CONSEQUENCES OF ARTICLE 67(7)(A) OF THE PROPOSAL FOR A NEW EU MEDICINES DIRECTIVE

1. INTRODUCTION & BACKGROUND:

In order to be able to import a pharmaceutical product from one Member State to another, parallel importers may have to adapt the product packaging to the legal requirements and language of the import country. They do so by affixing a sticker with all mandatory information to the outer packaging ("re-labeling") or by repackaging the product into a completely new outer packaging ("re-boxing"). Being a greater interference with, and risk to, product integrity, repackaging in new secondary packaging is allowed only in exceptional circumstances, the conditions of which have been established by the case law of the ECJ.

In April 2023, the European Parliament adopted the Commission's proposed revision of the EU pharmaceutical legislation, including a new Medicines Directive which includes a new provision, Article 67(7)(a): "*For the purpose of patient safety, Member States may decide that medicinal products imported or distributed in parallel shall be repackaged in new outer packaging.*"[1]

The reasoning behind the new Art 67(7)(a) is unclear. The Parliament's reports do not explain who proposed it and what the background of the provision is. One thing, however, is certain: Re-boxing severely interferes with the integrity of a medicinal product's packaging and will never be able to contribute to patient safety. Moreover, the new provision will lead to an unnecessary amount of packaging waste, unduly interfere with legitimate intellectual property rights of the manufacturers and violate fundamental principles of EU law.

The principles of free movement of goods under the Treaty on the Functioning of the European Union (TFEU) and regional trademark exhaustion have been balanced against the national regulations ensuring the safety and integrity of medicines. The result has been to recognize, on the one hand, that the EU single market for pharmaceuticals requires allowing controlled interference with pharmaceutical product packaging when circulating across national borders (to adhere with national regulations), *and*, on the other hand, that such interference creates risks to the condition of the product and, therefore, to patient safety.

[1] Amendment 188 to the text adopted by the European Parliament of 10 April 2024, available here: https://www.europarl.europa.eu/doceo/document/TA-9-2024-0220_EN.html

Legislation and jurisprudence have therefore, for decades, sought to protect patients and even very recently, confirmed that patients are best protected by ensuring that interference with medicines should be limited to the necessary minimum and only be possible under careful control. Parallel traders may therefore change the packaging of original pharmaceutical products only in compliance with certain requirements. In most cases, parallel traders can adapt the packaging by affixing a sticker with all necessary information in the local language to the outer packaging. The exception to this rule – replacing the original packaging with a completely new outer packaging – is only allowed when it is otherwise objectively impossible to sell the medicine in the importing country.

The suggested rule in Article 67(7)(a) allows Member States to turn this principle upside down and to generally require a re-boxing of parallel imported medicines. The draft provision proposes that the well-reasoned controls on the interference with packaging of medicinal products – controls that aimed to limit the inherent risk of compromising the product and patient safety – be abandoned. Its introduction will have problematic consequences that will severely disturb the present balance achieved over many years. Such consequences include setting aside 50 years of established case law of the European Court of Justice, including a recent clarification of the interplay between the Falsified Medicines Directive (FMD), the TFEU and the EU Trademark Regulation (EUTMR), and extend to sustainability and health policy considerations.

2. THE ”JUSTIFICATION” OF PATIENT SAFETY

Patient safety consequences

According to its wording, Art67(7a) is justified on patient safety grounds. There is, however, no evidence that re-boxing parallel imported medicines is in the interests of patient safety. Quite the contrary. Patient safety is best protected if medicinal products are delivered to patients from manufacturers without interference. This being impracticable in the case of parallel imported medicinal products in the EU, the ECJ and the FMD, significantly embracing patient safety, have determined the correct balance between patient safety, intellectual property rights and the free movement of goods by laying down the established requirements on importers of medicinal products.

The integrity of medicines and the interests of patient safety are best safeguarded by requiring that medicines arrive from the manufacturer to the end user without interference, in unopened packaging. If the packaging of the medicines must be opened, e.g. to replace the original package leaflet with a package leaflet in another language, the guarantee of integrity and authenticity of the product is compromised.

The opening of the product is, however, a prerequisite for parallel imports. For this reason, the FMD and the ECJ have determined how to safeguard authenticity and safety where a manipulation of the product packaging is necessary.

The FMD rules require that medicinal packaging have two safety features: i) a unique identifier (UI) and ii) an anti-tampering device (ATD) allowing the verification of illegitimate tampering.

The ECJ (in cases C-224/20, C-204/20 and C-147/20) held that the FMD rules, which have the essential aim of preventing falsified medicinal products from entering the legal supply chain, must be interpreted in such a way that re-boxing into new outer packaging does not provide a better guarantee of the authenticity of the product than in cases where parallel importers re-use the original outer packaging. The Court specifically stated that repackaging in new outer packaging and re-labelling of the original packaging must be regarded as equivalent forms of repackaging as regards the effectiveness of safety features required be the FMD (para 82).

Further, recent specific re-boxing practices of parallel importers that resulted in referrals to the Court of Justice, have been to debrand some or all of the range of trademarks used by manufacturers to distinguish their products, from the product names to the corporate identity to logos, colours and other distinctive signs. As the purpose of such signs is to distinguish products from one another and to assist in the prevention of medication errors, removing them is clearly not in the interests of avoiding confusion or medical error. Furthermore, original manufacturer packaging often contains additional hidden safety features enabling the detection of falsified medicines. Repackaging in new secondary packaging that does not replicate such features, as is often and would likely be the case for re-boxed parallel imported products, does not promote the same level or product security or patient safety.

Contrary to what Art67(7)(a) claims, therefore, re-boxing of medicines is not in the interests of patient safety as it does not better guarantee the authenticity or integrity of a product than when parallel imports are re-labelled.

Further, there is evidence that re-boxing compromises the legal supply chain. One of the main triggers for the enactment of the FMD in 2011 was a sharp increase in counterfeit medicines in the distribution chains since 2004, and several incidents of counterfeits found in parallel- distributed stocks of medicines.[2] There was alarming evidence that the regular supply chain and especially parallel traders were being increasingly targeted by counterfeiters, with the practice of repackaging creating a weak point in the supply chain.[3] In light of the risk that safety features could disappear, and the potential of

[2] See the EU Commission's findings in its consultation paper "Public consultation in preparation of a legal proposal to combat counterfeit medicines for human use – Key ideas for better protection of patients against the risk of counterfeit medicines", page 2 (Microsoft Word - 2008_03_11_Consultation Document FINAL _public_.doc (europa.eu)).

[3] "Public consultation in preparation of a legal proposal to combat counterfeit medicines for human use – Key ideas for better protection of patients against the risk of counterfeit medicines", page 2 (Microsoft Word - 2008_03_11_Consultation Document FINAL _public_.doc (europa.eu)); see "Parallel imports questioned as fourth counterfeit found", PharmaTimes, 7th June 2007 (Parallel imports questioned as fourth counterfeit found -

a misuse of original packs when discarded after repackaging, the EU Commission wanted to introduce a ban of manipulation of safety features, allowing practices of over-labelling only if safety features remain detectable and intact, and making the practice of exchanging the outer packaging (i.e. re-boxing) unlawful.[4]

While such a general ban of re-boxing was dropped in the further legislative process, this background shows the degree to which the proposed new provision in Art67(7)(a) contradicts the aims of the FMD to fight counterfeit medicines by strengthening the control of the distribution chain and the integrity of products.

3. OTHER CONSEQUENCES

Intellectual property rights considerations

The names, logos & other identifiers applied to medicinal packaging – the trademarks – play an essential function in guaranteeing origin and authenticity of the product and avoiding any confusion or medication errors between products.

Art67(7)(a) will weaken these trademarks and their function. Since 1978, the ECJ has ruled that any change brought about by repackaging creates by its very nature the risk of interference with the original condition of the product and the guarantee of origin which trademarks seek to protect.

The "guarantee of origin" is the essential function of a trademark enabling products to be distinguished from one another and providing consumers with certainty that a product has not been illegitimately interfered with.

The ECJ has stated *"[…] that the specific purpose of a mark is to guarantee the origin of the product bearing that mark and that a repackaging of that product carried out by a third party without the authorisation of the proprietor is likely to create real risks for that guarantee of origin."*[5]

PharmaTimes); "Parallel trade in drugs puts EU patients at risk", The Guardian, 29th June 2008 (Parallel trade in drugs puts EU patients at risk | Pharmaceuticals industry | The Guardian).

[4] See Commission Staff Working Document, Accompanying document to the Proposal for a Directive amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source – Impact Assessment, page 44 and seq. (https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2008:2674:FIN:EN:PDF); "Public consultation in preparation of a legal proposal to combat counterfeit medicines for human use – Key ideas for better protection of patients against the risk of counterfeit medicines", page 7 (Microsoft Word - 2008_03_11_Consultation Document FINAL _public_.doc (europa.eu)).

[5] C-297/15, *Ferring*, ECLI:EU:C:2016:857, paragraph 14; and C-348/04, *Boehringer II*, ECLI:EU:C:2007:249, paragraph 14.

Further, according to the ECJ, re-boxing constitutes a greater interference with trademarks and their function than re-labelling the original packaging. Parallel importers are only allowed, therefore, to re-box when it is otherwise impossible to sell the medicine in the importing country i.e. it is "objectively necessary". In the absence of this "objective necessity", the repackaging can be opposed on the basis of trademark rights.

Art67(7)(a) will, in practice, completely eliminate the long established requirement of "objective necessity" and will freely allow, without any condition or requirement whatsoever parallel importers to re-box medicinal products into new outer packaging in those Member States where a re-boxing rule is introduced pursuant to the proposed new Article 67(7)(a). In those Member States re-boxing, previously only allowed as an exception, will become the general practice. Consequently, trademark rights will no-longer be a basis to oppose re-boxing despite the fact that such repackaging interferes with the essential function of the trademark and entails a greater risk to the original condition of the products than in cases of re-labelling. In addition, as with additional safety features deployed in original manufacturer packaging, re-boxing practices can significantly interfere with original trademarks by altering the packaging presentation and the distinctive signs used to protect patients from medication error. This would clearly not be in the interests of patient safety.
Summarizing, the provision will significantly weaken the trademark protection conferred on original manufacturers, as well as set aside the *doctrine of objective necessity* that the ECJ has developed over decades, carefully balancing the principle of free movement of goods, on the one hand, against the legitimate interest of trademark protection against abuse and free-riding, on the other hand.

As the "guarantee of origin" is best safeguarded in cases of re-labelling rather then re-boxing, "patient safety" is also best safeguarded if parallel importers are obliged to re-use the original packaging and maintain the existing trademarks .

Violation of fundamental principles of the EU

The suggested new provision in Article 67(7)(a) leaves it to the Member States to decide that parallel imported medicinal products must be repackaged in new outer packaging. Thus, every Member State can decide individually whether it wants to introduce that general requirement and, furthermore, how such requirement is implemented. This leads to a legal patchwork throughout the EU, which obviously contradicts EU harmonization and in no way increases patient safety in the EU. It is, therefore, highly probable that by leaving it to the discretion of each Member State whether to require the re-boxing of parallel imported medicinal products, the provision would be in breach of fundamental principles of EU law. The free movement of goods, on the one hand, is one of the four fundamental economic freedoms laid down in the EU founding treaties. The protection of intellectual property such as trademarks, on the other hand, is guaranteed as a fundamental right (Article 17(2) EU Charter of Fundamental Rights). As explained above, when it comes to parallel trade and repackaging, the ECJ has harmonized these two fundamental principles through a carefully balanced framework. On

numerous occasions the ECJ has found that (i) re-boxing does not provide a better guarantee of authenticity than in cases where parallel importers re-use and re-label the original outer packaging, and that importers may only re-box if it is otherwise impossible to sell the medicine in the import country ("objectively necessity"). It is highly questionable that it would be compliant with these two fundamental principles and the balance between them as defined by the ECJ if it were left to the discretion of the Member States to decide whether importers should re-box rather than re-label.

Sustainability considerations

Should Member States generally require parallel traders to re-box medicinal products, the packaging of practically every medicine that is imported into these Member States will have to be replaced by new packaging. The original packaging will be discarded, and an entirely new packaging will be manufactured for the same product, creating unnecessary waste. The new rule would thus have a tremendously negative effect from a sustainability perspective.

On 24th April 2024, the EU Parliament adopted the new EU Packaging Regulation. One of the main aims of the Regulation is to tackle constantly growing waste by reducing packaging waste and encouraging more sustainable packaging designs. Amongst others, it introduces clear reduction targets of 5% by 2030, 10% by 2035 and 15% by 2040.[6] Proposed Art67(7)(a) obviously contradicts these goals and measures because it encourages that a practice of unnecessarily discarding unused original outer-packages of pharmaceutical products and replacing them with newly produced boxes unnecessarily becomes the norm within the EU.

4. CONCLUSION

The case-law established by the ECJ, which has constituted the applicable law on this subject for decades, ensures a careful balance between the fundamental principle of free movement of goods, the protection of public health, including patient safety considerations, and the legitimate interests of trademark protection. This case-law should, therefore, continue to constitute the applicable law in the area and should only be set aside only where this is necessary to protect legitimate interests that are presented, debated and documented in a transparent manner.

[6] https://www.europarl.europa.eu/news/en/press-room/20240419IPR20589/new-eu-rules-to-reduce-reuse-and-recycle-packaging#:~:text=To%20reduce%20unnecessary%20packaging%2C%20a,banned%20from%201%20January%202030.