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European Commission
Enterprise and industry Directorate-General

Public Consultation in Preparation of a Legal Proposal to Combat Counterfeit Medicines for Human Use

Dear Sirs,

Introduction

Verband der Arzneimittel-Importeure Deutschlands eV (VAD) is the representative national association for six leading German pharmaceutical parallel distributors. These companies[1] account for 70% of the value of parallel-distributed medicines sold in Germany.

Parallel distributors are sometimes referred to as 'parallel importers', but this term is incorrect as every product handled as parallel distribution is exclusively sourced and supplied within the Internal Market of the EEA. Because it is a high cost country, most directly distributed medicines marketed in Germany by the trade mark owner or its licensee, with which parallel distribution competes, are in fact produced outside Germany. Indeed, the supply channels of 'domestic' medicines are often more convoluted than parallel distribution, which for simple economic reasons involves the minimum number of participants.

Under the terms of a long-standing contractual agreement between the leading association of sickfunds and the profession, community pharmacies in Germany are required to dispense parallel-distributed medicines to the value of 5% of their sickfund turnover each month, with only products offering a minimum list price saving of either €15 or 15% compared to the domestic version qualifying. Reimbursement by the sickfunds is based on the price of the actual product dispensed, so all savings from lower-priced parallel distribution accrue to the statutory health insurance system. Direct savings for 2004 alone were calculated as €145

1. [1] Axicorp Pharma GmbH, CC Pharma GmbH, EMRA-Med Arzneimittel GmbH, MPA Pharma GmbH, kohlpharma GmbH, and MTK-Pharma Vetriebs-GmbH.

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million in a study from the University of Southern Denmark, with the authors noting this figure was depressed that year due to 'temporary changes in regulatory measures'.

A 2006 study by Prognos, "Import of pharmaceuticals: Savings of the healthcare system and facts of the German healthcare relation act" also showed that use of parallel distributed medicines in Germany gave rise to substantial savings for the health insurance funds. Savings of up to €200 million per annum were generated for both the prescription drug market, which is the focus of this study, and the health insurance funds as the entities shouldering the costs.

In addition, as parallel distribution offers the only form of price competition to a brand during its patent life, there are also important indirect savings in a 'free price' market like Germany. Companies selling domestic brands wishing to compete with or inhibit parallel distribution are forced to moderate introductory prices and forego subsequent price increases.

Patients benefit from parallel distribution with lower out-of-pocket payments too, either when the product is reimbursed and costs between €50 and €100, or with all non-reimbursed products.

As in other European countries, the parallel distribution sector is very tightly regulated in Germany. Each VAD member is in possession of a manufacturing authorisation, granted by the competent regional regulatory authorities, to allow the necessary repackaging/relabelling to access the German market. Before any product is sold, the parallel distributor has to possess for it either a notice from the EMEA (if the domestic equivalent is centrally-approved) or an abbreviated marketing authorisation from the BfArM (if the domestic equivalent is approved nationally). This process allows the competent authority to check, in conjunction with the competent authority in the source country, that there are no differences of therapeutic significance from the German domestic version, and that all relabelling is correct. In Germany, wholesaling activities are covered under the distributor's manufacturing authorisation.

All VAD members employ an EU Qualified Person, strictly follow EU Good Manufacturing Practice, EU Good Distribution Practice and Good Parallel Distribution Practice Guidelines from VAD's parent European association, the EAEPC. They are also subject to periodic inspection by the federal and länder authorities. Suppliers are invariably long-standing and personally well known. Any new candidate supplier would be regarded with suspicion, audited and a check performed on its legal status to wholesale medicines before any purchases were made.

Incoming parallel distribution has existed in Germany since the late 1970s. In 2007, the country overtook the United Kingdom for the first time to become the top destination market of parallel-distributed medicines with sales of almost €2 billion, according to IMS. In excess of 40 million medicine packs are now parallel-distributed there every year.

Even with a high volume of high value parallel distribution producing large savings for the sickfunds over many decades the sector has an excellent safety record. Parallel distributors hold extensive liability insurance cover, though this has never once been needed. Not one

case of a counterfeit medicine reaching patients in the form of parallel distribution has ever been reported. This was confirmed in a 14 July 2003 written answer to a question in the Bundestag by Representative Anje Blumenthal and others by a spokesman of the Federal Ministry of Health and Social Security:

> *'The federal government does not know of any case where medicines with counterfeit contents were brought on to the market by an importer since the introduction of imported medicines.*
>
> *There is no objective connection between imported medicines, which are dispensed according to Section 129 SGB V, and the counterfeiting of medicines. The labelling and packaging of medicines is regulated in the relevant authorisation procedures and is under the surveillance of the responsible state authority. Deviations from the authorisation notice are not admissible and are subject to prosecution by the competent authority'.*

In addition we would like to highlight a survey by the German Federal Office of Criminal Investigation in 2007 that concluded there was no link between counterfeited pharmaceuticals and parallel trade in Germany.

VAD Submission

The VAD welcomes the opportunity to comment on the Commission's proposals designed to prevent European patients from accessing fake medicines.

...Counterfeiting in Context

The 'worrying trend' to more counterfeit medicines appearing in Europe, as the Commission alleges, seems based on the experience over the past three years in one member state only, the UK. The UK regulator, the Medicines and Healthcare products Regulatory Agency (MHRA) reported in November 2007 on nine recalls of specific batches of counterfeit medicines where the counterfeits had reached pharmacies and patients. There had been a further five occasions when counterfeits were discovered at the wholesale level, the MHRA said. The previous known incident of a counterfeit medicine appearing in the legitimate supply chain in the UK came to light in 1994, 10 years earlier. Even today, most other member states, including Germany, have yet to report a single case.

To put the ultra low prevalence of counterfeits into perspective it should be noted that there are over 100,000 different authorised medicines on the market across Europe with 28 billion deliveries made by wholesalers to community pharmacies alone every year.

A single European definition of counterfeit medicines should be adopted to prevent misunderstanding and incorrectly assigning medicines as counterfeit where this is not the case. The WHO definition ('one which is deliberately and fraudulently mislabelled with respect to identity or source') is suggested.

...Counterfeiting and Parallel Distribution

Evidence linking counterfeit entry with parallel distribution is ever scarcer, limited to four UK reports - out of the nine previously mentioned - affecting three different medicines, all over a period of just 12 days in the late Spring of 2007. The cases, which according to the MHRA are linked and therefore clearly not part of any trend, only came to light after detection of a minor labelling flaw by a parallel distributor carrying out the normal pre-release batch examination that is standard practice in parallel distribution. These checks are not carried out by any other type of distributor of medicines, making parallel distribution less likely to be an access point for counterfeit entry compared to other supply channels.

Over the years these quality assurance inspections by parallel distributors in the countries of destination have also proved valuable in highlighting a number of quality deficiencies in the original medicine, like empty blisters or unlabelled bottles. The batches of the medicines concerned have been destroyed and the manufacturer informed of the problems.

VAD is especially concerned to read the consultation document describing relabelling/repackaging operations as impairing product integrity and a likely factor facilitating the alleged rise in counterfeiting ('counterfeiters tend to target traders who accommodate the packaging for the market of destination'). Is there any evidence of this with parallel distribution? VAD members are not aware of any association. All such operations by parallel distributors, which are anyway required in accordance with national and European law and jurisprudence emanating from the ECJ over the past 40 years, are performed under Standard Operating Procedures in accordance with GMP.

Intermediaries other than parallel distributors repackage too, again in accordance with their manufacturing authorisation, and without recorded .problem. It should also be noted that in the world's two largest pharmaceutical markets, the US and Japan, the practice of repackaging of manufacturers' original packs by third-party intermediaries is widespread and, though subject to far less control than in the EU, has not been implicated with counterfeit entry.

Equally alarming is the Commission's unsubstantiated allegation of 'a potential for misuse of original packs, especially when discarded after repackaging'. Along with original manufacturers, parallel distributors pay particular attention to destruction of packaging waste in accordance with their SOPs.

Likewise, the implication that targeted recalls are made more difficult by parallel distribution is simply not true. VAD members have undertaken a number of recalls without problem.

That there has been a sharp increase in seized counterfeit medicines at EU customs borders is not relevant to parallel distribution, as the latter only involves intra-EEA trade. Import for export (e.g. to the US) without being placed on the market in the EU is also an unrelated topic. The Commission, in making reference to 'brokers, traders and business-to-business platforms', that it says might not be subject to current pharmaceutical legislation, should acknowledge these channels are unconnected to parallel distribution. Parallel distributors

hold manufacturing and/or wholesaling authorisations and trade in authorised medicines only with other parties holding manufacturing and/or wholesaling authorisations.

...Public Health Issues

VAD members employ many healthcare professionals, all of whom give patient safety their priority, but as well as maintaining constant vigilance against counterfeits they also recognise that all medicines carry potential risks. Whilst actual patient harm as a result of ingesting a counterfeit medicine in Europe is a very rare event, real medicines are associated with tens of thousands of predictable and unpredictable adverse events, many of which have necessitated admission to hospital, and some unfortunately have led to death. It is also not helpful to alarm patients about a theoretical hazard they can do nothing about if this results in them stopping taking important medication that is almost certainly genuine.

Rather than presenting a risk, in today's harsh economic environment where virtually every member state is forced to take measures to curtail the rate of growth of public pharmaceutical expenditure, parallel distribution contributes positively to public health. It provides savings without a detrimental effect on treatment quality, and without recourse by payers to market-distorting measures like reimbursement delisting, generic substitution or price cuts. Unaffordable medicines can neither be safe nor effective.

Conclusion

The VAD cautions

- against the use of alarmist language, unsupported by the facts, on the risk of counterfeit medicines in Europe,
- against disproportionate, costly, and potentially impractical and unproven counter-measures which are unnecessary,
- from associating ease of counterfeit entry with the parallel distribution process, without any evidence to support such a link, and
- allowing patient safety to be used as a guise to stop parallel distribution by vested interests with a profit motive.

Sponsoring an industry that only exists because of the irrefutable evidence base it has generated in support of the healthcare benefits of its products, the Commission should guard against destroying that credibility and losing the trust of the public by being associated with scare stories that are not supported by the facts.

As well-established, responsible and significant distribution partners in the largest national pharmaceutical market in the EU, VAD members look to continue to work with all other stakeholders to ensure a secure and counterfeit-impervious supply chain. Patient safety is not the monopoly of manufacturers

VAD

Kind regards.

Yours sincerely,

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