

## **Position Paper on proposal to ban repacking and re-labelling of pharmaceuticals by European Commission**

### **1. Introduction**

The European Commission links counterfeit pharmaceuticals with parallel trade. Therefore, as part of its “pharmaceutical package”, DG ENTR of the European Commission has issued a proposal for a Directive regarding the protection of human health against the risk of illegal medicinal products entering the legal supply chain. In this proposal a prohibition of repackaging and re-labelling of medicines is proposed and thus the basis of the parallel trade industry’s business model removed. The VAD is convinced that the measures proposed by DG ENTR are inappropriate to attain the objective of protecting public health from the risks of counterfeit medicinal products. Instead, national healthcare systems have to cope with increasing costs due to less competition over prices. The magnitude of employment reduction will furthermore lead to severe socio-economic consequences. Therefore, the VAD calls for a revision of the measures proposed by DG ENTR. An evidence-based discussion should seek to develop means of protecting public health without impairing free trade and distorting competition.

### **2. Lack of scientific evidence**

The European Commission so far has failed to produce satisfactory evidence regarding the higher risk of counterfeit medicinal products entering the legal supply chain through parallel distribution. Instead, the industry has evolved continually, creating a sound legal and regulatory environment in which it operates.

### **3. Cases of counterfeit medicines**

In the public debate, negative examples of counterfeit medicinal products entering the market through the legal supply chain are frequently cited. These examples, however, mostly refer to isolated instances in the United Kingdom in 2007. In that case an English importer had obtained counterfeit products from a European wholesaler. He identified the counterfeits as such and reported them. During the 35-year history of parallel trade, no evidence became known of an importer ever placing a counterfeit medicine on the market despite trading more than 140 million packages each year. Instead, as mentioned above, parallel trade has helped to discover counterfeits in the legal supply chain. The parallel trade industry has shown that there is no link between parallel trade and counterfeit medicines. Parallel trade of pharmaceuticals has even helped to discover counterfeit products in the legal supply chain.

### **4. Regulatory framework**

In parallel trade, genuine, original, branded medicines that are authorised in accordance with Community legislation and marketed in one Member State are transferred to another Member State by “exporting” wholesalers and “importing” parallel traders. As a result, they are competing with a therapeutically identical product already marketed there at a higher price by or under the license from the owner of the brand’s intellectual property. All repack-

aging and re-labelling operations by parallel distributors are performed under Standing Operating Procedures and in accordance with national and EU law. The exporting wholesaler has to be authorised to trade. The activities of the parallel trader are regulated with regards to the market authorisation of individual products and the packaging as well as re-labelling. Several official documents set out strict requirements. Although tighter controls by authorities would dissuade counterfeiters from targeting the supply chain, in certain instances parallel trade have identified counterfeits in the legal supply chain and reported them to the competent authorities.

## **5. The illegal distribution chain as a key threat**

Contrary to the opinion of DG ENTR, several official studies from reputable international organisations and authorities have identified illegal distribution chains, namely the internet, to be the real source for counterfeits entering the market of the European Union (see studies by Federal Criminal Police Office and the International Narcotics Control Board of the United Nations). In developed markets such as the European Union, “lifestyle” medicinal products belong to the most commonly counterfeit products. They enter the market through specific orders of patients at illegal online pharmacies managed by persons with criminal intent. Additionally, statistics by the European Commission itself reports the seizure of a total of 2,711,410 medicinal products (number of articles) at EU customs borders in 2006 (see consultation paper by Commission from March 2008). This is an increase of 384% compared to 2005. This clearly shows that imports from third countries such as China and India for instance are one major gateway for counterfeit medicines into the European Union that urgently need to be considered.

## **6. Potential consequences of prohibiting repackaging and re-labelling**

### **6.1. Overall economic implications**

The parallel distribution industry in Europe employs between 10,000 to 15,000 individuals, many of whom are highly skilled and work in jobs both directly and indirectly linked to the sector. Many of these jobs are located in geographically disfavoured regions. Some of the distributors are also the biggest employers in their regions. Whether a re-distribution to wholesale distribution and research-based industries as expected by the DG ENTR can fully compensate such far-reaching negative social consequences needs to be evaluated more carefully. The VAD assumes that wholesale turnovers will also be reduced so that higher employment in this branch becomes unlikely. Original manufactures will also not be able to employ more people as their imported products stem from their supply chain to begin with. Prohibiting the repackaging and re-labelling of medicinal products, which will predominantly affect parallel traders, an industry with a stable trade volume of EUR 3.5 billion Europe-wide.

### **6.2. Price competition and cost savings for national healthcare systems**

If a prohibition of repackaging and re-labelling drastically reduces the size of parallel trade, price competition on the European market will be impaired severely. It will be left to health insurance companies to negotiate prices with the original manufacturer of a product. As parallel traders compete with original producers for market share of basically identical products that differ only in price, the economic effect of prohibiting repackaging and re-labelling should not be underestimated. However, the use of parallel distributed medicines

can give rise to substantial savings for health insurance funds. For high-cost countries such as Denmark, the United Kingdom, Germany or Sweden, savings are estimated to be in the two to three digit million range. According to the German government, for example, a study carried out in 2006 showed that savings of up to EUR 200 million per annum had been generated by parallel distribution.

## **7. No solutions!**

### **7.1. Over-boxing**

In many cases, over-boxing would make it impossible for parallel importers to offer the specific pack size authorised on the local market. Re-boxing is mostly a necessity for gaining market access. The parallel industry will lose between 50 and 80 per cent turn over in most of the member states. Over-boxing would run counter to GMP and European and national regulations. For example, parallel importers would no longer be able to change the language of information/instructions printed on the blister packaging (a mandatory requirement in the UK), change the PIL number or perform visual inspections of the product. Over-boxing would undermine product traceability given that the outer and inner boxes would risk being separated. If the original box and the original PIL remain unchanged during over-boxing, it would be impossible to trace them back to the parallel importer in the absence of the outer box. For the same reasons, over-boxing would encourage product diversion and – worse – the infiltration of counterfeits into the supply chain. Over-boxing would pose patient compliance problems: Patients using an over-boxed product would be faced with two sets of packaging and two PILs. Only the outer packaging and PIL would be suitable for the local market. The additional packaging and PIL would create confusion and raise compliance issues.

### **7.2. Seals**

Seals are also not a solution to the problem increased counterfeit medicines in the European Union. Counterfeiters who have a criminal intent and deliberately harm public health can easily cope and/or fake any seal. They will not be prevented by a seal that can be copied in any copy shop throughout Europe taking into account that more than 140 million packages needed to be sealed each year.