



**AFFORDABLE
MEDICINES
EUROPE**

WORKING IN PARALLEL FOR A BETTER DEAL

IMPORT & EXPORT OF MEDICINES IN ITALY

AIFA PRESENTATION

KASPER ERNEST

30 MARCH 2021 | BRUSSELS



WHO WE ARE

- Formed in 1998, located in Brussels
- 125+ individual member companies in 23 EU Member States
- All member companies are EU licenced wholesalers, subject to GDP
- Importer members repackage under GMP
- All members subject to audit by TÜV
- All members sign up to a code of conduct: 'Good Parallel Distribution Guidelines'
- Founding member of EMVO (with EFPIA, MfE, GIRP, PGEU)

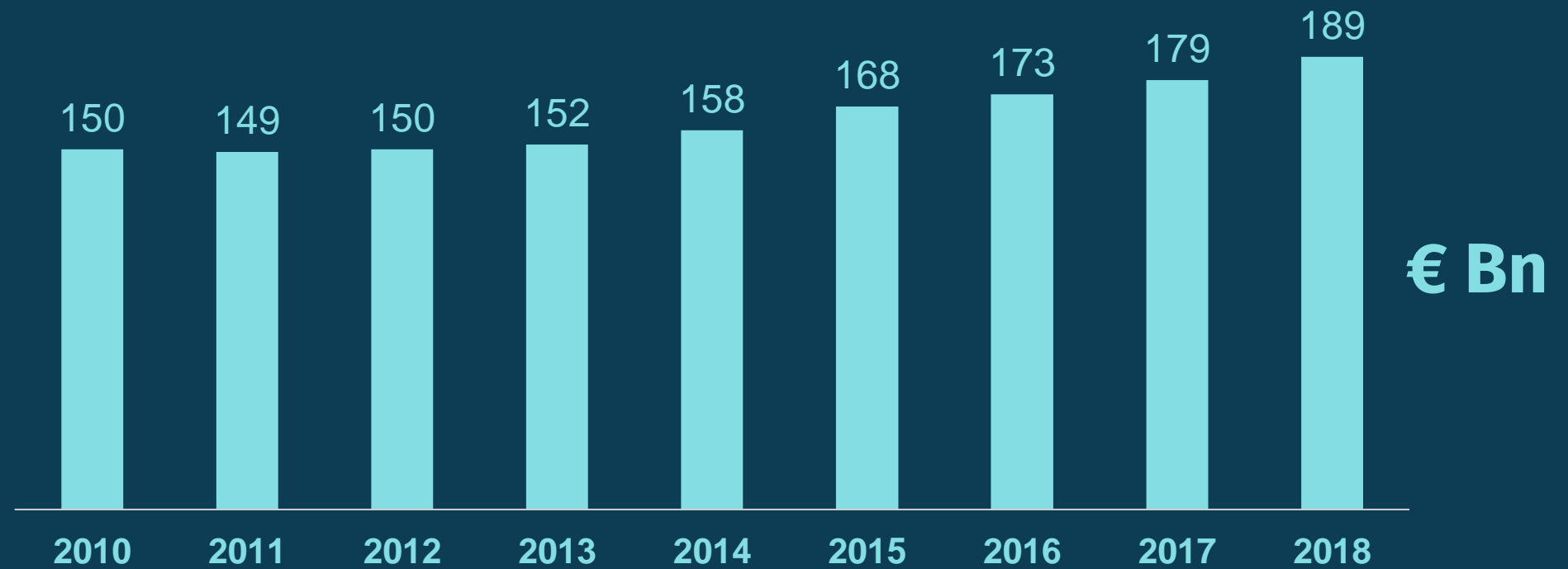


VISION

To Bring Europeans
Affordable Medicines



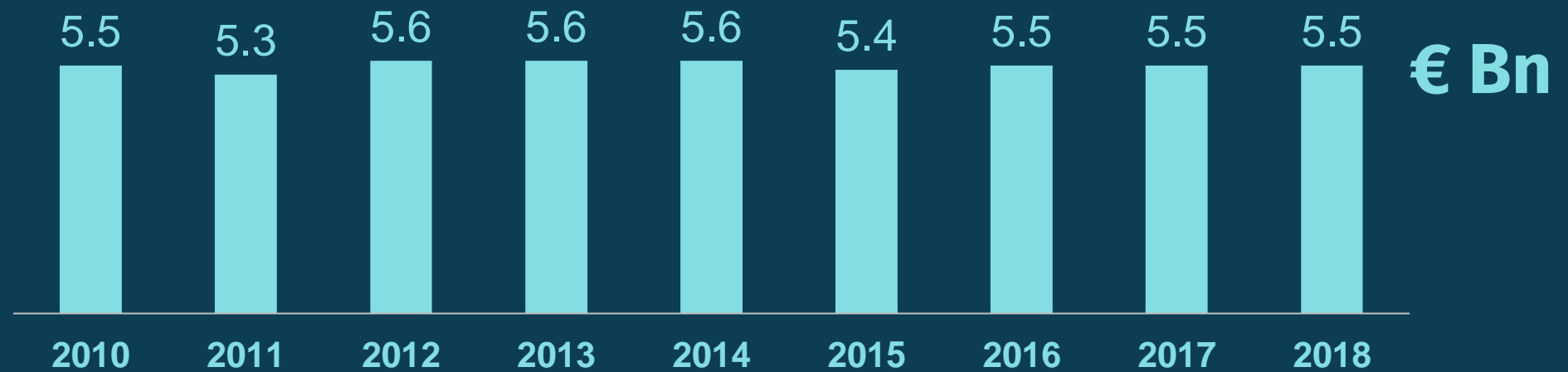
TURNOVER OF PHARMACEUTICALS



Source: EFPIA



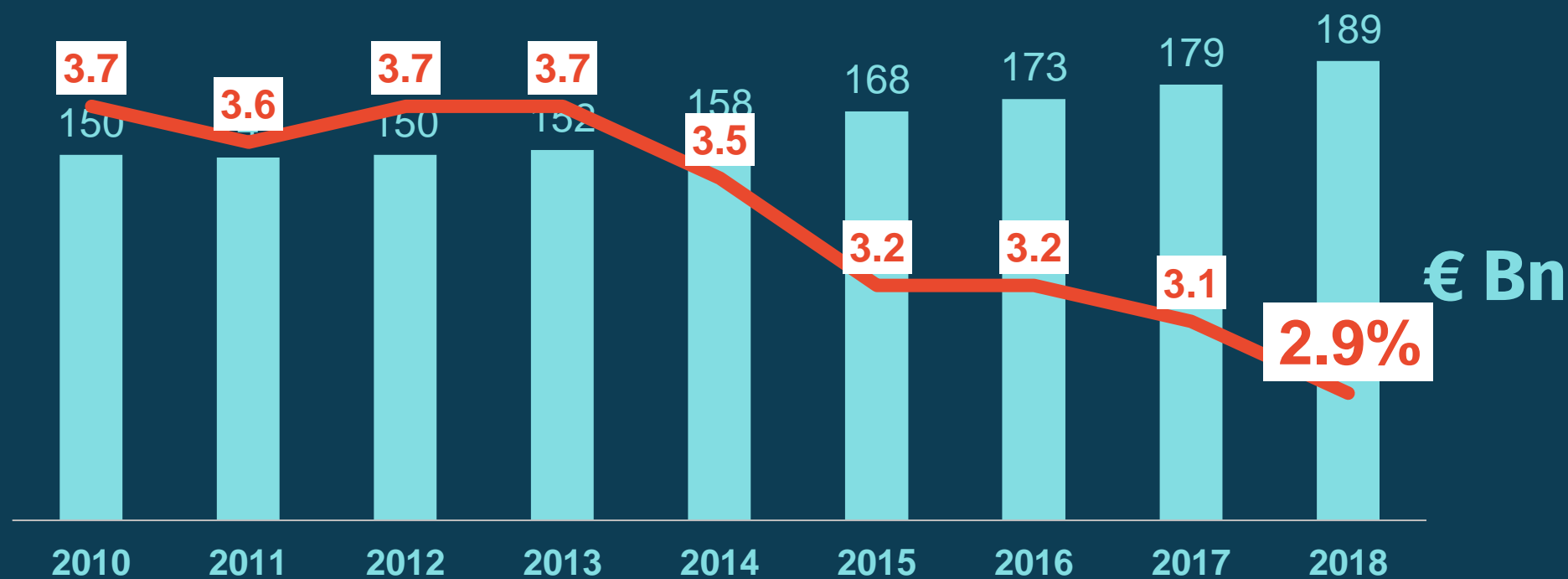
TURNOVER OF PARALLEL IMPORTS



Source: IQVIA

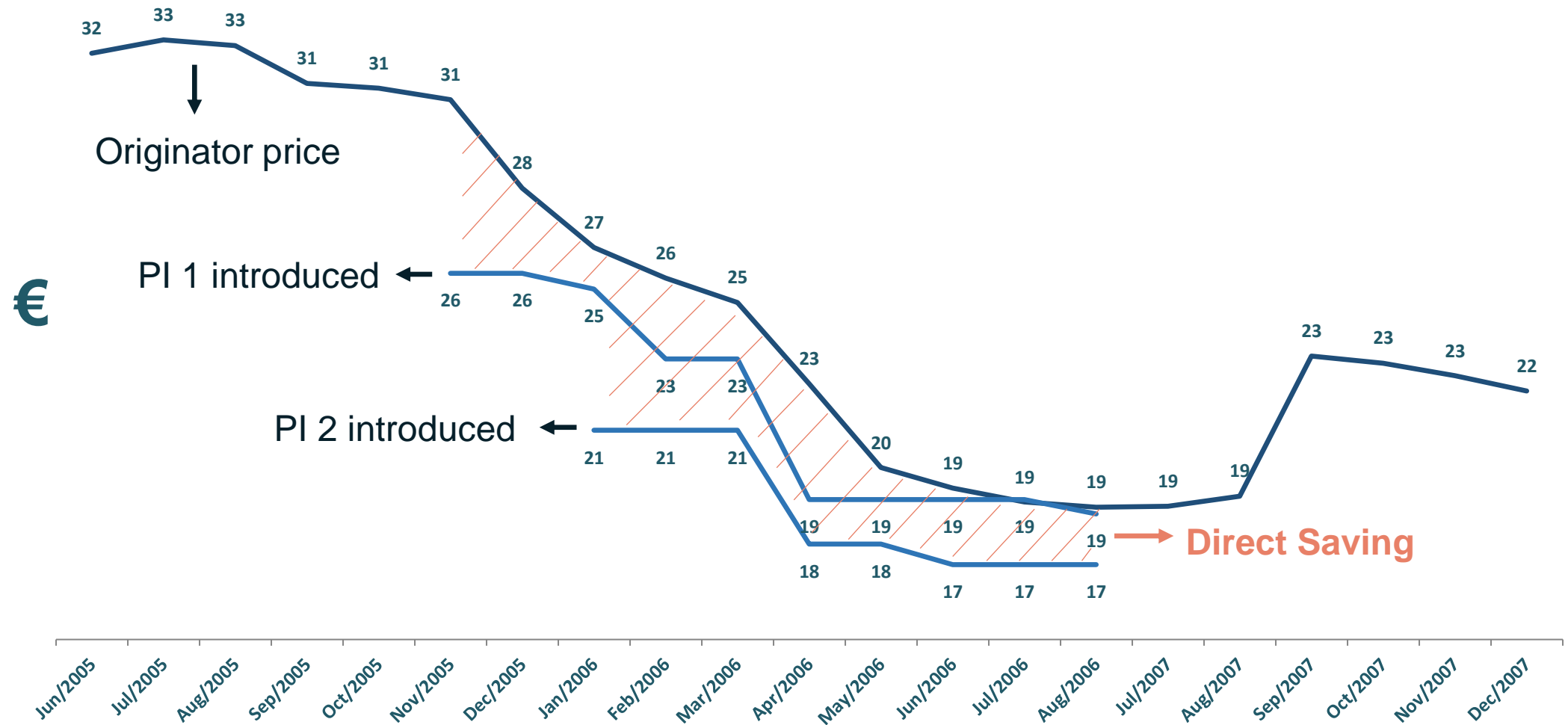


SHARE OF PARALLEL IMPORTS



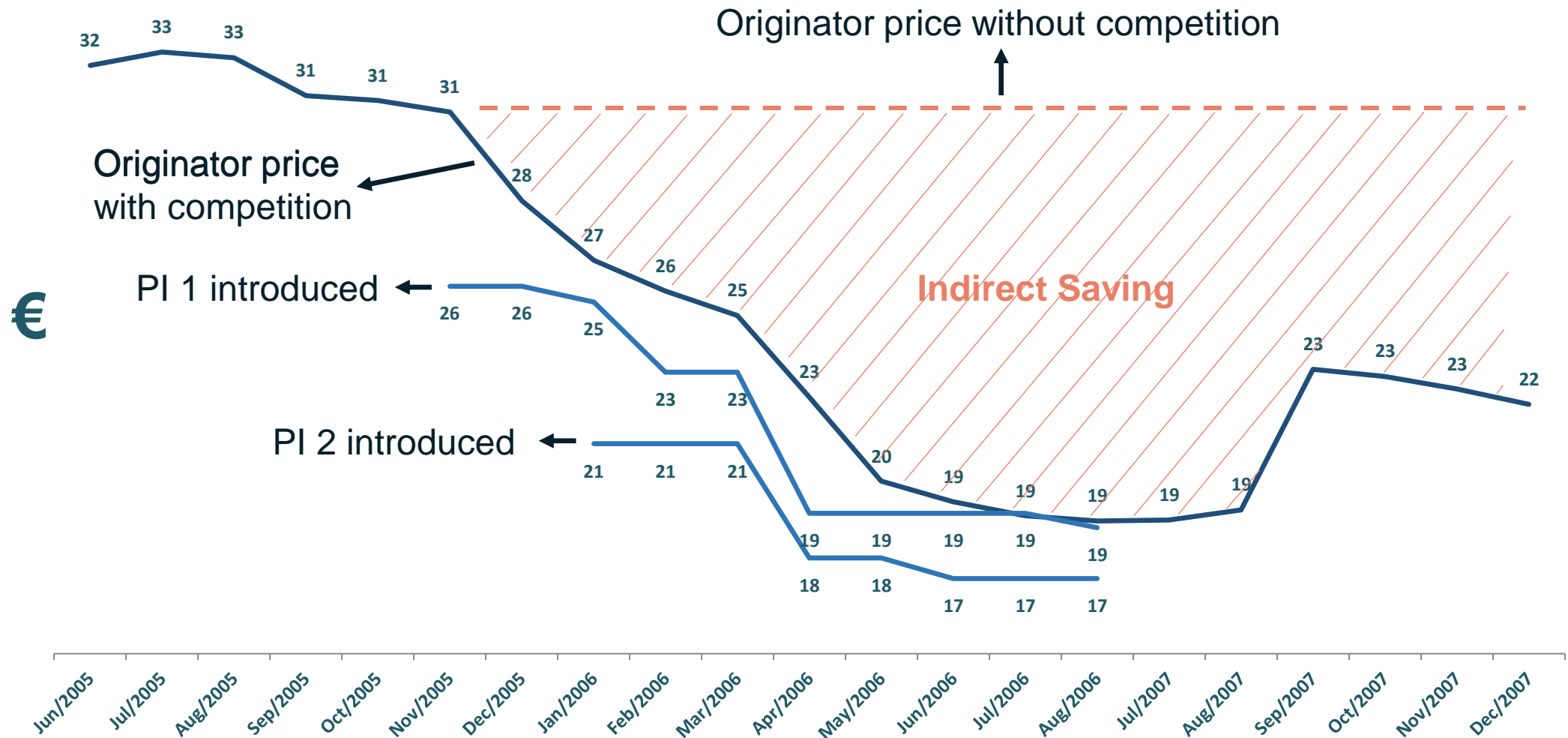


Case – Cilest in Poland





Case – Cilest in Poland





MAIN RESULTS

	POLAND	GERMANY	SWEDEN	DENMARK
DIRECT SAVINGS	€ 51.7M	€ 202M	€ 50.0-70.0M	€ 31.5M
INDIRECT SAVINGS	€ 56.8M	€ 2,600M	€ 175.4M	€ 50.5M
PATIENT SAVINGS	€ 15.4M	N/A	N/A	N/A
TOTAL SAVINGS	€ 123.9M	€ 2,802M	€ 235.4M	€ 82.0M





PI FRAMEWORK IN ITALY

From 2004 to
2016

Legal & Regulatory framework: Regional Administrative Court of Lazio (Sent. N.1944/2007)

- **Public Price (PP) of parallel brand product = PP Originator brand**
- **Payback PI products = Payback Originator = 1,83%**

From 2017 to
April 2021

Legal & Regulatory framework: D.L. 158/2012 «Balduzzi» + Council of State (Sent. n.6612/2020 e 6613/2020) + D.M. 02 Aug 2019 & AIFA Guidelines for the P&R negotiation of pharmaceuticals (30 Dec 2020)

- **1. Mandatory negotiation of Public Price for all new parallel products applying for reimbursement**
- **2. PP parallel brand product = PP of the cheapest generic product or Delisting (no reimbursement for parallel products)**

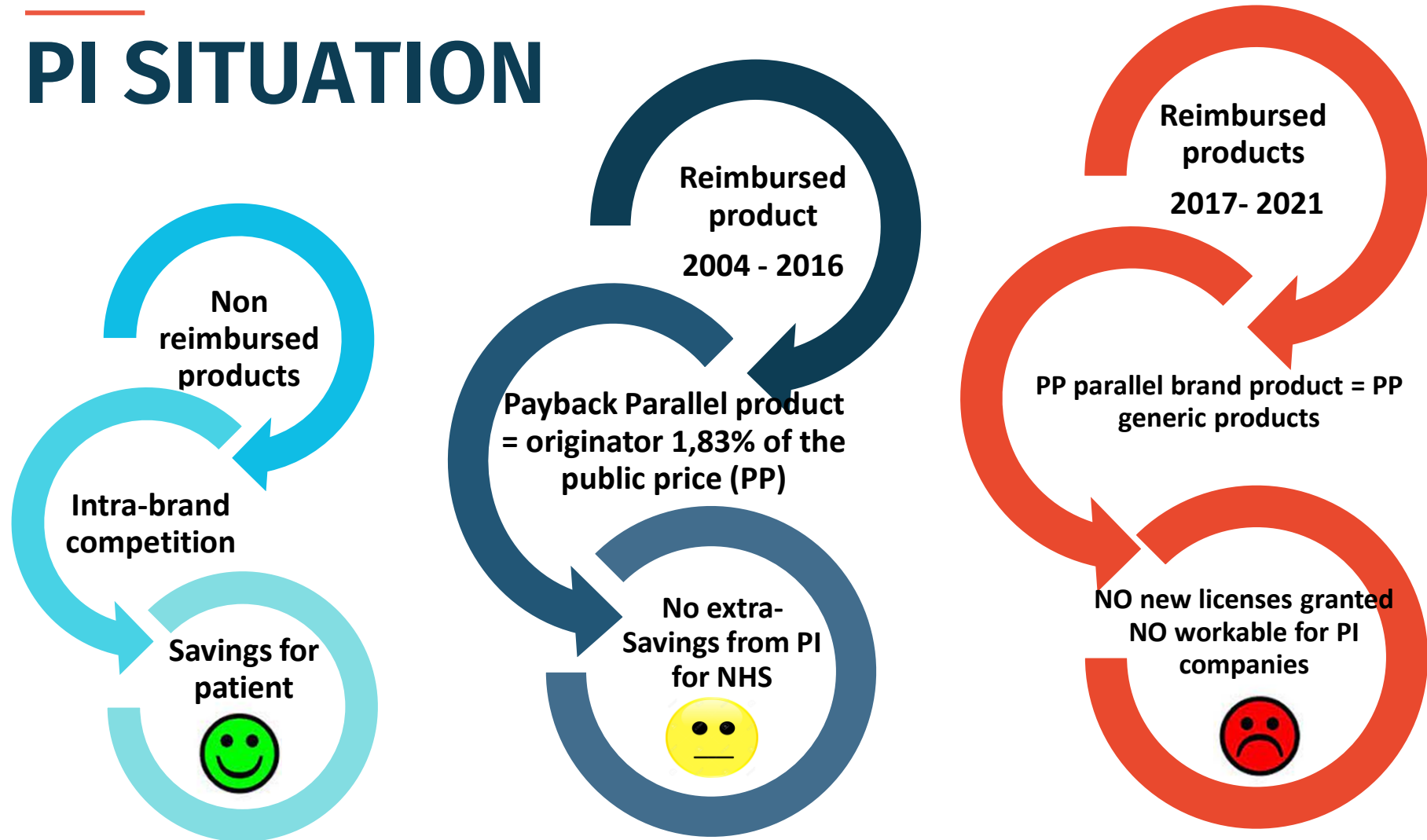
From April
2021

Legal & Regulatory Framework: All rules in force from 2017 + Determina D.G. AIFA (to be published on the Italian Official Journal)

- **1. Negotiation of PP**
- **2. Simplified Procedure for access to reimbursement of parallel brand product, on the condition that its PP is 10% lower than the PP of the originator brand**



PI SITUATION





PI POTENTIAL IN ITALY

- Attracting more investment in PI licenses require:
 - ✓ A stable framework
 - ✓ A balanced financial approach of mutual benefit
 - ✓ Right incentives at dispensing level



THE REPORT - IMPORTS

- **Measure import in licenses – not value or volume**
- **47.2%** of IT imports come from top-10 GDP countries
 - So 72.3% from small import markets is highly overestimated
- **35.7%** of IT imports come from medium/large PI markets
 - So 17.3% is underestimating their contribution to IT imports



THE REPORT - IMPORTS

Conclusions on import?

- Healthy level of competition (i.e. several PI companies in the market)
- The market seems to have more potential if framework would improve (i.e. larger market would allow more investments, incl. in logistics etc.)

TRADE FLOWS

51%

of parallel imports come
from high-income countries



Definition of high-income countries

We consider high-income the twelve countries with the highest GDP per capita in 2018 in the EU according to Eurostat plus Norway, which also has a relevant PI market





REPORT

Free translation:

“The decision to request an AIP for products referable to a particular ATC or for a single medicine is determined by the opportunities offered by the single supply market rather than by the obvious logic of purchasing in EU countries with low per capita income.”



THE REPORT - EXPORTS

- **Measure exports to non-EU countries as well**
- Include direct exports by manufacturers – not for PI
 - Our data suggest that only around 50% of IT exports registered go to parallel import \approx €350m. Not $\frac{3}{4}$ as suggested.
- Parallel export per capita according to our data = 5.9€. This is less than e.g. UK and NL, and far below EU average.



THE REPORT - EXPORTS

Conclusions on export?

- Exports seem to be on a downward trend
- **Parallel** export is not significant in Italy per capita. Only 19th in EU/EEA.
- We look forward to Italy joining the FMD. Cases like Volcano cannot infiltrate legal supply chain today.



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THANK YOU !

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