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Ex Post Assessment of European Competition Policy:

The Pharmaceutical Parallel Trade Cases

5 February 2021

Jan Blockx & Benoît Durand

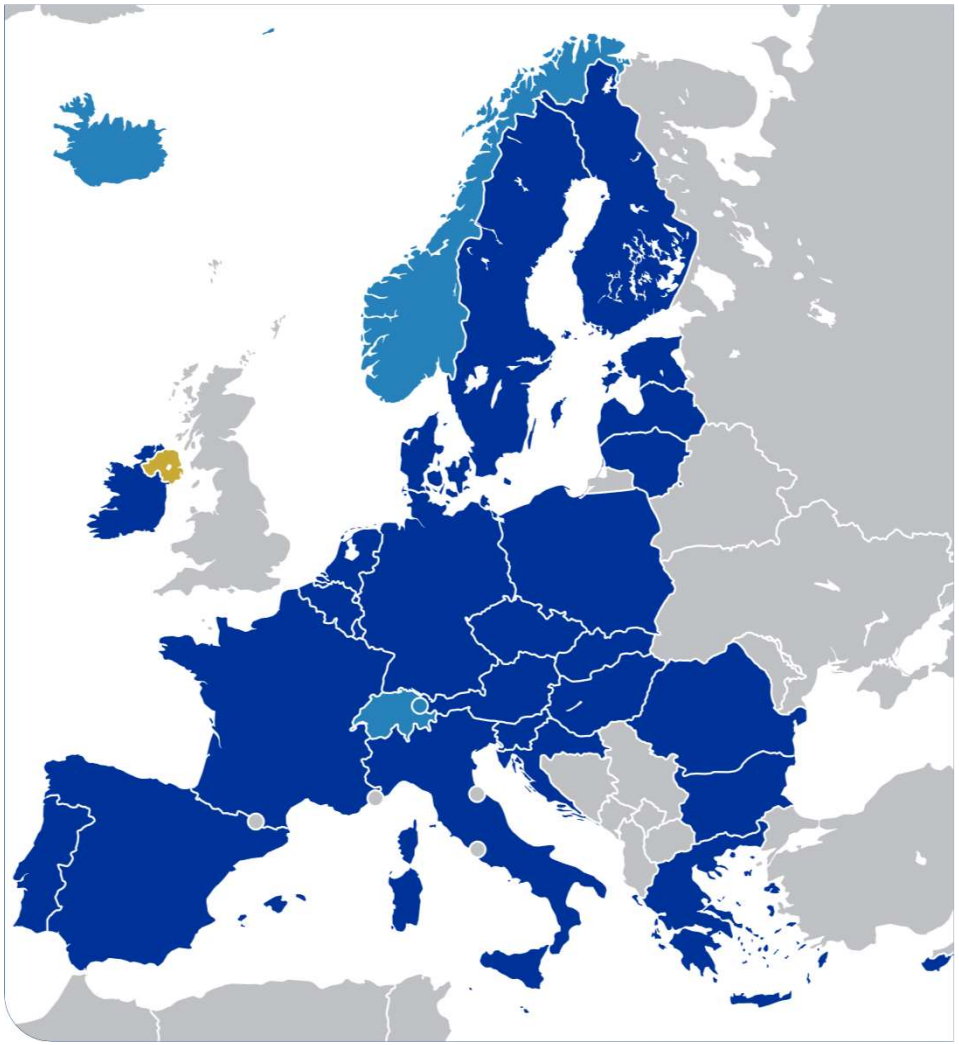
University of Antwerp

RBB Economics

Pharmaceutical regulation and pricing

- Ensuring safety and quality
- Ensuring availability
- Limiting medical expenditure
- Encouraging innovation

(mostly at national level)



EU single market imperative

- Member States cannot restrict free movement of drugs
- EU rules to facilitate single market in pharmaceuticals
- Also meant to enhance economic efficiency

  <u>But</u> clashes with national regulation

COURT OF JUSTICE
OF THE EUROPEAN UNION

Bayer Adalat

1996 EC decision finding that Bayer's policy of restricting parallel trade infringed Art. 101 TFEU

2000 CFI judgment held that unilateral limitations of supply do not constitute an agreement

2004 CJEU judgment upholds CFI ruling

⇒ Art. 101 TFEU not applicable to unilateral policy of supplier to restrict supplies

Glaxo Spain

2001 EC decision that Glaxo's dual pricing policy infringed Art. 101 TFEU by object and effect & could not be justified under Art. 101(3) TFEU

2006 CFI judgment held that dual pricing is not restriction by object & that EC had not properly assessed Glaxo's arguments under Art. 101(3) TFEU

2009 CJEU judgment overturned CFI judgment re restriction by object

⇒ Dual pricing is a restriction by object but can possibly be justified under Art. 101(3) TFEU

Glaxo Greece

2008 CJEU preliminary ruling held that Glaxo's refusal to supply 'ordinary orders' was an abuse of dominance

'Ordinary orders' to be determined in light of previous business relations and size of the market

⇒ Art. 102 TFEU prohibits a dominant undertaking from refusing to supply 'ordinary orders'

The importance of parallel imports of pharmaceuticals in the EU

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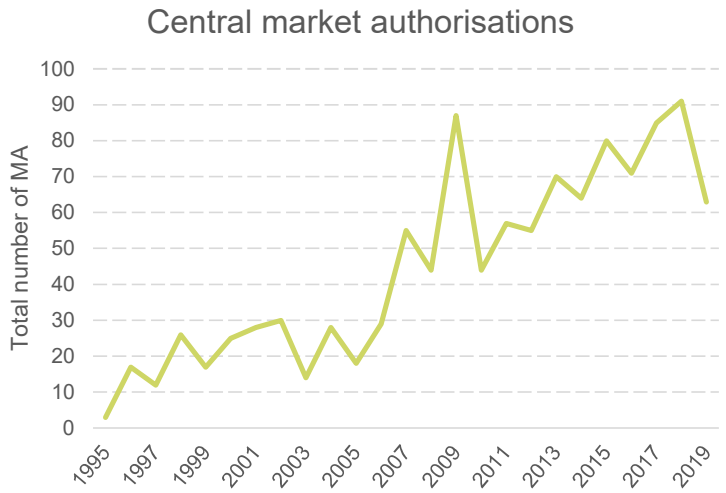
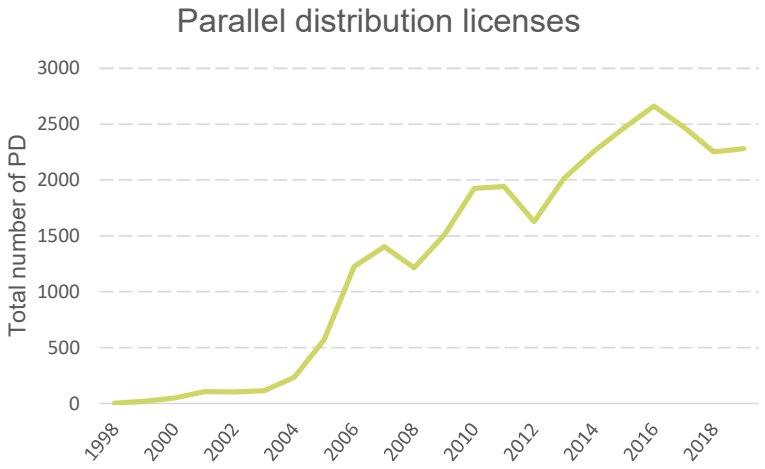
Data from the European Medicines Agency (EMA) show that the number of central market authorisations as well as the number of parallel distribution licences have increased steadily over the last two decades.





Which EEA countries benefit from parallel imports?

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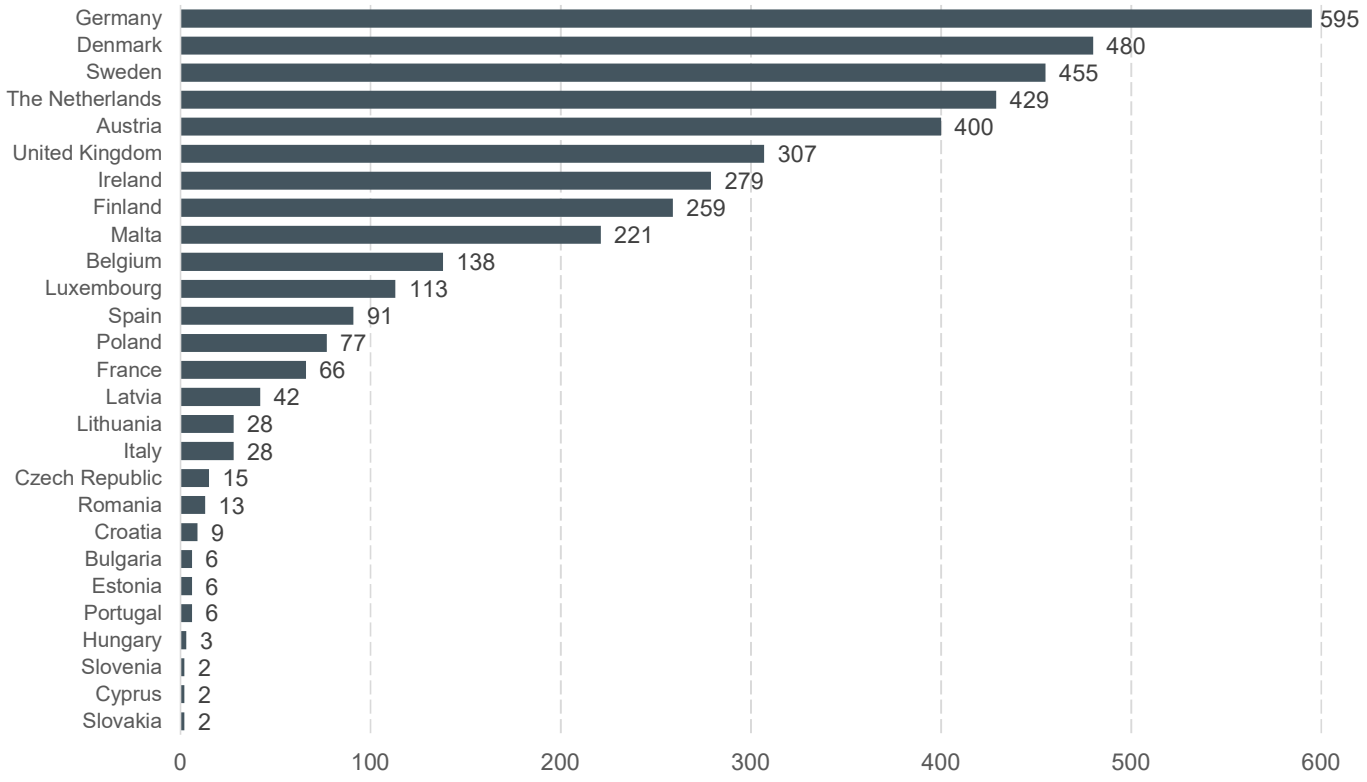
Destination countries by number of medicines subject to parallel distribution (EMA - 1995-2020).



The penetration of parallel imports in destination countries (EFPIA estimates)

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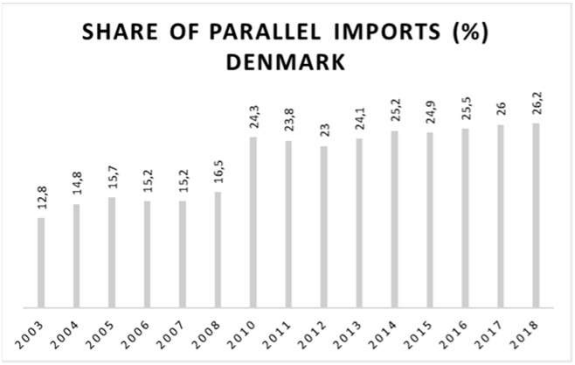

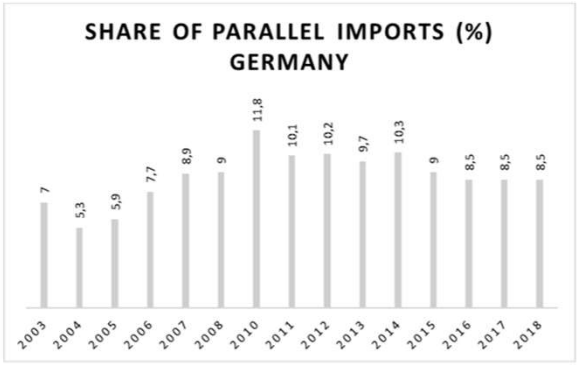

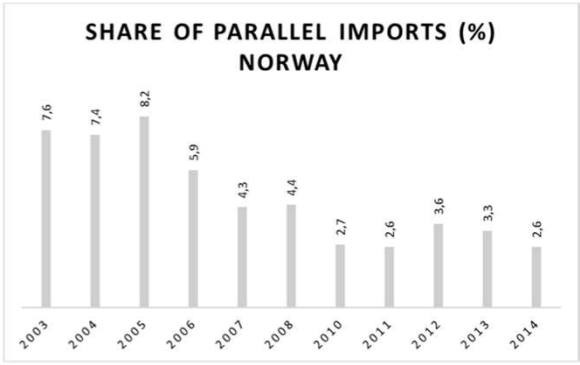

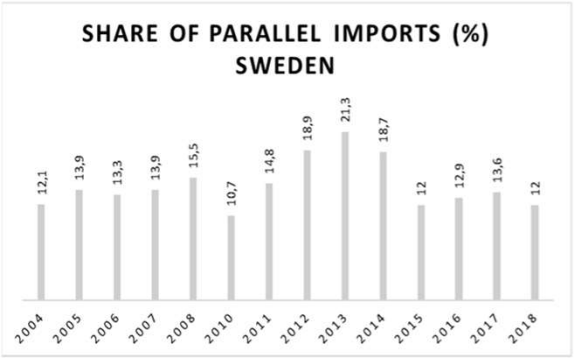

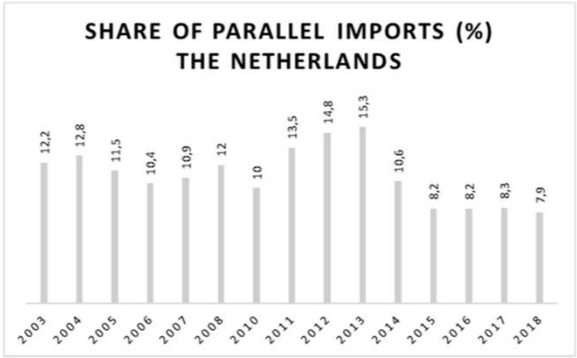

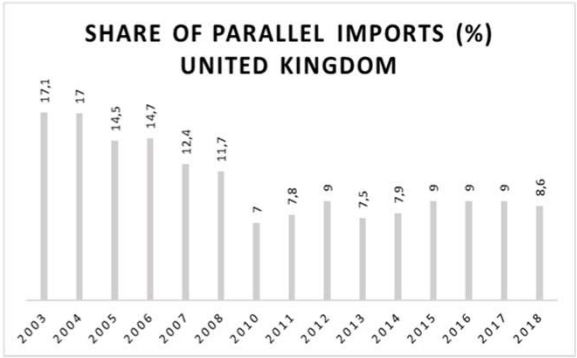

The effects of parallel imports on the price of medicines in the EU

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- Some evidence that parallel imports reduce prices of manufacturer's "direct exports", but not always conclusive
  - This finding would be consistent with national regulation that encourages parallel imports to constrain pharma's prices

- Some evidence that parallel imports improve the bargaining power of local distributors when negotiating with pharmaceutical companies
  - More stringent price regulation (e.g. reduction of price cap) would harm distributors more than the pharmaceutical companies
    - A lower price cap would reduce the attractiveness of parallel imports

- No evidence of price convergence within the EU
  - The objective of market integration is not met
  - Regulatory arbitrage: parallel imports strive largely because of price differences that are directly or indirectly controlled by national regulator (prices are not determined by market forces)

The effects of parallel imports on innovation

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- Parallel imports are expected to reduce the returns on R&D
  - Europe represents a little more than 20% of global pharmaceutical revenue

- Advances in economic theory highlight a complex relationship
  - Grossman and Lai (2008) challenges the notion that parallel imports have a negative impact on innovation
    - Parallel imports force regulator of low-income country to set relatively high price, otherwise pharmaceutical companies would “walk away”
  - Bennatto and Valletti (2014) and Reisinger, Sauri and Zenger (2018) extend this analysis to show that in some circumstances parallel trade actually reduces the incentive to invest in R&D

- Ultimately, this hypothesis should be tested empirically

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