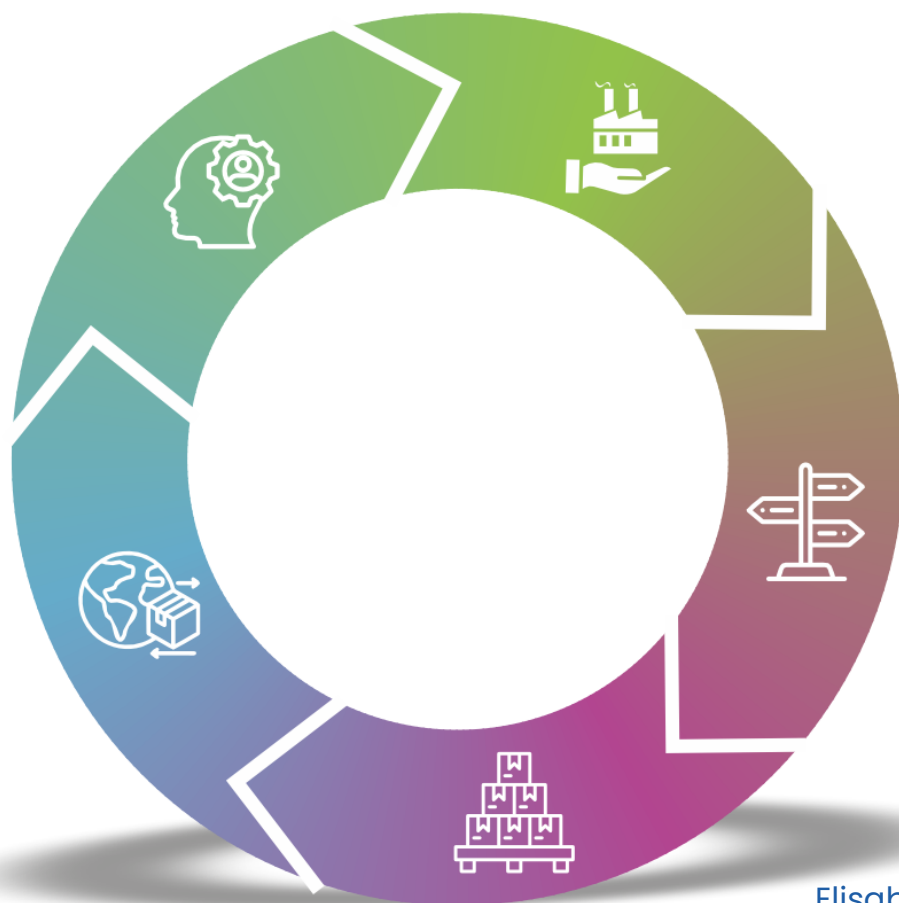


# Hearing on 'Overreliance on imports of Active Pharmaceutical Ingredients (APIs)'

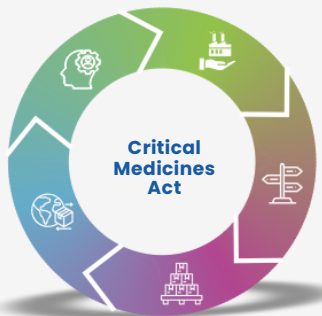
**Committee for Public Health (SANT)  
European Parliament**

29 January 2025

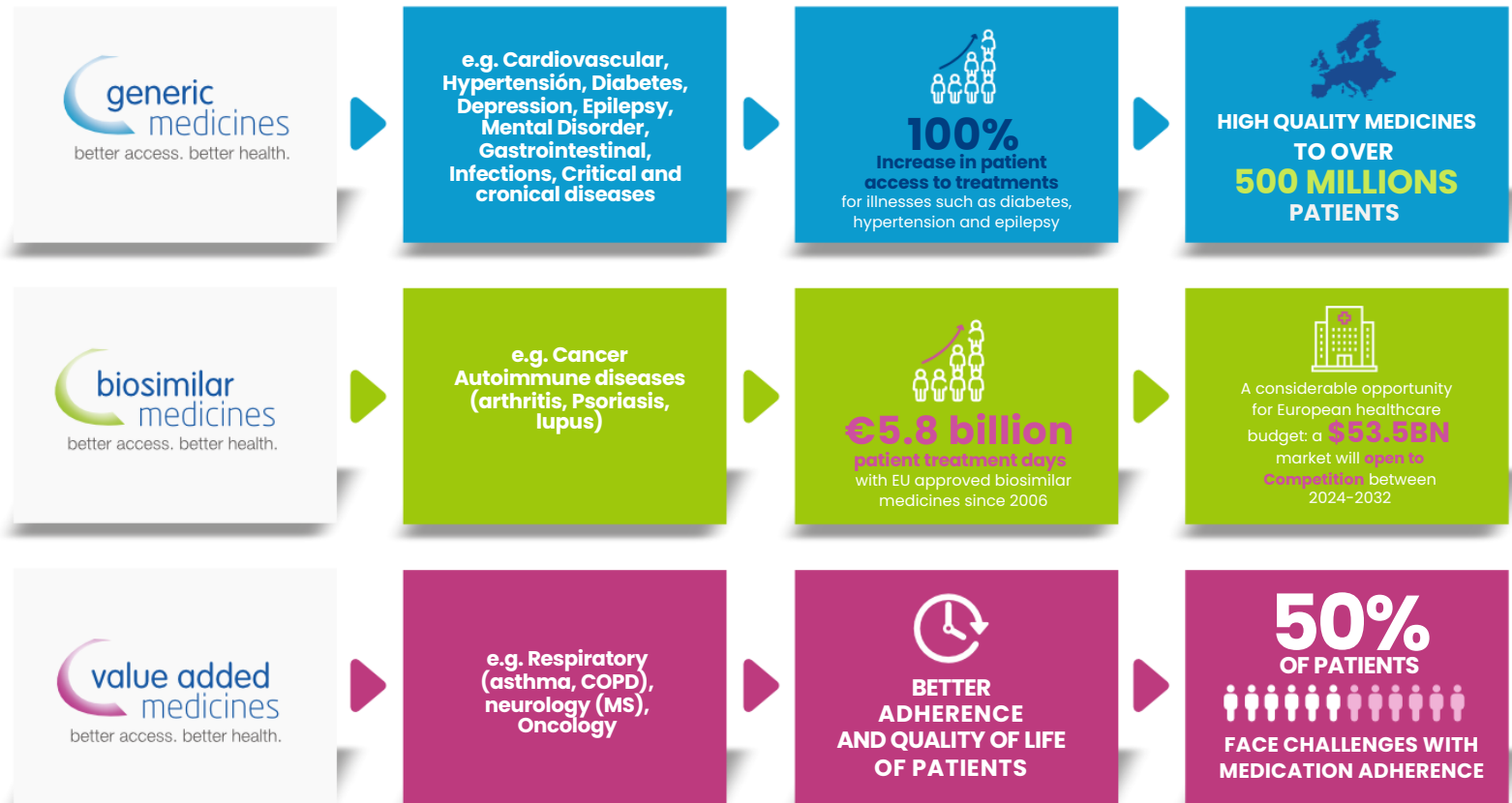
Elisabeth Stampá, VP Medicines for Europe, Chair Board Medichem SA



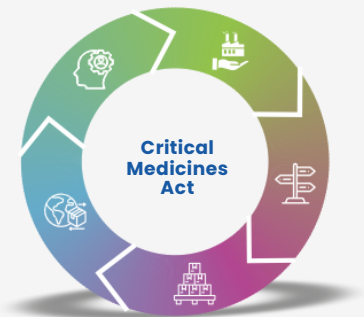
Hearing on  
'Overreliance on  
imports of Active  
Pharmaceutical  
Ingredients (APIs)'



## European off-patent medicines sector in numbers



Hearing on  
'Overreliance on  
imports of Active  
Pharmaceutical  
Ingredients (APIs)'



## European off-patent medicines sector in numbers



We supply **70% of dispensed medicines in EU** and  
**account for around 4% of total healthcare expenditure in Europe**



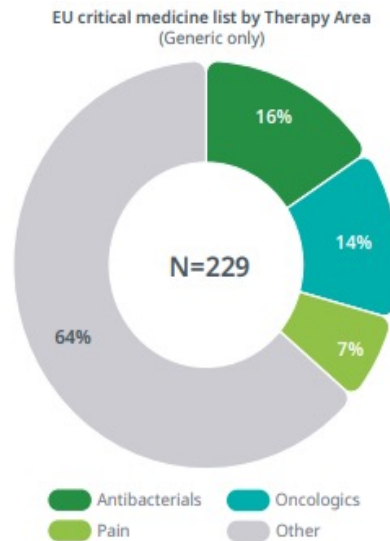
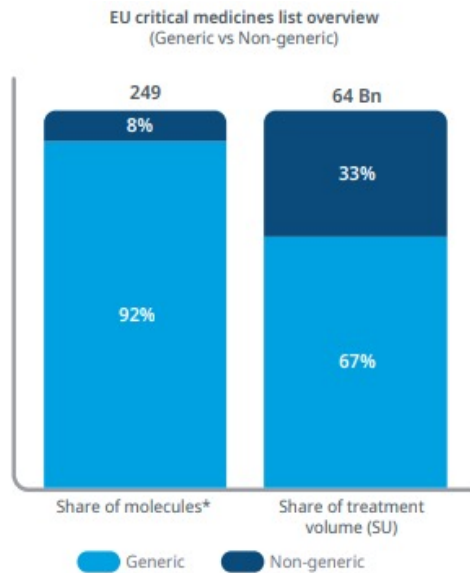
Between **70% and 90% of Covid-19 ICU medicines**  
were off-patent medicines



The off-patent medicine sector accounts in Europe over  
**400 manufacturing sites** and employees  
more than **190.000 high skilled workers directly**

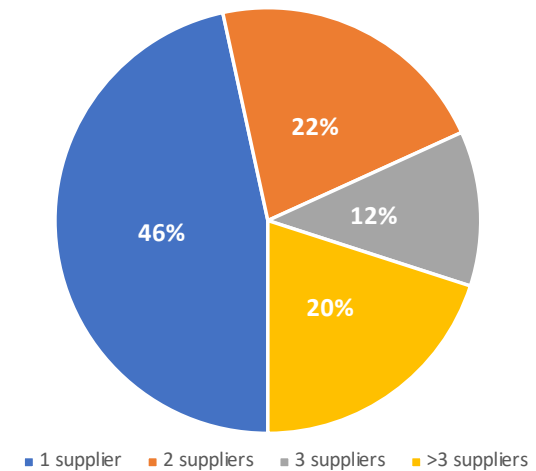
# 9 in 10 critical medicines are generic medicines

## Composition of Union Critical Medicines List



46% of critical generic products have only one supplier...

## Number of suppliers per critical generic product in 2024



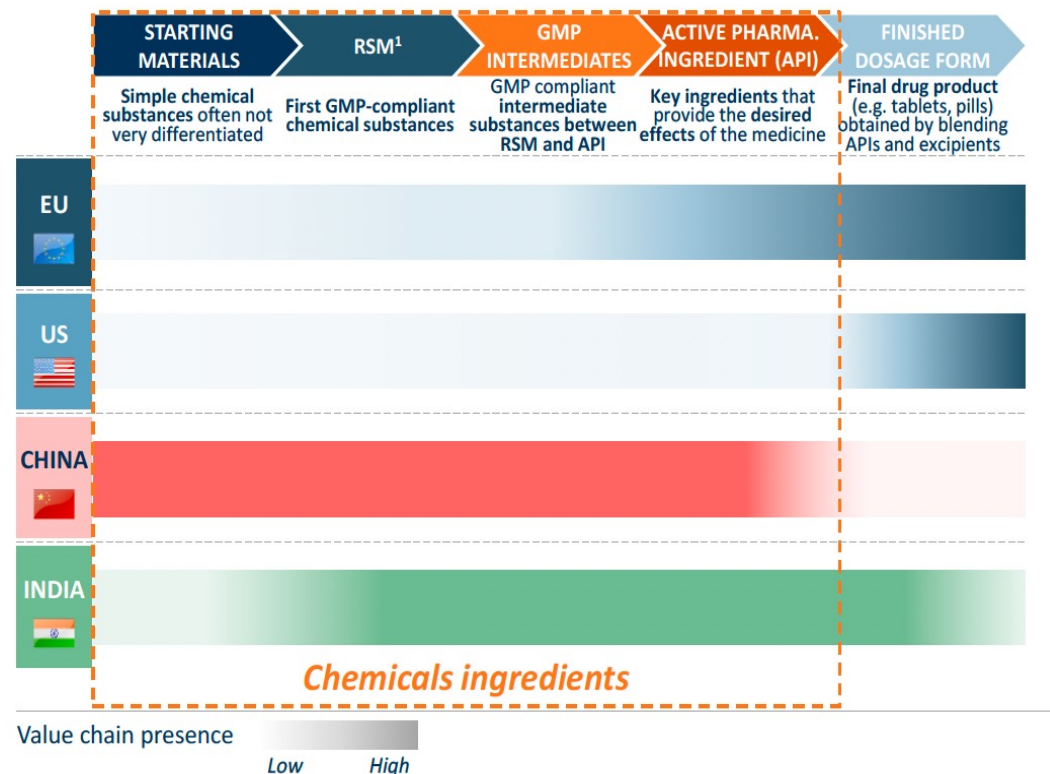
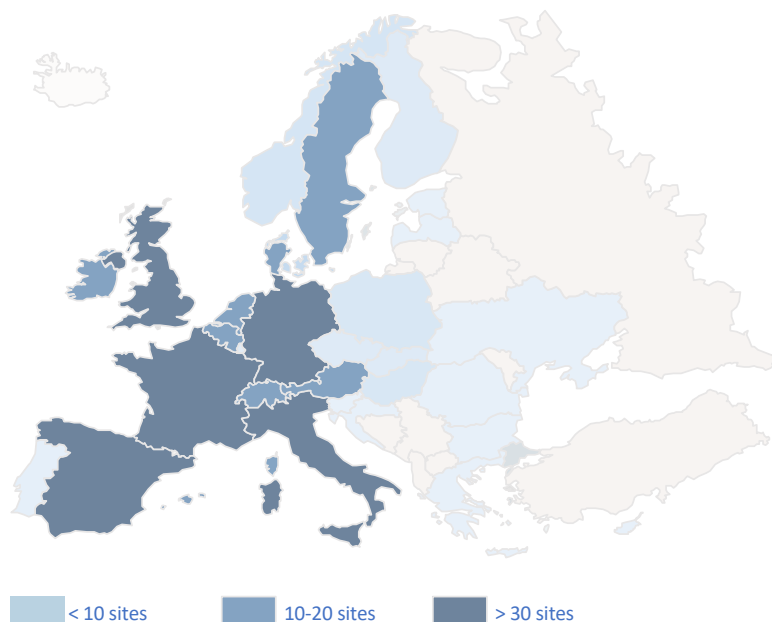
The majority of the market is defined as a supplier with more than 60% volume market share for the critical generic product

Sources: Beneath the Surface, unraveling the True Value of Generic Medicines, April Teva study Gx Health Check to CMA presentation Nov. 2024

# Active Pharmaceutical Ingredients manufacturing generates €60 bn per year and employs 150.000+ people throughout Europe

European CDMO facilities | 2024, # production sites per country, Europe

API & INTERMEDIATES PRODUCTION FOOTPRINT (C. 440 SITES & C.30% GLOBAL API AND INTERMEDIATE CDMO MANUFACTURING)



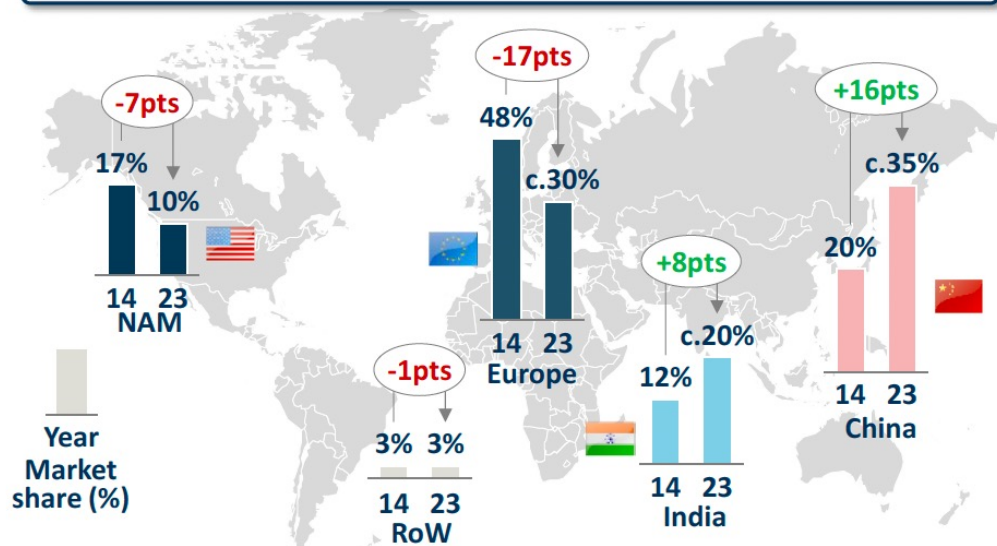
Notes: (1) Regulatory Starting Material; GMP: Good Manufacturing Practices; (2) c.3% of European Industrial Production; (3) from the merchant market (c.€70bn)

Sources: EFPIA, IQVIA, APIC, Company information, Advancy analysis

# 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

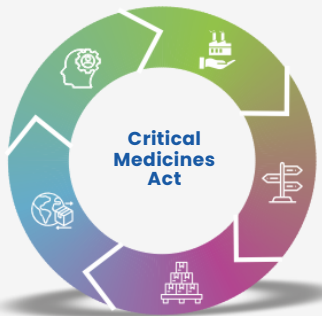
API



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

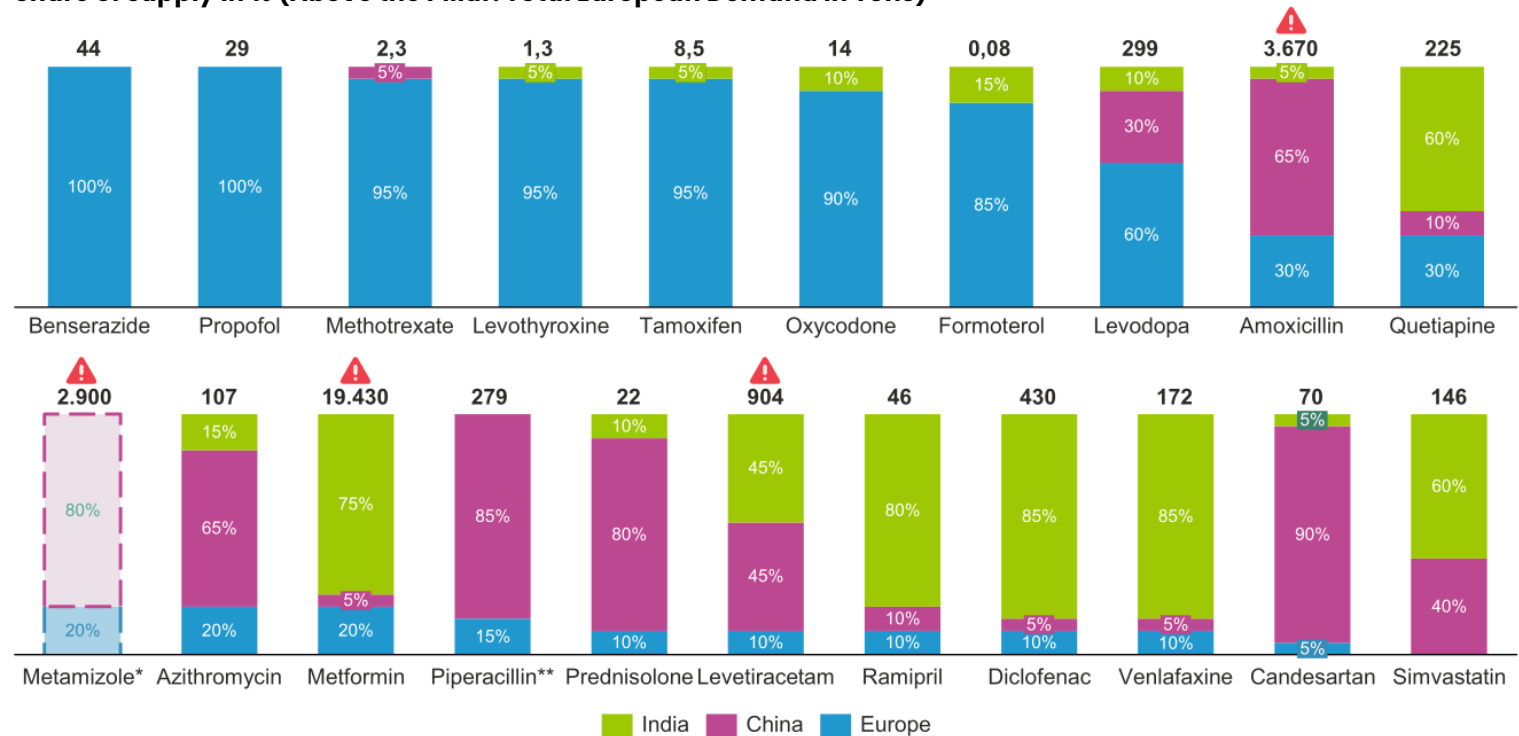
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## Examples of dependency per molecule

### ESTIMATED SHARE OF SUPPLY FOR EUROPEAN DEMAND BY REGIONS

Share of supply in % (Above the Pillar: Total European Demand in Tons)



\*) Estimation, Data basis limited; \*\*) API mainly in combination with Tazobactam (exclusively produced in Asia)

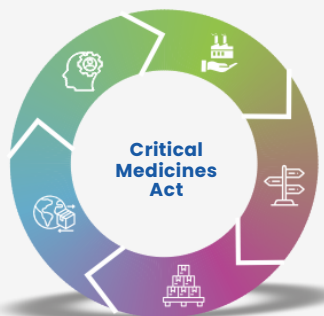
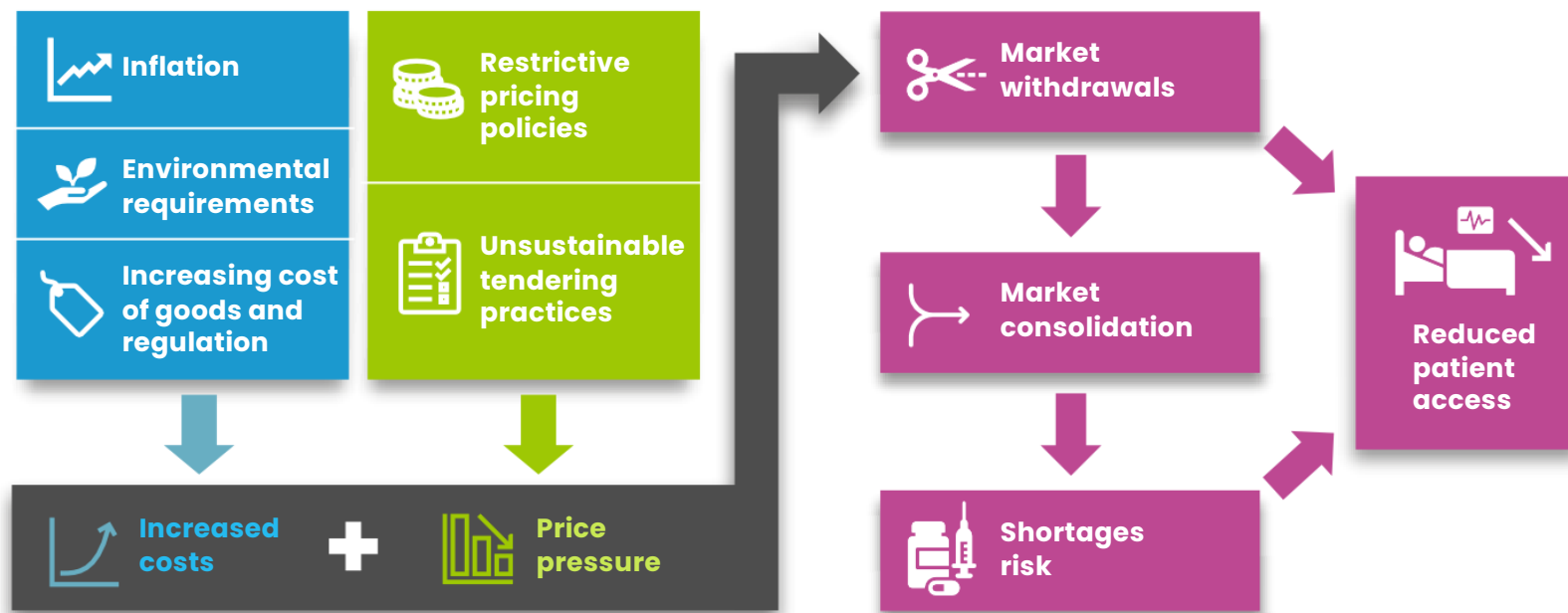
Source: Supplier Interviews, Import Data Analysis QYOB Market Platform, CEP Database, Pharmaoffer; IQVIA..

MUNDICARE Life Sciences Strategies

**The vast majority of these molecules  
target oncological, cardiovascular,  
and autoimmune diseases**



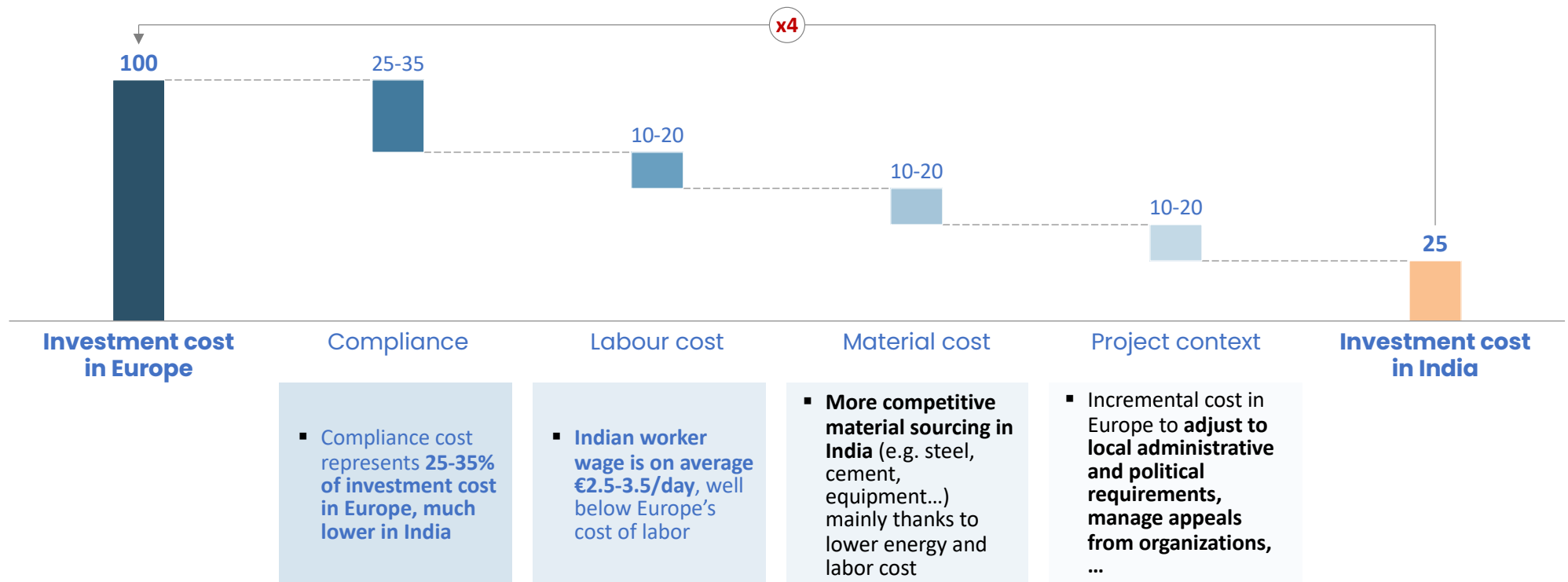
## Different root causes generate increased costs at times of high price pressure























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

European and Indian investment cost compared | index 100, 2023



Sources: Advancy analysis

# European regulations are numerous and have strong impact on cost competitiveness in Europe

THEME	MAIN SOURCES OF BURDEN	IMPACT	
		OPEX	CAPEX
 <b>WATER &amp; AIR PROTECTION</b>	<ul style="list-style-type: none"> <li>▪ IED, WFD</li> </ul>		
 <b>WASTE MANAGEMENT</b>	<ul style="list-style-type: none"> <li>▪ Waste burning regulations, waste recycling regulations, overall industry structure</li> </ul>		
 <b>ENERGY &amp; CO2 EMISSIONS CONTROL</b>	<ul style="list-style-type: none"> <li>▪ Carbon credit mechanism (EU-ETS)</li> </ul>		
 <b>WORKFORCE SAFETY AND WELLBEING</b>	<ul style="list-style-type: none"> <li>▪ European Directive on Safety and Health at Work, CMR directive, CAD, Machine directive, European social policies, Pregnant Workers Directive, employment code, Work-life balance and gender equality, administrative (CSRD, NIS2) ...</li> </ul>		
 <b>PROCESS SAFETY</b>	<ul style="list-style-type: none"> <li>▪ Operational risks: SEVESO</li> <li>▪ Transport of hazardous substances: ADR, AND, RID</li> <li>▪ Other hazardous substances regulations: REACH, CLP, BPR, POP/PIC</li> </ul>		
 <b>OTHER REGULATIONS &amp; FRAMEWORKS</b>	<ul style="list-style-type: none"> <li>▪ Construction: CPR, Biodiversity regulation, Protected Natural Areas regulation, Flora and Fauna Protection, Environmental Assessment Regulations, Impact Study assessment, RED, Preventive archeology, water consumption...</li> <li>▪ Other: DCE, Quality guidelines of the European pharmacopeia, Nagoya protocol, GMM, DSI, taxations and customs...</li> </ul>		

Sources: Advancy analysis

# Shortages dynamics in Europe 2016–2024 & Domestic support policies

2016-2024, Europe

	CLASS	MOLECULE	EU SHARE OF PRODUCTION	SHORTAGE ON 2016-24
TOP 10 API IN EU <sup>1,2</sup>	NSAID <sup>3</sup>	Paracetamol		YES
		Aspirin		YES
		Diclofenac		YES
	CARDIO-VASCULARY <sup>4</sup>	Atorvastatin		YES
		Ramipril		YES
		Bisoprolol		NONE REPORTED
	DIABETES	Metformin		NONE REPORTED
	RESPIRATORY	Salbutamol		YES
	GASTRO-INTESTINAL	Omeprazole		YES
	HORMONES	Levothyro-xine sodium		YES

SHORTAGES OBSERVED FOR MORE THAN 300 MOLECULES IN RECENT YEARS

European production share Low → High

Importance Low → High

(xx%): Support intensity defined as support measure budget divided by the value of the domestic industry

Importance Low → High

## SUPPORT TO DOMESTIC PRODUCTION

## BARRIER TO ENTRY ON API MARKET



<€0.25bn  
(c.1%)

- Investments (~€0.25bn, <1%) through IPCEI Med4Cure for **pharmaceutical R&D**, and "Critical Medicine Alliance" launching in 2024



- Fully open to foreign competition



>€1bn  
(c.15%)

- Large investments (>€1bn, ~15%) in **domestic manufacturing**, promoting generic drug production via the "Pills Act"
- Partial restrictions (Buy American Act)



- Restricting some markets to **Chinese players**



>€1.5bn  
(c.7%)

- National and provincial investments (~€1.5bn, ~7%) supporting local competitiveness
- No formal barriers, but transparency in processes is required



- No formal barriers, but **disclosure of process details limits participation of foreign players**



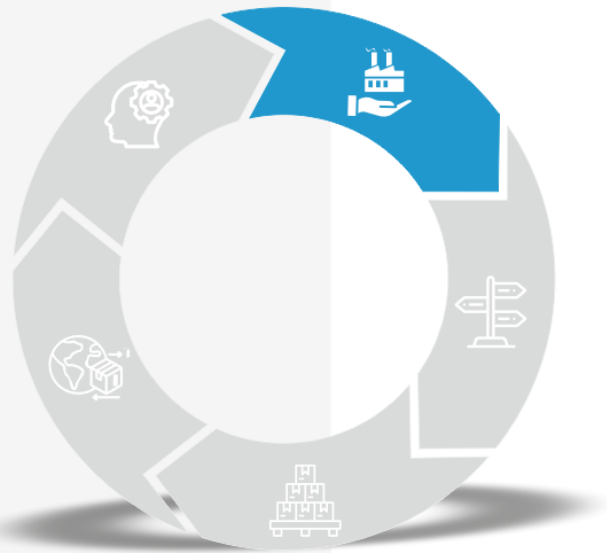
>c.€3bn  
(25%)

- Stimulating **local production** (>€2.5bn, ~25%) to reduce import dependency



- Fully open to foreign competition

Notes: (1) In standard units; (2) EU5: FR, DE, IT, ES, UK; (3) Non-steroidal anti-inflammatory drugs; (4) Include antithrombotic; (5) Custom Processing Fees; (6) Special Economic Zones; (7) Production Linked Incentive; (8) Strengthening of Pharmaceutical Industry  
Sources: IQVIA, EFCG, European Commission, Advancy analysis



## Proposal (i)

1

### DESIGNING AN INVESTMENT FRAMEWORK FOR RESILIENT MANUFACTURING OF CRITICAL MEDICINES AND APIs IN EUROPE

**Supporting manufacturing technology and production in Europe is critical for open strategic autonomy in healthcare and competitiveness with Asia and reduce shortages.**

As per IQVIA, c.2/3 of all reported shortages between January 2023 and 2024 are associated with medicines **with low supplier count** (i.e., less than 5 suppliers).

**The Critical Medicines ACT should prioritise investments in manufacturing critical medicines and APIs by:**

1. Expanding the **definition of innovation for State Aids and IPCEI** – in line with the Draghi report– to include **manufacturing processes that support green and digital transitions**, as well as security of supply, to enable greater investment in this sector.
2. **Simplifying the funding procedures and the allowance of regional aid** for the development of sustainable and secure pharmaceutical manufacturing in Europe.
3. **Dedicating funds under the Multi-Annual Financial Framework (EU4Health).**

## Proposal (ii)

2

### MORE SUSTAINABLE MARKET POLICIES

Current economic policies, especially aggressive pricing strategies, have unintentionally **increased the risk of supply shortages** by consolidating production and limiting adaptability.

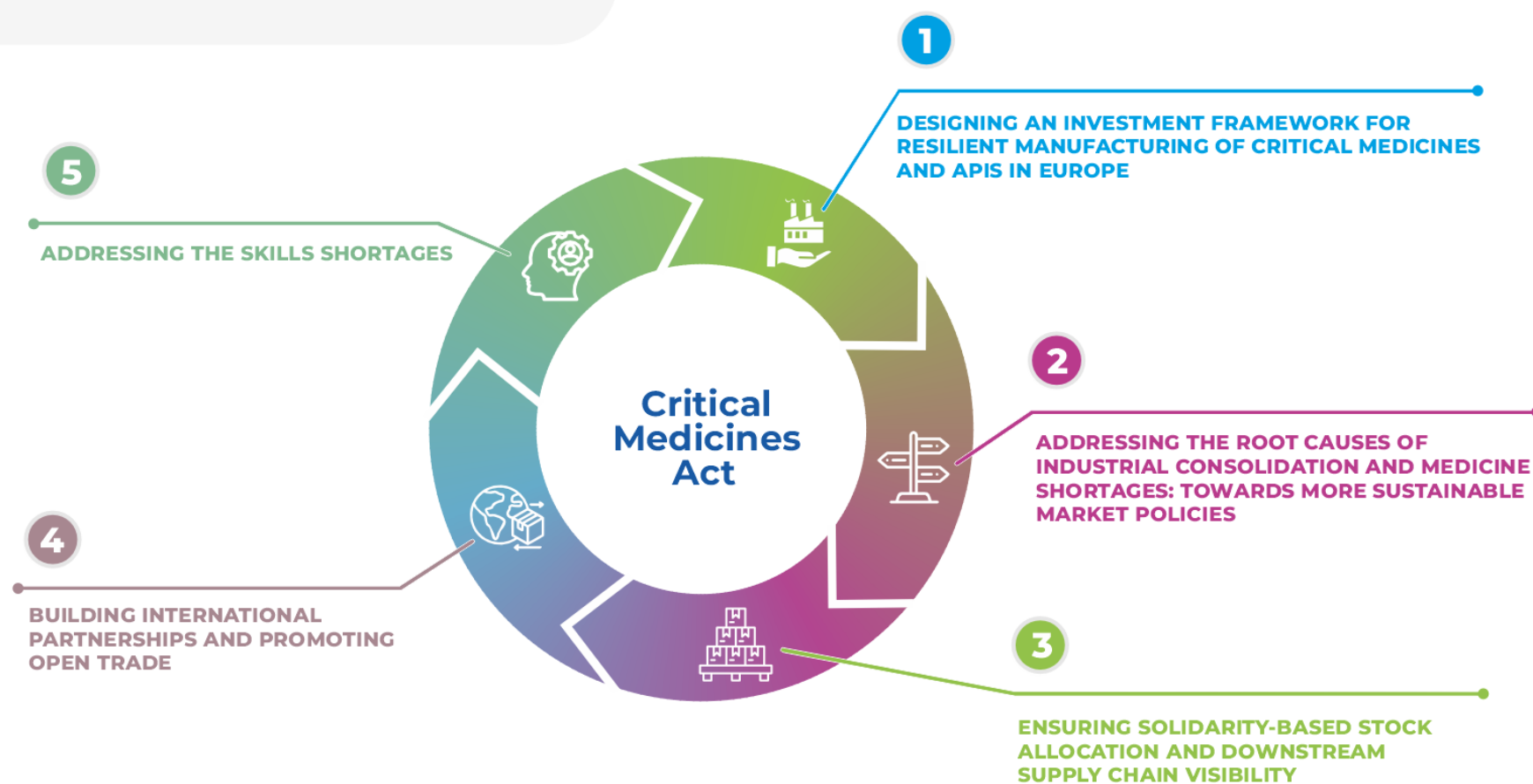
The **Critical Medicines ACT** must address root causes of shortages by:

- Introducing a **dedicated procurement framework** mandating the use of MEAT criteria to prioritise **supply chain security, sustainability, and reliability** alongside cost considerations.
- Enforcing the **Transparency Directive as a framework**, the EU could build a more **responsive and resilient pricing system** to ensure **supply security**.
- Establishing a specific criterion for European Commission **impact assessments on legislation affecting critical medicines and API production**, aligning environmental protection with cost-effective, resilient supply chains to ensure access to medicines.



## European Critical Medicines Act

The EU's off-patent medicines manufacturers are committed to providing equitable access to essential medicines in Europe. For that, they need a favourable and sustainable policy framework in place.



**Special thanks for the data and slides contribution from:**

