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CJEU rules in quartet of cases that Falsified Medicines Directive no excuse for repackaging of products

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The Falsified Medicines Directive (2011/62/EU) (**FMD**) was introduced in 2011 with the aim of safeguarding the public against medicinal products within the EU whose identity, history or source had been falsified. The FMD requires that the packaging of these products now bears certain safety features, such as a "unique identifier" verifying their authenticity and an "anti-tampering device".

Parallel importers sought to take advantage of this change in the law to support a complete repackaging of medicinal products imported into Member States, previously only allowed in exceptional circumstances. Pharma companies opposed this, arguing that less invasive methods such as relabelling should be used instead.

In late November 2022, the CJEU handed down four judgments in this complex area, clarifying the extent to which a parallel imported medicinal product can be repackaged.

The quartet of judgments comes following preliminary ruling requests made by:

1. The Regional Court in Hamburg, Germany in the cases of 1) Novartis Pharma GmbH v Abacus Medicine A/S (Case C?147/20) and 2) Bayer Intellectual Property GmbH v Kohlpharma GmbH (Case C?204/20);
2. The Court of Appeal in Brussels, Belgium in respect of joined proceedings by 1) Impexeco NV v Novartis AG and 2) PI Pharma NV v Novartis and Novartis Pharma NV (Cases C-253/20 and C254/20); and
3. The Maritime and Commercial Court, Denmark in respect of the case of Merck Sharp & Dohme BV and others v Abacus Medicine A/S and others (Case C?224/20).

In each of the above cases, medicinal products were being repackaged by parallel importers before being put on the market in Germany, Belgium and Denmark respectively. In some cases, the trade mark of the original manufacturers was then affixed to the new outer packaging. In other cases, the original manufacturers' mark was replaced with a new product name, but the packaging still indicated that the product corresponded to the original manufacturer using their trade mark, and the blister packs inside the new packaging also bore the original manufacturer's mark.

The parallel importers in each case argued that such repackaging was necessary to meet the relevant marketing requirements following the FMD and that any opposition from the proprietor of a trade mark to the reaffixing of their mark to new packaging would create artificial partitioning of

the market, as they could not then import these products.

The original manufacturing companies countered this on the basis that their trade mark rights had not been exhausted, as relabelling the products would be enough to satisfy the relevant marketing requirements. Further, it was settled case law that the repackaging of a product bearing a trade mark by a third party (without the authorisation of the trade mark proprietor) was likely to create real risks for the guarantee of origin of that product, providing grounds for them to object.

Upon consideration of these cases, the CJEU ruled that a trade mark proprietor may oppose replacement packaging where a parallel importer is able to legitimately reuse the original packaging by affixing labels to that packaging instead. The FMD did not prevent the reuse of the original outer packaging of a medicinal product, provided that an equivalent “unique identifier” and “anti-tampering device” could be applied.

Repackaging of a medicinal product was only permitted where it was objectively necessary for that product to be marketed. If, therefore, there should exist within a relevant market a strong resistance from a significant proportion of consumers to the relabelling of medicinal products, or to the purchasing of products whose packaging bears visible traces of having been opened, due to the replacement of the existing “anti-tampering device”, then repackaging of these products would be viewed as necessary and could not be opposed. This was to be assessed on a case-by-case basis.

This is a useful decision for those in the pharma industry as it sets the parameters within which a medicinal product can be repackaged. Crucially, it also prevents generic medicines being removed from those Member States where there are patients in need and then repackaged to be sold as an original brand in another country at a higher cost.

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