from another member state; this applies likewise for nationally and centrally approved medicines and gives the manufacturer transparency as to the potential flow of products between markets. The parallel distributor must further submit a fully repackaged physical sample of the product on request; this allows the manufacturer to monitor compliance of packaging and information on the package with all relevant legislation.

Separately, under the provisions of the Human Medicines Directive 2001/27, as amended in 2004, yet another notification requirement has been established: after having received a marketing authorization, a parallel distributor must give notice to the regulatory authority on the intention to import, i.e. move medicines from one member state to another.

Because parallel distributors must carry out relabelling and repackaging processes, they are fully subject to GMP rules, like any other pharmaceutical manufacturers, and must be in possession of a valid manufacturing authorisation from the competent authorities, which will also exercise regular inspections in the facilities of parallel distributors. From the GMP rules it follows that parallel distributors must keep full batch tracking reports of incoming and outgoing goods, and have responsibility for batch recalls and reporting of adverse effects, and keep reference/retention samples of each batch for inspection.

However, some in the industry allege that parallel trade leads to a lack of transparency in the supply chain, and to substandard or wrong packaging. Considering the existing regulatory framework and the meticulous observation of these rules by EAEPC member firms, such allegations are completely unfounded. Why should there be substandard packaging, if the authority and the manufacturer can see it before distribution? Why a transparency problem, if both the regulators and the manufacturer know of the source and the destination markets?

On the contrary: the existing obligations **add additional layers of safety on the supply chain**. Furthermore, by means of an optical check of incoming goods at the start of the repackaging process, PI companies detect substandard medicinal products, which they eliminate from the market and report to the manufacturers and regulators alike.

Smear campaign in the name of patient safety

Still, some in the industry allege that parallel trade poses a safety risk.

The latest critique against parallel trade is a serious attack on the reputation of parallel distributors as some in the industry attempt to tarnish a legal business practice by calling into question the safety profile of parallel trade. These voices claim – against clear evidence – that parallel distributors serve as an entry point for counterfeit medicines into the legal supply chain.

The debate surrounding public health and consumer protection should not be abused to advance industrial policy or commercial objectives. The EAEPC believes that the real threats to consumers and public health are linked to increasingly globalised trade in pharmaceutical products and active pharmaceutical ingredients, the boom of internet pharmacies, as well as prescription, medication and dispensing errors. Pointing the finger at parallel trade is the wrong answer.

Regulators from Germany, the UK, Denmark and Sweden said that there is no evidence of a counterfeit product reaching pharmacies or patients through parallel distribution. We have submitted this evidence in the EAEPC submission to DG Enterprise in May 2007. Germany, the largest pharmaceutical market in the EU, demonstrates this clearly: not one single case of counterfeit in connection with parallel trade since this business started more than 30 years ago.

In this submission we have also commented on the counterfeit cases that were reported in the UK parallel distribution chain in April and May 2007. To our knowledge, these products were purchased from authorised wholesalers, and it was the Qualified Person, the person responsible for quality control, of one of the parallel importers that detected the counterfeit product. The regulatory requirement to employ a EU QP as responsible for quality control distinguishes parallel distributors from ordinary wholesalers, who must employ a "Responsible Person" (a position requiring less stringent qualifications). Albeit affecting 3 different products in 4 different cases, the regulators seem to have come to the conclusion that these were one deliberate attack on parallel traders, orchestrated by a dubious wholesaler in Luxembourg, using products containing reduced quantities of the active substance and packaging from Chinese source. This was the first, and so far hopefully the last, case of counterfeits in parallel distribution in the EU.

Allegations by some in the industry that parallel distribution of medicines is a risk to public health are currently culminating in an industry-driven campaign, which, against evidence from national regulators, seems to have pushed DG Enterprise to take legislative action in the area of parallel trade.

EAEPC initiatives in the area of patient safety

As the EAEPC wishes to demonstrate beyond any doubt its willingness to pre-empt any case of counterfeits reaching the markets, we are currently introducing further measures beyond the existing legal framework to further improve supply chain safety:

- This includes a warning platform for members to exchange information on doubtful product sources or doubtful transaction propositions.

- We are introducing a system to audit suppliers, on the basis of agreed standards set by the QPs of our member firms, clearly demonstrating that EAEPC members take the safety of the supply chain and patient safety very seriously.

- We demand cooperation from manufacturers, EFPIA, GIRP, EGA and the authorities, to become integrated in the ongoing initiatives for securing the pharmaceutical supply chain.

EAEPC recommendations

With a view to gain enhanced safety for patients and for the supply chain, the EAEPC advocates for the following solutions, which have been submitted to DG Enterprise:

- **Mandatory re-boxing for PI products**: Requirement of re-boxing (i.e. producing a new outer carton equivalent to that of the original manufacturer) instead of keeping the trademark driven mix of relabelling and reboxing for all repacking operations of parallel distributed products. Consolidated case law confirms, as recently as in the Boehringer/Dowelhurst case, that reboxing does not impair the trademark of the brand owner as such. Some member states already have such provisions in place, eg. Finland, or Poland (for nationally approved products). Producing its own box (with controlled discarding of original packaging material) will not only lead to tidier packaging from a patient viewpoint, but also enable the parallel distributor to affix his own safety seals to confirm the integrity of the product, while on relabelled packages the original safety seal flipped over the box must by necessity be broken to exchange the PIL.

- **More stringent standards for cross-border wholesale trade** - Subject all operators who "import" medicines from one member state into another to the same requirements as parallel distributors are already subject to. At present, any wholesaler can legally ship products between countries as long as he does not market them in his own market, but is not obliged to obtain a marketing authorisation.

- **Maintain free movement and competition** – We oppose a general ban on repacking, as suggested by Efpia. This would stop parallel distribution and deprive patients and payers of the benefits of the Single Market and price competition. But it would also eliminate manufacturers own production and subcontracting of packaging to pre-wholesalers or contract manufacturers, to which they resort increasingly for cost reasons. These operators are subject to exactly the same rules and regulations under GMP as parallel distributors. As in the case of parallel importers, who may subcontract packaging to a GMP approved operator, the responsibilities between original manufacturers and contract manufacturers are laid down in a Technical Agreement, a standardised GMP procedure.

Obstacles to parallel trade

Pharmaceutical manufacturers try to limit their exposure to parallel trade for understandable commercial reasons. They have an interest in foreclosing national markets and practicing price discrimination with a view to maximising profits in each national market.

But in impeding parallel trade they engage in methods in conflict with "good commercial practice" if not EU competition rules.

The key impediments being put in place against parallel trade are:

- **Trademark driven product differentiation** (pack sizes, dosage, or name of product) beyond what is linguistically strictly necessary for the various geographic markets;
- **Refusal to supply** wholesalers that are known or suspected to "export";
- **Dual-pricing** in Spain: imposing an artificial "international" price on domestic wholesalers and crediting them with the official Spanish price against documentation of sales to domestic pharmacies or wholesalers; this results in an effective export ban and impediment of intra EU trade; In the framework of the EU Pharmaceutical Forum (from which the EAEPC has deliberately been excluded), pushing for implementation of Recommendation 6 of the G-10 expert group. This recommendation aims in the industry view at a de facto dual-pricing model for supplies to wholesalers;

- **Quota systems** based on an estimated domestic consumption for supplies to wholesalers, imposing a kind of "COMECON economy" on pharmaceutical distribution;
- **"Direct to Pharmacy" (DTP) supply**, eliminating the traditional wholesale model of distribution, and replacing it with exclusive logistics providers, thereby controlling the market down to the pharmacy and eliminating pharmacy choice and competition at the wholesale level;

Supply chain safety cannot be entirely disconnected from the attempts of manufacturers of patented pharmaceuticals to control the supply chain and the quantities supplied to wholesalers. Quota systems and other supply restrictions lead to scarcity in the market, which is then exploited by criminals trying to infiltrate the legal supply chain with counterfeits.

The legal qualification of supply restrictions is clear to some extent: Arrangements in the vertical distribution chain that establish a de facto export ban inside the EEA area are anti-competitive per se and because they have a negative effect on consumer welfare. The legal test for such practices is pending before the ECJ in cases relating to Glaxo Greece (refusal to supply) and Glaxo Spain (dual-pricing).

Quota systems, insofar as they are a unilateral measure of a manufacturer, and observe a number of precise criteria, are – for the time being – tolerated under Article 81 EC, although the final word of the courts on aligned commercial behaviour of manufacturers is not a foregone conclusion, as there is no indication that the pharmaceutical sector is any different from other regulated economic sectors and should thus escape the normal application of competition rules. And, indeed, manufacturers exploit this legal void in a shameless manner on wholesalers across Europe.

The latest step in curbing supplies lies in DTP, or direct to pharmacy supply, started by Pfizer in the UK. One or two logistics providers are selected as exclusive suppliers of a manufacturer's drugs, eliminating all small or regional wholesalers from the supply. Pfizer in the UK is said also to set quotas on the deliveries to single pharmacies, thus restricting the market further. The UK competition watchdog OFT has analysed the impact of such distribution models on the UK NHS, but omitted to address the wider impact on intra EU trade. Even in the limited focus on the NHS, however, the OFT said prices for drugs would increase due to the elimination of competition at the wholesale level and the service to pharmacies would decrease. Despite these negative effects on what would normally be "consumer welfare", the OFT refrained from taking action and transferred responsibility to the DoH. If such distribution models take off across the EU, competition at the wholesale level will disappear and give the manufacturer, already a monopolist in regard to patented medicines, full control of the downstream market.

It would seem appropriate for the EU Commission to include such a scenario in DG Competition's sector analysis of the pharma market, as more market power for branded drugs will inevitably also hamper the entry of generics on the market, and it will eliminate intra EU or parallel trade as the only source of competition for prices of branded drugs during the patent period.

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