Pharma Intellectual Property
Novartis Pharma AG

Parallel trade and transparency: empowering patients

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A universal trend among consumers increasingly demanding transparency.

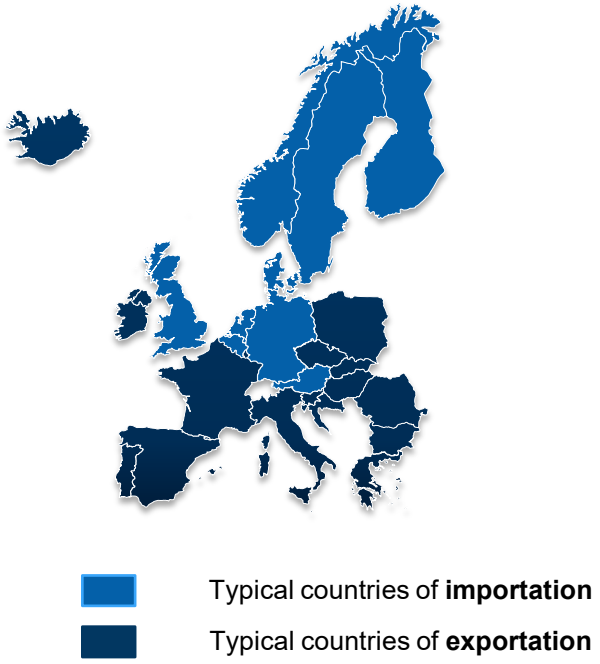
- A 2019 report of Label Insight and FMI showed that shoppers want to know exactly what a **food item** is made from, where it is sourced from, and manufacturers' business practices and ethical positions.
- «The State of **Fashion** 2019» reports a shift towards radical transparency; consumers increasingly worry about production and supply chain, including issues like labor and sustainable resourcing.
- In 2019, the European Parliament approved additional consumer protection rules, requiring **online marketplaces** to ensure that consumers can identify from whom they are buying goods or services.
- In 2018, the WHO adopted a resolution encouraging countries to improve transparency about available **medicines**, patent status and pricing.

Transparency increases the accountability of manufacturers, and can facilitate responsive actions enabling consumers to make more informed decisions.

Transparency in parallel trade: do patients have a choice?

- Parallel traders exploit price differences among EEA states
- Due to different languages and regulations, imported products are modified:
  - by **re-labelling**;
  - by **re-boxing**; and/or
  - by **re-branding**
- Many parallel traders prefer re-boxing and try to market products in their own packaging.

This is not always known to patients, who may be unaware of parallel trade.



Not all are parallel imports are equally easily recognizable

Here:
EXFORGE 10/160 mg
re-boxed imports into Germany

Differences include:

- Type of packaging (white vs. design copy)
- Colors used
- Box sizes
- Font types and sizes
- Use of ®

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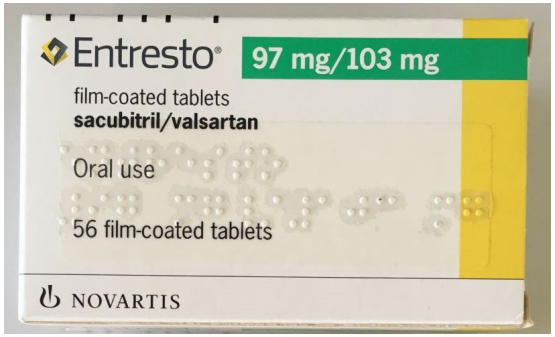
One step further: some parallel traders try to appear as brand owner



1. Re-labeled original packaging

- Novartis branding with house marks
- Easily recognizable as import due to label on back of the packaging

2. Re-boxed product (NOT ACCEPTED)

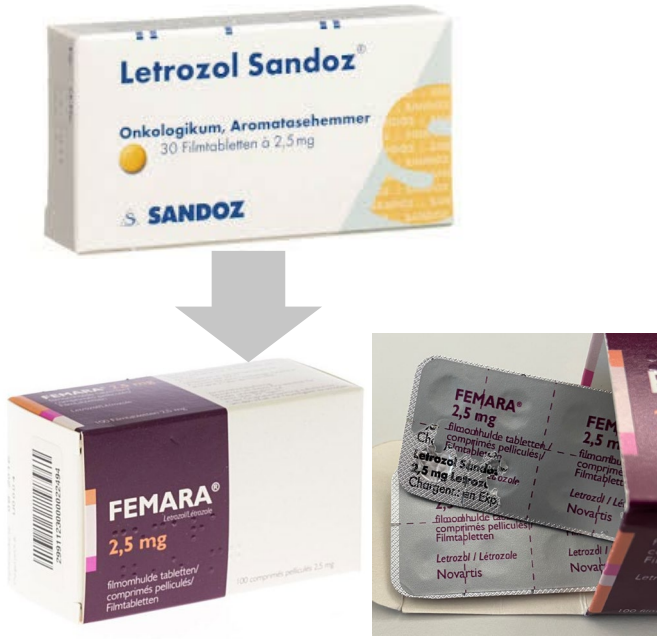
- Addition of «Fisher Farma» logo
- Implies association between ENTRESTO and Fisher Farma

Another step further: re-branded generics

Belgian parallel traders buy **Sandoz generics** and re-sell them using **Innovative Medicines brands**.

- Payers are charged originator prices for generic products.
- High profit margins: re-selling prices are 10-30x the original price (usual margin for parallel traders around 20%).

Court decisions at the Brussels Commercial Court have been inconsistent; matter is now **pending before the CJEU**.



Right: «Letrozol Sandoz» appearing under «FEMARA» sticker on blister

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Patients have a legitimate interest in identifying parallel imports

Re-packaging can conceal parallel imports and limit patients' ability to make an informed decision.

- Parallel trade occurs outside of the manufacturer's authorized supply chain.
- Re-packaging activities are a significant interference with product integrity.
- There are instances in which counterfeits were sold to parallel traders.

Patients should be empowered to make a decision in accordance with their personal preferences.

- Re-labeling is more transparent, as parallel imports can be easily identified.
- Severe interferences with product integrity should be complemented by rules enabling an easy identification of parallel imports.

The Falsified Medicines Directive (FMD): background and objective

In 2019, the FMD came into force, requiring all medicines to contain «**anti-tampering devices**» (ATD). Several parallel traders interpret this to **justify re-boxing of all products** into own, new outer packaging.

- Parallel traders claim that this is because they damage the original ATD when opening the packaging to replace the patient information leaflet.
- Coincidentally, this would allow parallel traders to standardize packaging procedures, substantially decrease operational costs and increase profits.

Cases about how parallel traders can re-label products in compliance with the FMD are currently pending before the CJEU.

Re-labeling in compliance with the FMD: examples and advantages

- The FMD allows safety features to be replaced by «equivalent» features.
- ATDs simply need to be functional; it does not mean that signs of the prior ATD must not be visible.
- It just needs to be understood by whom the new ATDs were affixed.

This way, patients can see that a product was imported and by whom it was modified.

This level of transparency cannot be reached through re-boxing.

Left: ATDs with parallel traders' company names or logos
Right: re-labeled packaging with parallel trader's silver ATD

Parallel trade and transparency: summary

- Consumers and patients demand transparency to enable them to make their own, personal choices.
- Parallel traded products have deficiencies regarding transparency, especially if products are re-boxed or re-branded.
- Parallel traders favor that conduct due to its commercial appeal: re-boxing can save costs, and re-branding allows for a different positioning in the market.

A restrictive approach to significant interferences with products is in the interest of patients, payers, and businesses.

Thank you

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