



Estonian Presidency
of the Council of the
European Union

Availability of medicinal products after Feb 2019

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WITHOUT FALSIFIED
MEDICINES**



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Medicines For Europe
VISION



PATIENTS



QUALITY



VALUE



SUSTAINABILITY



PARTNERSHIP

PATIENTS • QUALITY • VALUE • SUSTAINABILITY • PARTNERSHIP



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Activities in Patient Safety & The Fight Against Counterfeiting

Medicines for Europe: forefront of fight
against counterfeiting

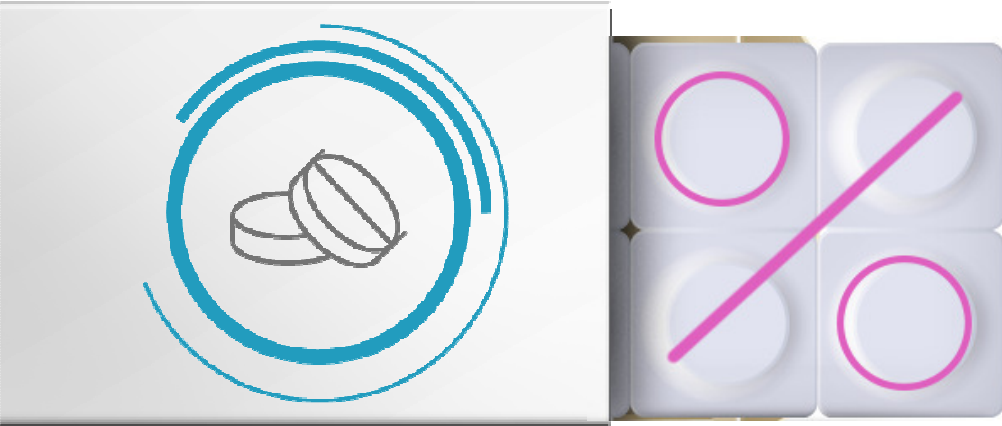


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- EMVO (European Medicines Verification Organisation, 2015)
- Fight the Fakes (2016)
- UNICRI (Organised crime and internet sales, 2012)
- ASOP EU (Alliance for Safe Online Pharmacy, 2012)
- Participation in the EC Observatory of Piracy and Counterfeiting (2009)
- EC Stakeholder Meeting on Internet - Internet Dialogue (2009)
- WHO IMPACT (2006, Anti-Counterfeiting Task Force)
- GS1 Healthcare (2005, Global Coding Entity)
- Council of Europe (2004)

Generic medicines manufacturers operate cost efficiently to offer maximum benefit to patients

Source: Medicines for Europe members survey



- Generic manufacturing is a **high-volume / low-margin** business (MS: 29% in value / 62% in volume)
- **Competition is fierce** - Average price reduction after patent expiry **50%, increasing** over time
- A single manufacturer can have **25 000** market authorisations in Europe
- A manufacturer can ship to **50 000+** customers in Europe
- **20 billion doses** per **year produced** in a single manufacturing site
- **350 European** manufacturing facilities
- Complex supply chains for cost and flexibility (many supply chain partners)
- **R&D investment** to bring new devices, formulations and biosimilars to bring competition and access to specialty markets

Regulatory compliance impacts cost structure



Large manufacturer may employ **1000+** people in regulatory and **250+** people on PV



300+ people on maintenance activities



Around **40%** of **RA staff (400 people)** support EU regulatory activities



75% of **EU regulatory budget** (up to 20-25 Million Eur) on **MA maintenance cost** e.g. renewals, Annual fees, PSUR's, Safety Variations, CMC Variations



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Costs of FMD compliance

Average company

Update packaging
and production lines:
€ 50 million

Annual running and
maintenance costs:
€ +2 million

Total pharma industry

Update packaging
and production lines:
€ 5 billion

EMVS:
- implementation cost: € +90 Mio
- annual running cost: € +90 Mio

- Implementation cost: details from technical workshop at EGA on 22 February 2012
 - Annual cost: cost for repository systems per year: € 90 million

The ability to supply
negatively affected by:

- regulatory costs
- price pressure



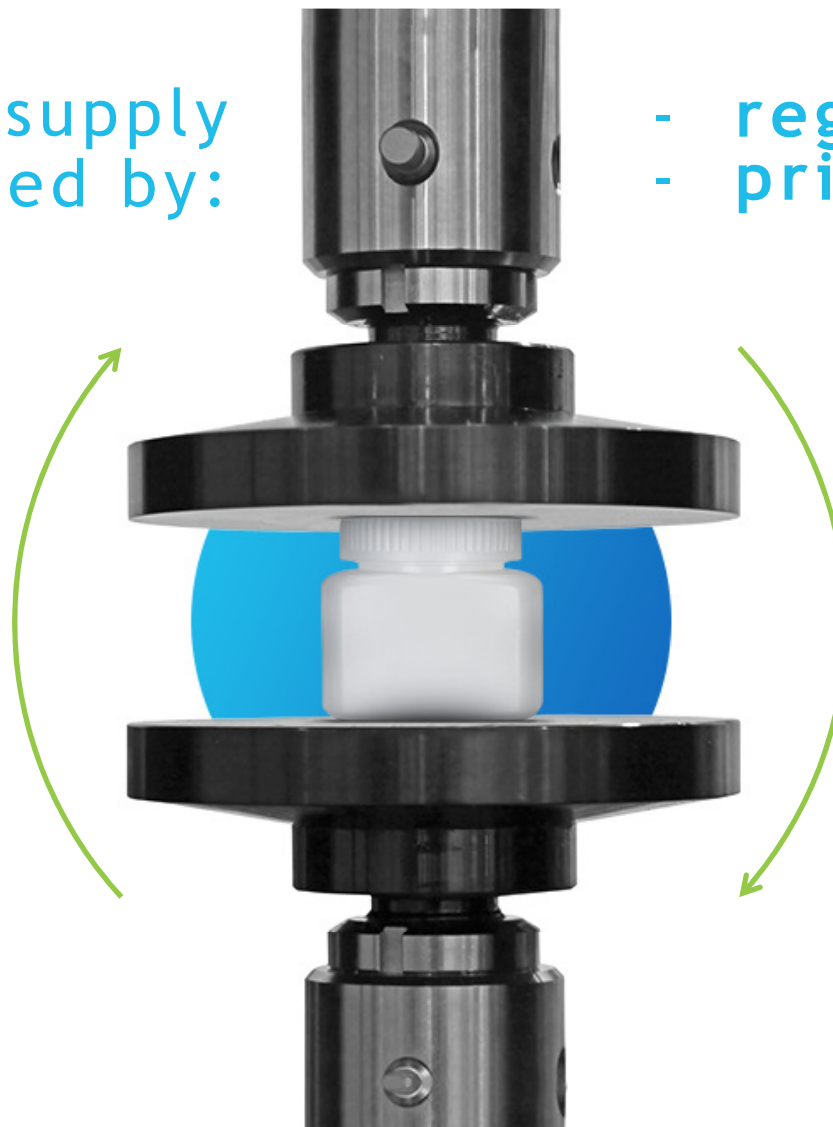
Regulatory compliance

- FMD
- GMP / GCP / ...
- Variations, notification
- PV regulation

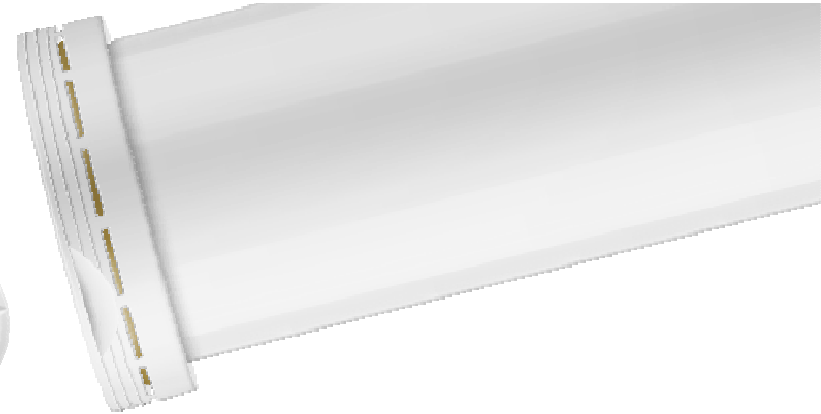
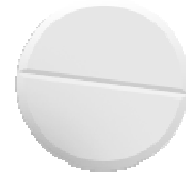


Price

- Price cuts
- Tendering
- External Reference Price
- Claw-back



Creating and Maintaining a Multi-Source market



**MORE
MANUFACTURERS
=
LESS SHORTAGES**



- Regulatory efficiency can reduce admin burden for products in the market
- Ensure market predictability
- Address impact of parallel trade
- Manage available market stock information



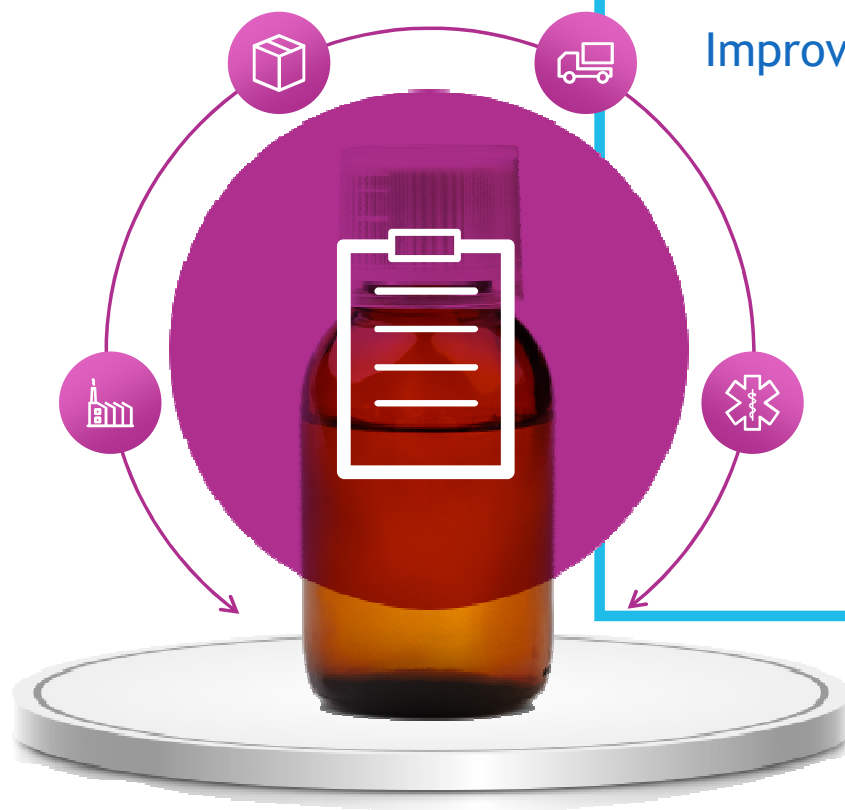
Mitigate shortages



- Specific regulatory measures to mitigate imminent shortage(s); e.g.
 - eLeaflet
 - Flexibility on pack sizes
 - Guarantees for alternative suppliers...



FMD related recommendations to Prevent shortages



Improve available information

- **Leverage the European Medicines Verification System**
 - for authorities and manufacturers & supply chain to improve stock management
 - In market vs checked out products
- **Harmonised Manufacturing**
 - Voluntary use of safety features
 - Standard coding/printing (key for multi-market packs)



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Thank you!

