



European Parallel Distributors Helping to Combat Counterfeits

The issue of counterfeit (or fake) drugs is a serious problem for public health. Counterfeiting medicines is illegal and threatens the lives of patients. According to the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), 7% of all medicines marketed around the world are counterfeit. Rightly so, the debate on counterfeits has risen up the political scale and regulators are considering initiatives to fight against this illegal practice.

While cases of counterfeits in Europe itself are rare, certain pharmaceutical manufacturers have leapt on the debate to try to perpetuate the myth of a link between counterfeits and legitimate and highly regulated European parallel distribution. There is no evidence of such a link. On the contrary, the practice of parallel distribution adds an additional layer of safety to the European pharmaceutical supply chain.

WHAT ARE COUNTERFEIT MEDICINES?

According to the definition of the World Health Organisation (WHO) a counterfeit medicine is one:

"which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeit products may include products with the correct ingredients, wrong ingredients, without active ingredients, with insufficient quantity of active ingredient or with fake packaging."

In contrast, European parallel distribution of medicines is safe and 100% legal. The European Commission has defined parallel distribution as:

"a lawful form of trade in goods between Member States of the European Union. Parallel trade is based on the principle of the free movement of goods within the Internal Market. It is known as 'parallel' to the extent that it takes place outside and – in most cases – in parallel with the distribution network that the manufacturers or original suppliers have established for their products at a Member State, while it concerns products which are in every respect similar to the ones marketed by the distribution networks."

Thus, a parallel distributed pharmaceutical product is one that was initially placed on the EU market by the original manufacturer and then repackaged, re-labelled and distributed by a distributor authorised by all relevant regulations. Such a product is

not, and can never be, a counterfeit product.

PARALLEL DISTRIBUTION IS NOT AN ENTRY POINT FOR COUNTERFEITS

The safety record of the parallel supply chain is impeccable. There has not been a single proven case of a counterfeit medicine entering the legitimate European supply chain as a result of European parallel distribution. It is therefore not surprising that the German government – commenting on the situation in Germany - stated to the Bundestag in 2003:

“There is no objective connection between imported medicines [...] and the counterfeiting of medicines.”

Similarly, UK Secretary of State for Health Jane Kennedy stated in July 2005 that:

“There is no evidence to suggest that licenced parallel trade provides any more of an opportunity to introduce counterfeit medicines into the country over non-parallel traded products.”

Moreover, counterfeiters have very little economic incentive to launch their fraudulent products via parallel distribution channels. This is because:

- Volumes are generally low: parallel distributors handle only a fraction of the supply volume in the European medicines market and the industry is highly fragmented, comprising a large number of small and medium-sized enterprises.
- On the one hand, parallel distributed products are sold at cheaper prices than their directly distributed counterparts, and, on the other hand, they are more costly to manufacture. The increased manufacturing cost is due to the fact that parallel distributed medicines require supplementary labels and/or printed information on the packaging.

Parallel distribution is therefore not an entry point for counterfeit medicines into the supply chain.

THE PARALLEL DISTRIBUTION SUPPLY CHAIN IS SAFE

Extra layer of safety

Parallel distribution helps to improve the level of safety in the European pharmaceutical market by providing an additional layer of product control. It does not increase in any way the risk of counterfeit medicines entering the medical supply chain.

Every parallel distributed product is effectively approved twice. It will have a full marketing authorisation and an abbreviated marketing authorisation. Any company that repackages or re-labels parallel distributed products has a manufacturing authorisation – similar to original manufacturers’ like Bayer, GlaxoSmithKline and Pfizer -, employs a Qualified Person in accordance with EU regulations, and is subject to binding guidelines and periodic inspection from the regulators. But it is not only the regulators who review parallel distribution. Parallel importers are required by ECJ

case law to make available to the original trademark owner in the importing member state a complete product sample before marketing the product.

In addition, parallel distributors ensure that repackaging operations cannot result in potential counterfeiters getting access to discarded original packaging because they adhere to strict requirements which oblige them to destroy any redundant packaging.

In reality this additional step in the supply chain ensures the medicine receives a second "quality control" check. Parallel distributors often find faulty products in the supply chain and quarantine the relevant medicine. Without this additional check these medicines would stay in the system and, ultimately, be dispensed to the patient. Most of our member companies regularly detect supplies of ill-packed or otherwise defective products produced by the original manufacturer.

Strict regulation and guidelines

Parallel distribution is a highly regulated and safety-conscious industry. Parallel distributors operate in some of the highest quality, state of the art facilities, are subject to regular inspection and all products marketed are approved by the relevant regulatory agencies, national or European. They employ pharmacists who, in close cooperation with the relevant regulatory authority, check every product according to common industry safety rules, which include recording batch numbers and expiry dates.

Typically, medicines imported by parallel distributors are repackaged at a dedicated facility and distributed directly to the retail pharmacist or via a wholesaler/distribution warehouse. When problems occur, parallel distributors perform all product recalls as efficiently, promptly and comprehensively as any other pharmaceutical distributor.

No cases of counterfeits entering the supply chain via parallel distribution

The German Federal Ministry of Health and Social Security, in a written answer on 14 July 2003 to questions from German members of the Bundestag, responded:

'The Federal government does not know of any case where medicines with counterfeit contents were brought on the market by an importer since the introduction of imported 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.'

Other EU countries have similar records, including Sweden where the Swedish Medical Products Agency says that there have never been any counterfeit products detected.

This is not to say that Europe is immune against the threat of counterfeit medicines. However, no objective facts have ever identified parallel distributors as the entry point for counterfeits. In reality, parallel distributors face the same risk as pharmacies and regular wholesalers of sourcing counterfeit products that have already entered the legitimate supply chain. However, parallel distributors are in a

better position than pharmacies and other wholesalers to detect such counterfeits when handling products given that they are required to apply additional controls during the repackaging and re-labelling process.

THE EAEPc ENGAGING IN THE COUNTERFEIT DEBATE

As the association representing the interests of parallel distributors of medicines in Europe, the EAEPc is developing – in addition to national and European regulation – additional guidelines which members must abide by. This is intended to remind regulators, payers, patients and the industry that parallel distributors operate under the strictest legal and ethical guidelines.

The EAEPc is also actively engaging with decision makers and the industry to find ways to fight counterfeits. As one example, the EAEPc and its members participated in the Council of Europe stakeholder survey on counterfeit medicines, the results of which will be presented at a Stakeholder Forum in September 2005. The EAEPc is looking forward to sharing its experience, best practice and recommendations on how to combat counterfeits.

Through its actions, the EAEPc fulfils its moral and legal obligations under existing EU law on counterfeiting. The EAEPc fully supports all initiatives to combat counterfeit medicines at a national, European and international level. But it resents the attempt to link legal and legitimate parallel distribution to the wholly illegal practice of counterfeiting.

The European Association of Euro-Pharmaceutical Companies (EAEPc) is the representative voice of pharmaceutical parallel distribution in Europe. All products handled by EAEPc members have national or EU regulatory approval and are exclusively sourced from and sold to EEA countries using authorised distribution channels. EAEPc's primary aims are to safeguard the free movement of medicines, as laid down in Article 28 EC.

For more information please contact:

Dr. Heinz Kobelt, Secretary-General, EAEPc
Tel.: +32 478 797 949
Email: heinz.kobelt@eaepc.org
www.eaepc.org