



HERA HEALTH EMERGENCY
PREPAREDNESS AND
RESPONSE AUTHORITY

#HealthUnion

HERA Industry days

Health Emergency Preparedness and Response Authority

2 & 3 June 2025, Brussels

Plenary panel

**Future-proofing EU manufacturing:
competitive and resilient supply chains
for medical countermeasures**

Future-proofing EU manufacturing: competitive and resilient supply chains for medical countermeasures



András KULJA
Member of the European
Parliament



Emer COOKE
Executive Director, EMA



Elisabeth STAMPA
Chair of the Board at Medichem
SA and Vice-President
Medicines for Europe



Juan López-Belmonte ENCINA
EFPIA Board Member & CEO of
Rovi Pharmaceuticals

Future-proofing EU manufacturing: competitive and resilient supply chains

EMA activities

Emer Cooke
Executive Director



EMA's extended mandate three years on: What has already been done (focus on supply chains)



Operational group

Medicine Shortages SPOC Working Party

- Continuous monitoring of events and medicine shortages
- Mitigated and prevented critical shortages of antibiotics through a supply and demand exercise in preparation for winter of 2023/24
- Dialogue with companies
- Escalation of critical shortages to MSSG
- Monitoring of geopolitical situation
- Preparation of Critical Medicines Lists
- Addressing vulnerabilities in the production and supply of specific medicines



Executive group

Executive Steering Group on Shortages and Safety of medicinal products (MSSG)

- Activation of emergency measures for COVID & mpox
- Lists of critical medicines in public health crises (extensive monitoring)
- Approaches and recommendations to manage shortages, including regulatory flexibilities (e.g. labelling exemptions)
- Hearings with companies – resulting in e.g. new sites in EU, increased production capacity
- Multistakeholder workshop (anti-obesity)
- Voluntary Solidarity mechanism
- Oversight of European Shortage Monitoring Platform (ESMP)



SOME SUCCESSES

Prevention and mitigation of medicine shortages in the EU

- ✓ **Voluntary Solidarity Mechanism (VSM) for Member States**
 - Activated seven times in 2024 for critical shortages of oncology products
- ✓ **Critical shortages**
 - MSSG recommendations to tackle shortages of GLP-1 RAs, thrombolytics, antibiotics, eye disease medicines
- ✓ **Ensuring security of supply for critical medicines**
 - Two versions of union list of critical medicines – human medicines whose continued supply is considered a priority in the EU
 - Recommendations for radiopharmaceutical and anti-D immunoglobulins
 - Vulnerability Assessment methodology – work in progress
- ✓ **European Shortages Monitoring Platform launched in Jan 2025**
 - Provides more information (shortages, supply and demand)
 - Facilitates EU coordination for faster actions to prevent shortages
- ✓ **International cooperation**
 - Sharing information and best practices, seeking supplies



EMA's extended mandate three years on: What more can we do?

- ☑ **Proposing solutions to ensure security of supply**
 - Transition from a reactive management approach to a proactive prevention strategy
 - MSSG recommendations on structural measures to strengthen supply of critical medicines
 - Further advancement of harmonisation initiatives (e.g. implementation of shortage definition)
 - Vulnerability assessment methodology
 - Shortage Prevention Plans

- ☑ **Further development of European Shortages Monitoring Platform**
 - Gap analysis with EVMS
 - ESMP version 2 (e.g. VSM)

- ☑ **Continue enabling innovation in manufacturing**



WHAT HAVE WE LEARNT?

What EMA cannot do – why we need Critical Medicines Act and HERA

Need for industrial policy solutions and other non-regulatory measures

- ✓ Improve EU manufacturing capacity for **critical medicines**
- ✓ More flexible and coordinated use of **procurement solutions** (public, collaborative, joint)
- ✓ More **strategic international partnerships** to diversify sourcing of critical medicines to increase the security of supply
- ✓ Safeguards related to national measures on security of supply, in particular **contingency stock requirements** – avoiding the unintended consequences



EMA Extended Mandate

- **Monitoring, preparedness and crisis management**
- Improved coordination at EU level

Proposed pharmaceutical legislation

MONITORING AND MANAGEMENT:

Coordinated EU level monitoring and management of **critical shortages at all times**

PREVENTION:

Security of supply of medicines on the Union list of **critical medicines**, needed for health systems at all times

Supply chain **vulnerability assessment** of critical medicines informs:

MSSG Recommendations to address structural vulnerabilities

Certain provisions in Critical Medicines Act

Proposed Critical Medicines Act

- Complements the proposed pharma legislation
- Providing **industrial policy solutions to address vulnerabilities** and strengthen supply of medicines in the EU

Future-proofing EU manufacturing: competitive and resilient supply chains for medical countermeasures



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HERA Industry Days

High-level Panel Discussion: Future-proofing EU manufacturing:
competitive and resilient supply chains for medical counter-
measures

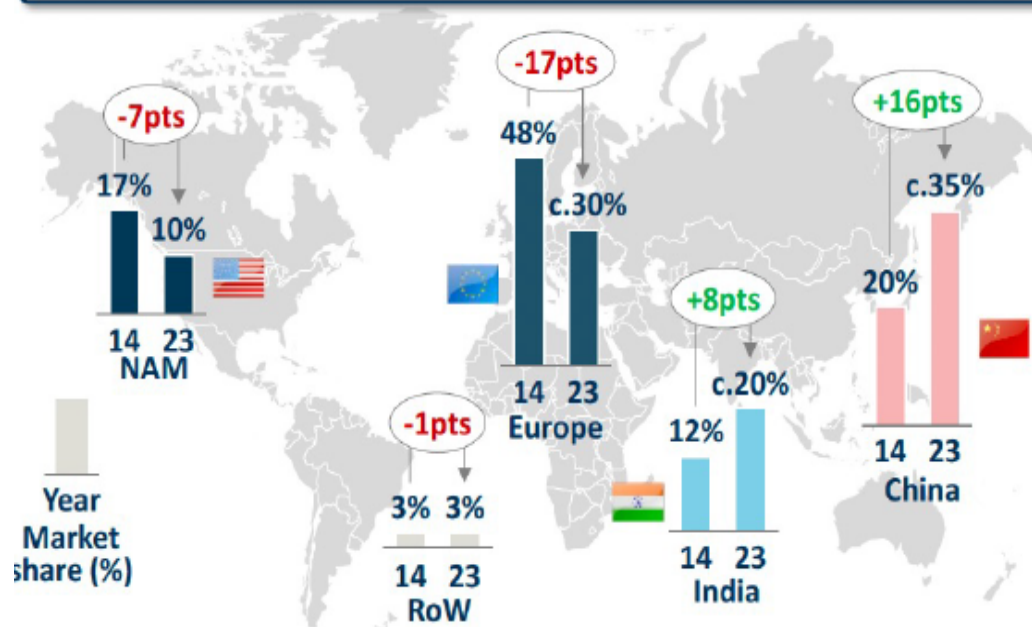
2 June 2025, 9:50-11:15

Elisabeth Stampa, Chair at Medichem SA and Vice President at
Medicines for Europe

European market-share has **decreased** and dependency **increased**

Merchant market, small molecules, €bn, %, 2014-2023, World

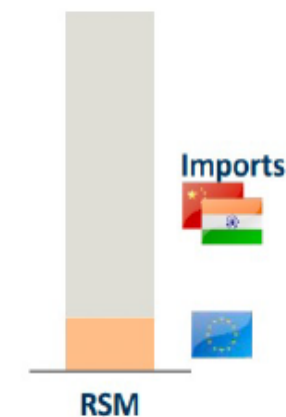
Small molecules merchant market (2023): c.€60bn



- Structural shift of small molecules API and related Intermediates production towards ASIA
- Production delocalisation enabled overall APIs cost reduction over the years but led to longer delay, risk of shutdown of production (non-compliance with regulatory standards after arbitrary inspection) and strong supply disruption (abrupt closure on government decision) players

Zooming in on European supply chain (base 100, 2023)

REGULATORY STARTING MATERIALS



RSMs are first chemical substances compliant with GMP mainly **imported from cost competitive regions** (China and India) to Europe

GMP INTERMEDIATES



In recent years, the share of imported GMP intermediates has increased with the development of regulatory-compliant Asian suppliers

API

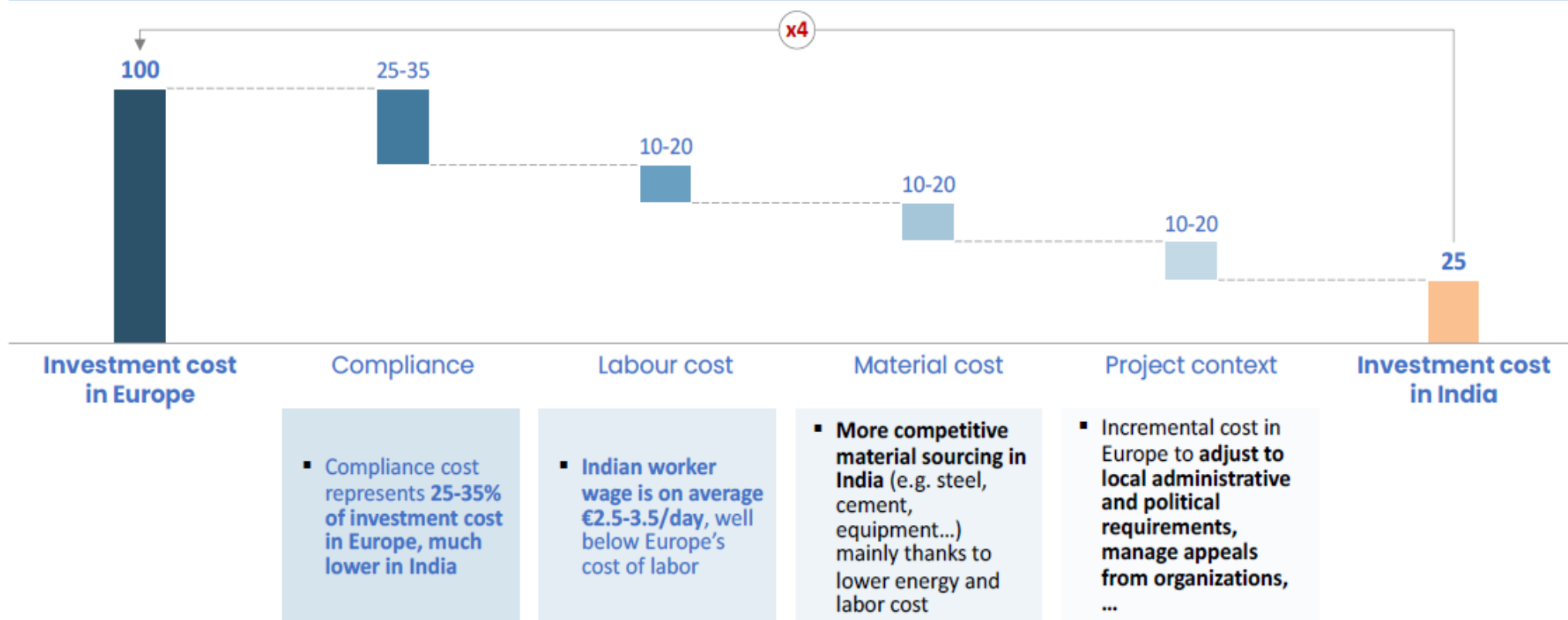


APIs with simple molecules being mainly imported while patented or more complex APIs are still produced locally

>74% of the European medicines value chain depends on imports

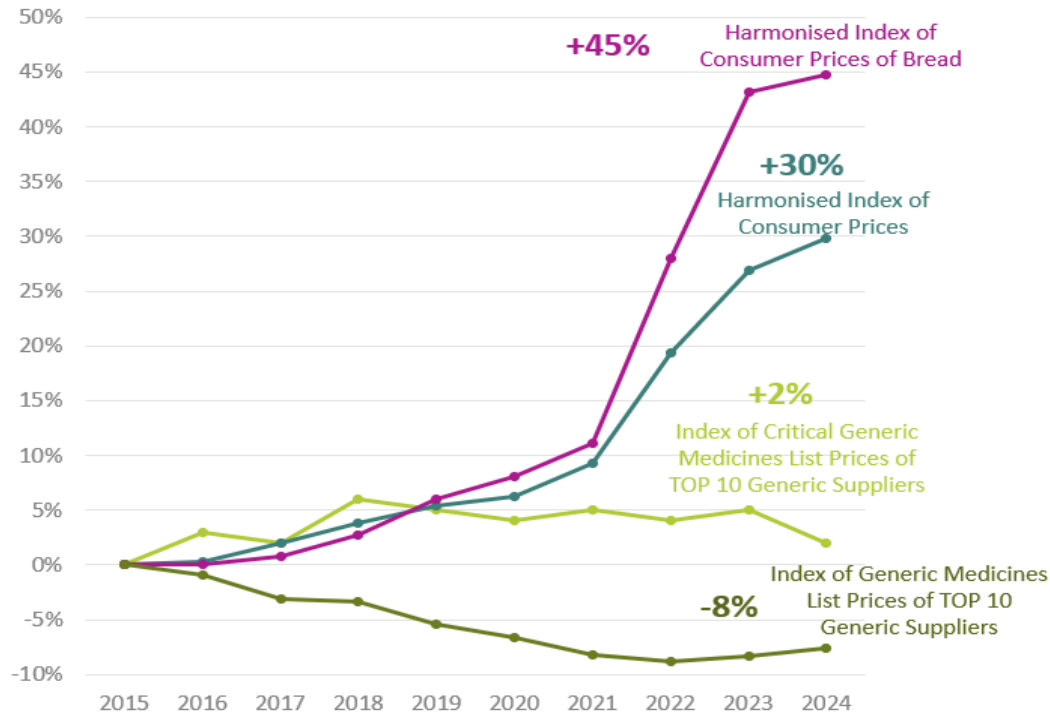
On average, investment in Europe is c.4x higher compared to India

European and Indian investment cost compared | index 100, 2023



Sources: Advancy analysis

Indexation of prices of generic medicines vs other goods



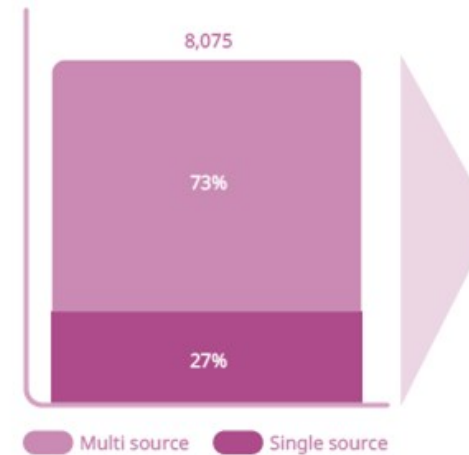
12 | TOP 10 generic suppliers provide 48% of the whole generic medicines volume

- Significant **difference** between off-patent medicines sector and **other industrial sectors** that operate in free pricing markets.
- Whereas industrial goods or commodity prices have increased between 30-45%, **generic medicine prices have decreased over the last ten years.**

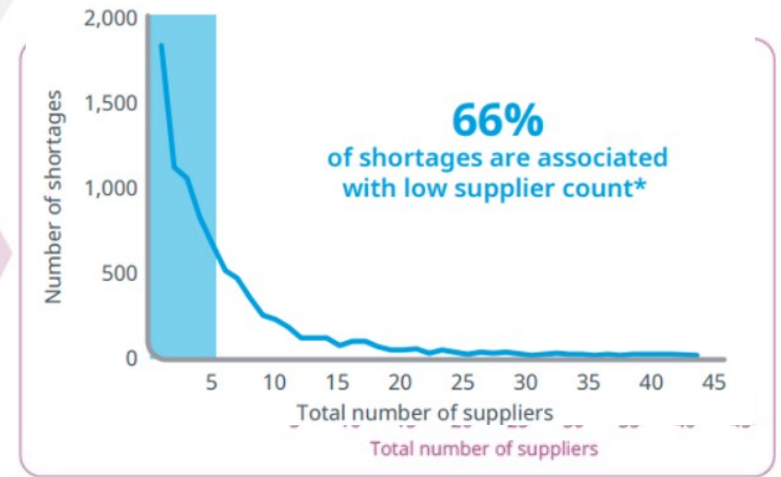
Shortages of medicines are associated with a low supplier count

Multisource markets can mitigate the impact of shortages by redistributing volumes

Overview of European shortages (2023)



Number of shortages by supplier count



Source: Beneath the Surface: Unravelling the True Value of Generic Medicines | April 2024; Derived from IQVIA Shortage Transparency Platform (based on NCA-reported shortages publicly available for all EU27 markets between January 2023 and January 2024. Low supplier count refers to instances where product is available via less than 5 suppliers in Europe

At National level



Ensure predictable and sustainable market environments



Stop taxing off-patent disproportionality in clawback/payback schemes



Improve tenders design to meet objectives beyond securing lowest price (multi-winner, MEAT criteria)



Allow for inflation adjustments



Consider New pricing models for generics

What can we do to?



Secure Supply through Better Pricing and Procurement (allow for better supply diversification)



Regulatory optimisation and digitalisation



Support investment to strengthen EU manufacturing and competitiveness (via CMA, Biotech Act, EU MFF)

At EU level

Thank you!

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Thank you