

# The case of Europe's disappearing medicine cabinet

New data brought by Teva Pharmaceuticals Europe

NPS-TPE-NP-00717



# Disclaimer

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The analysis presented using IQVIA data was conducted by Teva Pharmaceuticals Europe alone, and does not constitute an IQVIA position on Generic product erosion or market shortages

# Introductory remarks

# About Teva in Europe

## Teva's mission

Is to be a global leader in generics and biopharmaceuticals, improving the lives of more than 200 million patients across the world everyday.

As a European employer and manufacturer, Teva creates jobs and contributes to the economies in which it operates.

Manufacturing facilities in **15** countries across Europe

**65%**

of Teva's global portfolio is manufactured in Europe

**96%**

of Teva medicines sold in Europe are manufactured at Teva's European sites

**40%**

of the APIs that Teva uses in Europe are produced in Europe

# About Teva in Europe

**In 2021  
across  
Europe...**



The company supported  
**100,000 jobs**



Generated  
**€4.9B**  
in labour income



Generated  
**€25.8B**  
in economic output



And saved healthcare systems an estimate of  
**€8.4B**  
across these markets

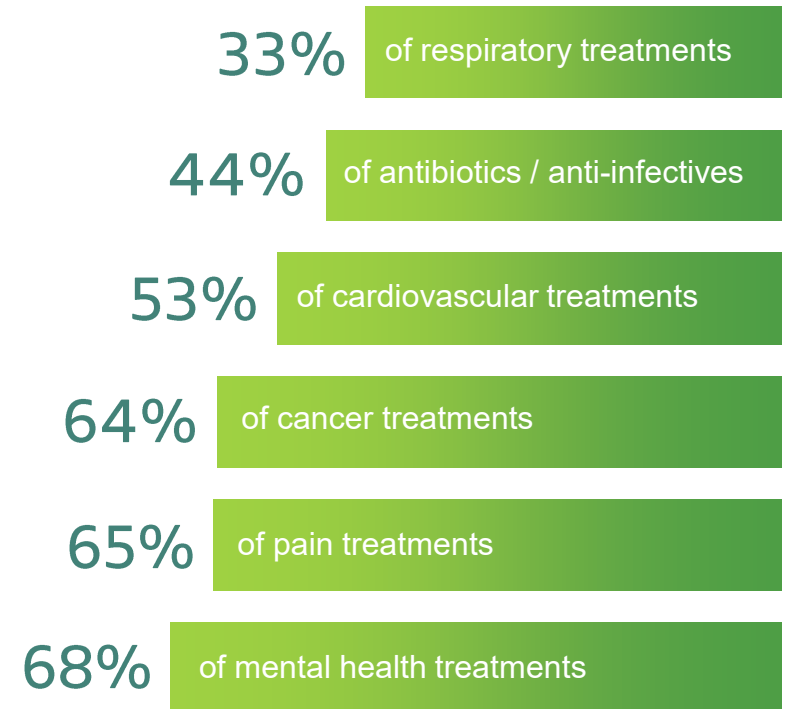
# You may remember seeing this....unfortunately not a one-off



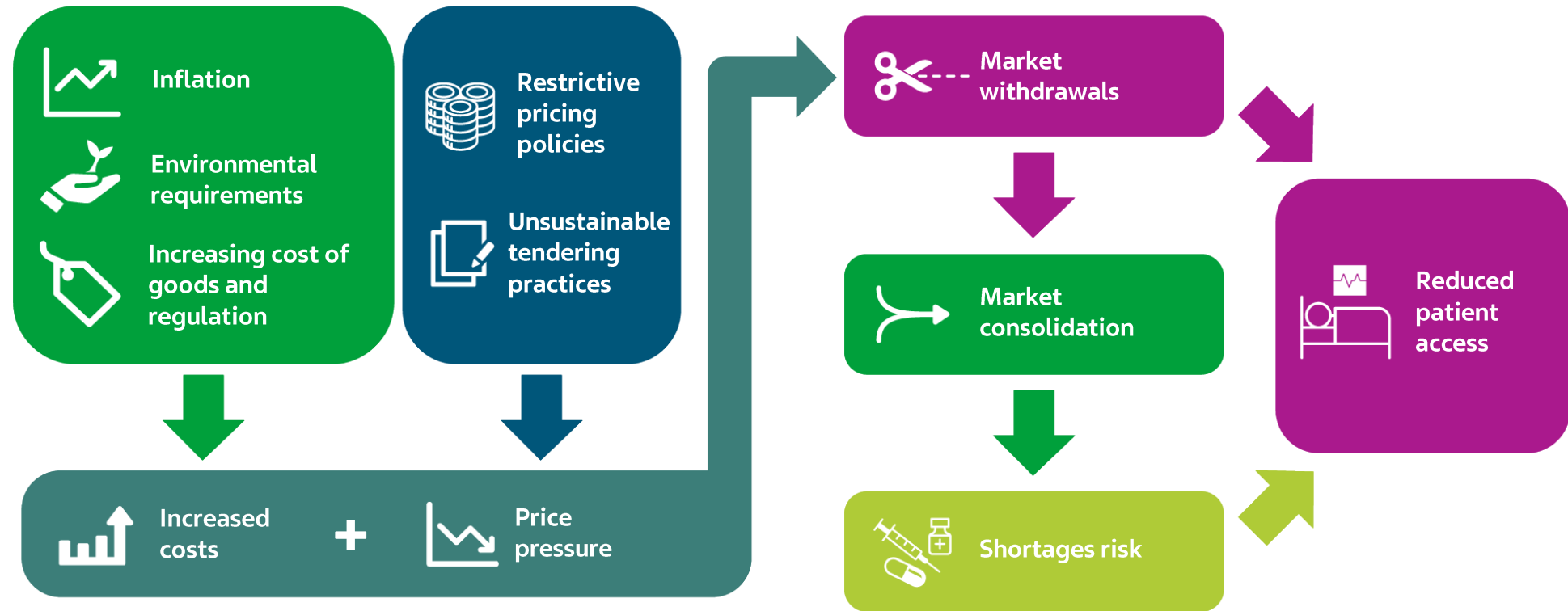
# What's the goal of our analysis?

- Over the past years, European countries have reported shortages of medicines such as antibiotics and oncology medicines impacting patients' access
- Many of them are part of the WHO essential list which includes mature generics
- COVID-19 highlighted the importance of these medicines
- The increased cost of living post COVID-19 and the energy crisis add extra pressure on the economic stability of low-price generics
- How far can the generic market further absorb shocks without further compromising patients' access?
- Teva's mission is to improve lives through access to quality medicines. As a leader in generic medicines, access to medicines is in our DNA
- Our goal? To create an accurate assessment of what and where we are – a “health check” of the generic market supply

Of the World Health Organization's essential medicines, Teva's portfolio covers:



# Our analysis provides the underlying facts of the generics' market challenges



From active pharmaceutical ingredients (API) to finished products

# What the analysis shows: Europe's medicine cabinet is in decline!

- Over the past 5 years the Generics market has increased affordable access to medicines for patients
  - Although the market looks healthy, generic competition has decreased dramatically
- Reduction in competition directly challenges supply and reduces options for patients
  - Some treatments options are disappearing at a local level
- The decrease is driven by a race to the bottom on pricing and an onerous regulatory regime
- This issue is systemic across Europe:
  - Not exclusive to antibiotics and oncology medicines, nor to a specific market
- We are seeing the same issue in finished products as in active pharmaceutical ingredients

There is an urgent need to stop the race to the bottom, via complementary reforms at EU & national level to drive synergies that will protect patients' access to generics

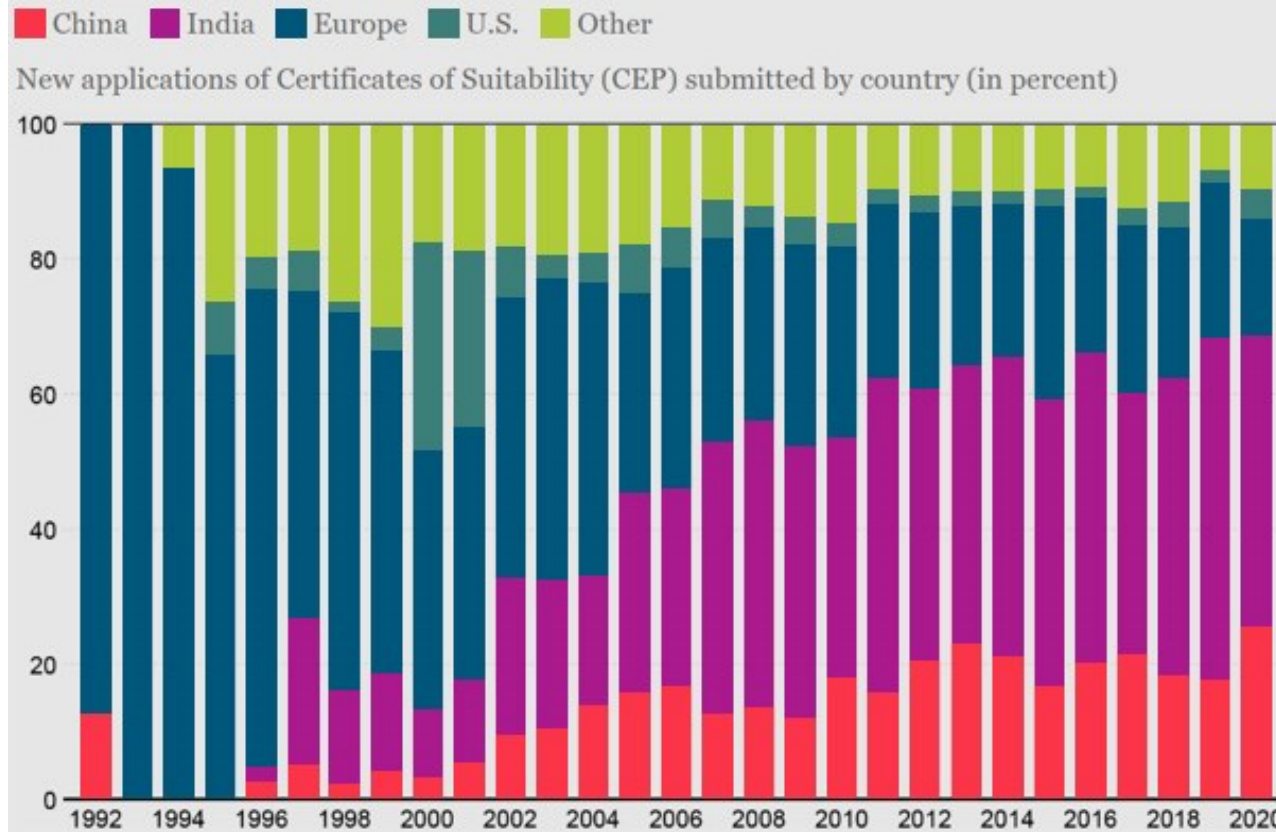


# Chapter 1: upstream consolidation of the active pharmaceutical ingredients (or API)

A dramatic reality highlighted by COVID19

# Active ingredients for Europe's medicines have moved East

## China's share of API production is growing rapidly



Source: European Directorate for the Quality of Medicines & HealthCare (EDQM)



**“China’s API manufacturing share rapidly increasing - it now accounts for more than 20% of new API applications.**

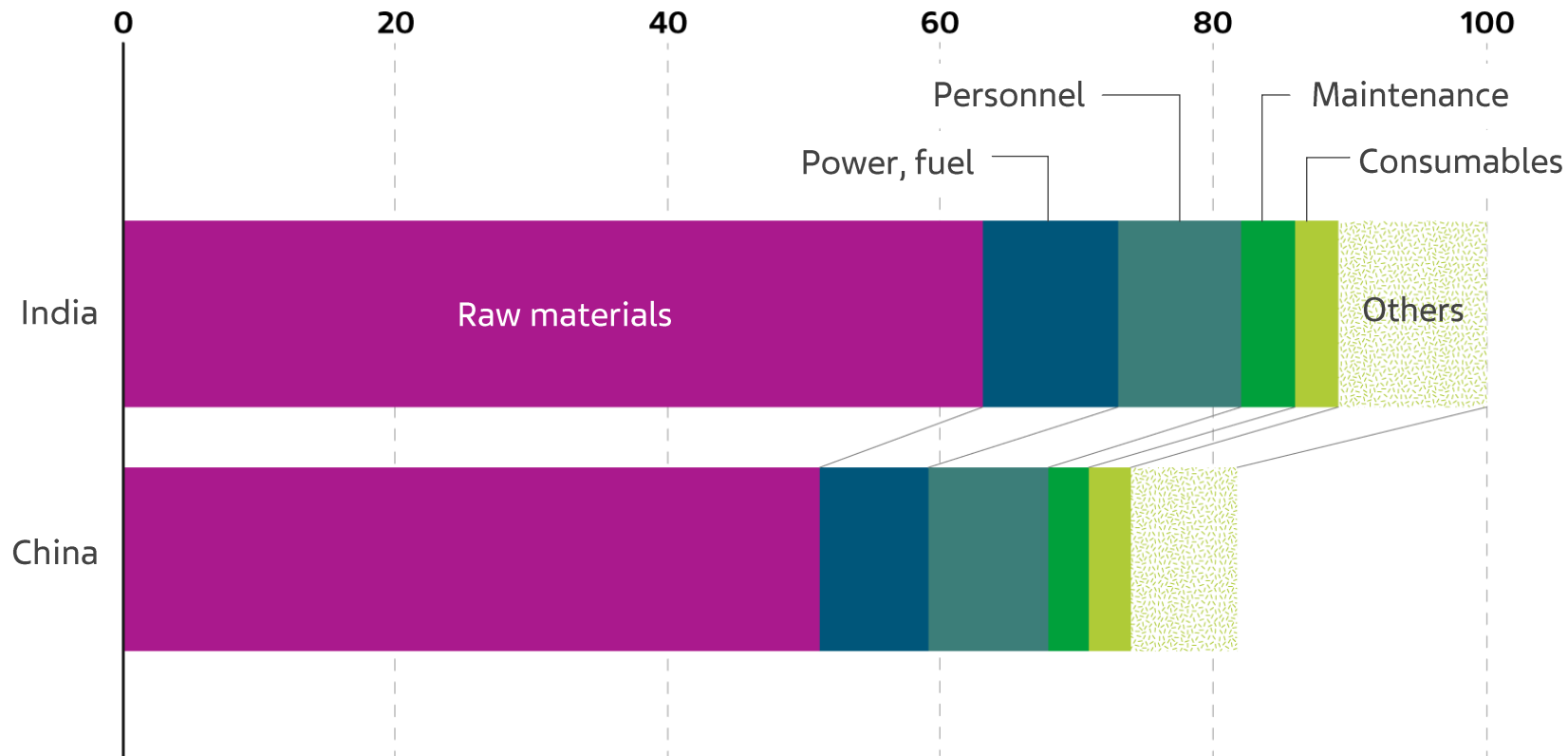
The trend continues – some cholesterol medicines don’t even have European certificates behind them.

# China enjoys a significant Cost Production Advantage



**Compared to India\***

API production total cost breakdown; India = 100%



A drug can be produced for 20% less in China than in India

# China enjoys a significant Cost Production Advantage



## Compared to Europe

	West	East
Factory labour costs (2005)	20–30\$ per hour	1\$ per hour
Electricity costs (€ cost for kWh) (2021)	Germany: €0.317 Spain: €0.242 Italy: €0.214	China: €0.078 India: €0.072
Water costs (€ per cubic meter)	France (2020): €4 Italy (2020): €2	China (2016): <€0.50 China (2021): €1.26

A cost savings of between 20% to 60% if produced in China

# China enjoys a significant Cost Production Advantage



## EU inflation widens the gap

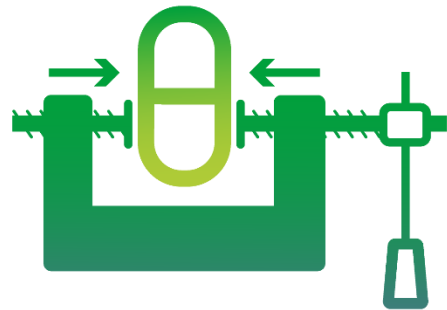
Inflation  
over 9%

Transportation  
costs  
up to 500%

Raw material  
costs between  
50%-160%

Packaging  
costs raise  
to 20%-33%

Energy prices  
+65% for gas  
+30% for electricity



Current pricing  
models for generic  
medicines are not  
fit for purpose

Inflation over 9% in  
Europe in 2022

**It's time to protect  
Europe's medicines  
cabinet !**

## A picture that worries patients very much

“

“Of course, it is about manufacturing drugs. Will it be possible to receive EU support in order to manufacture drugs within the EU?”

- German stakeholder



“

“The long-term goal is certainly to maintain and strengthen the quality of supply and security of supply.”

- German stakeholder

# A picture that worries patients very much

## Patients surveyed call for support in supply security and manufacturing

**84%**

of patients want their government to support manufacturing investments to avoid overdependencies.

**71%**

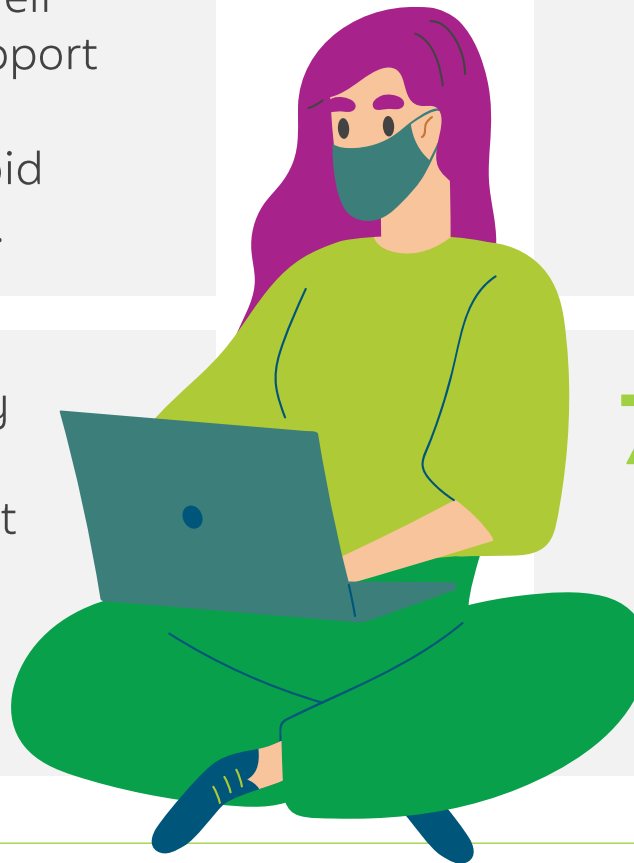
is interested in knowing Europe remains as competitive as other regions.

**72%**

believe that supply security should be the most important criteria to be considered by health insurers.

**74%**

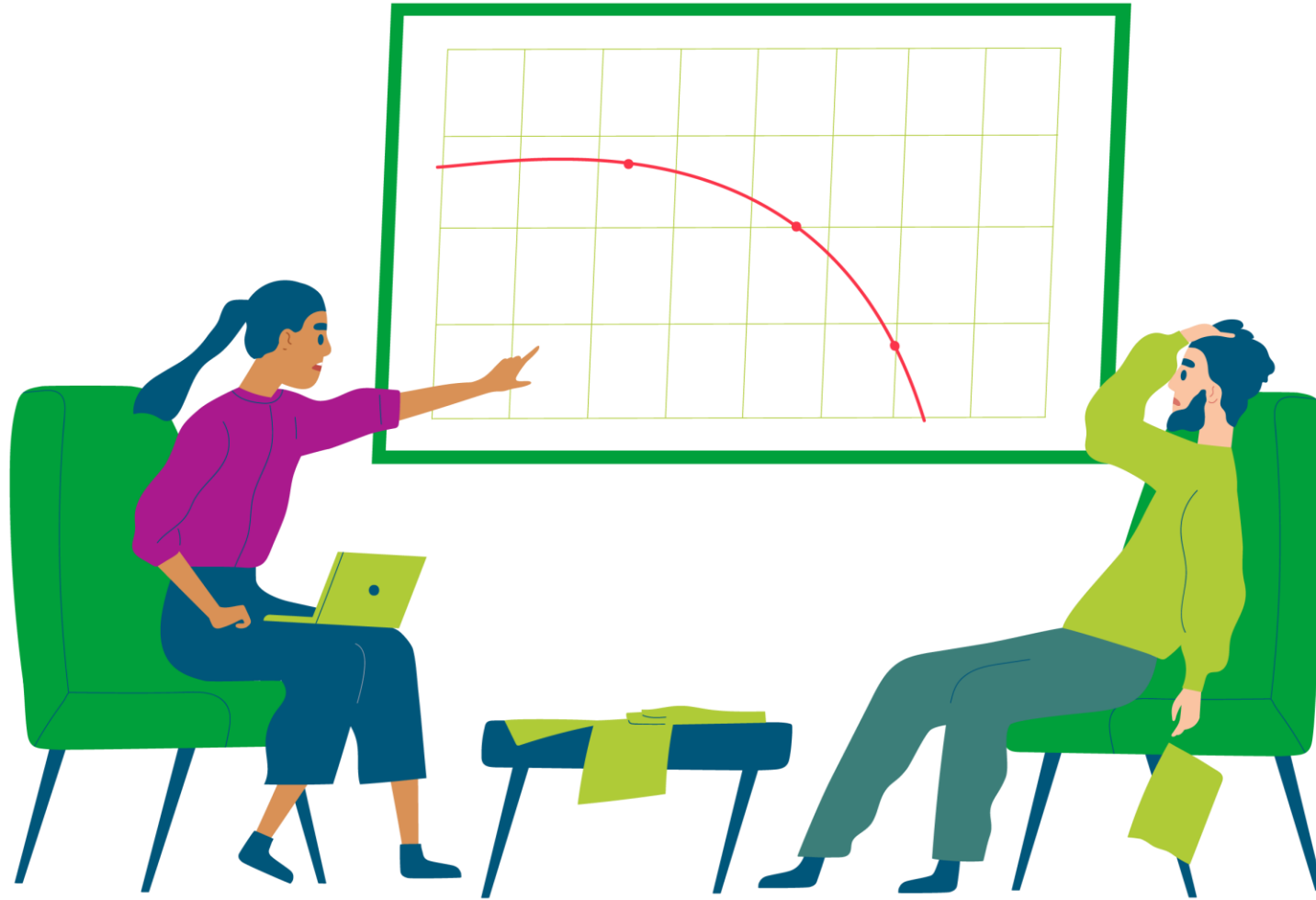
also find it important to know that their government cares about attracting medicines manufacturing investments.



# Chapter 2: downstream consolidation of finished medicines

Patient access risk is increasing as further consolidation happens

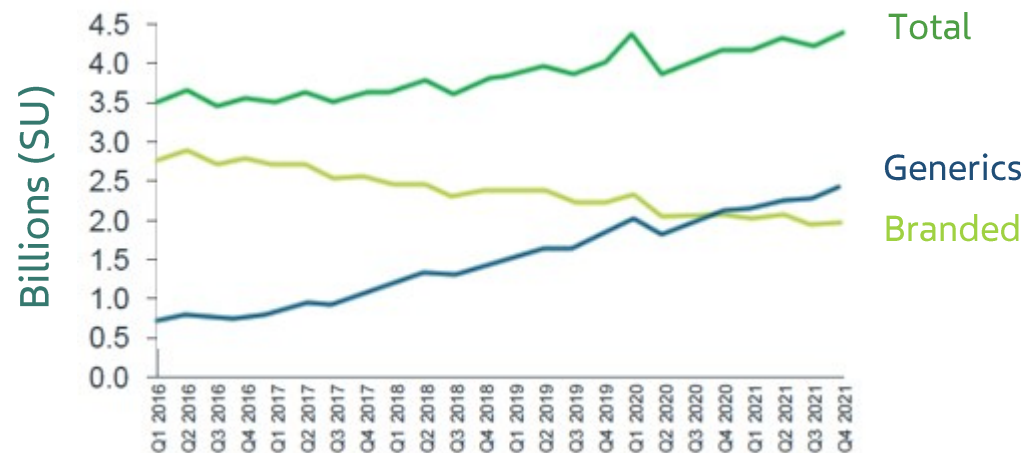
# We've moved from gentle slide to massive cliff edge!



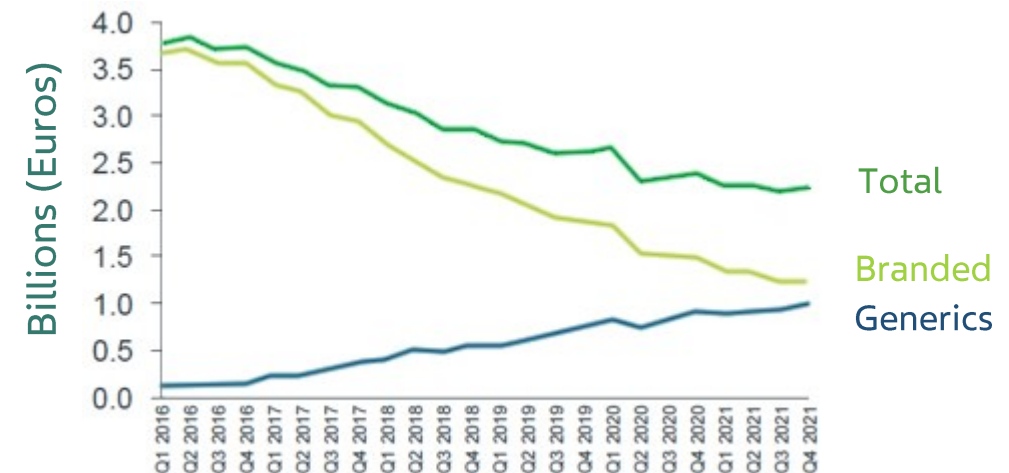
# Over the past five years, generics launches brought more savings than access

- In Europe, a new IQVIA study showed generics reduced costs by 41% between 2016 and 2021, despite a 27% volume growth
  - Total savings for payers was significant with a CAGR of -8% from 2016 – 2021 products alone

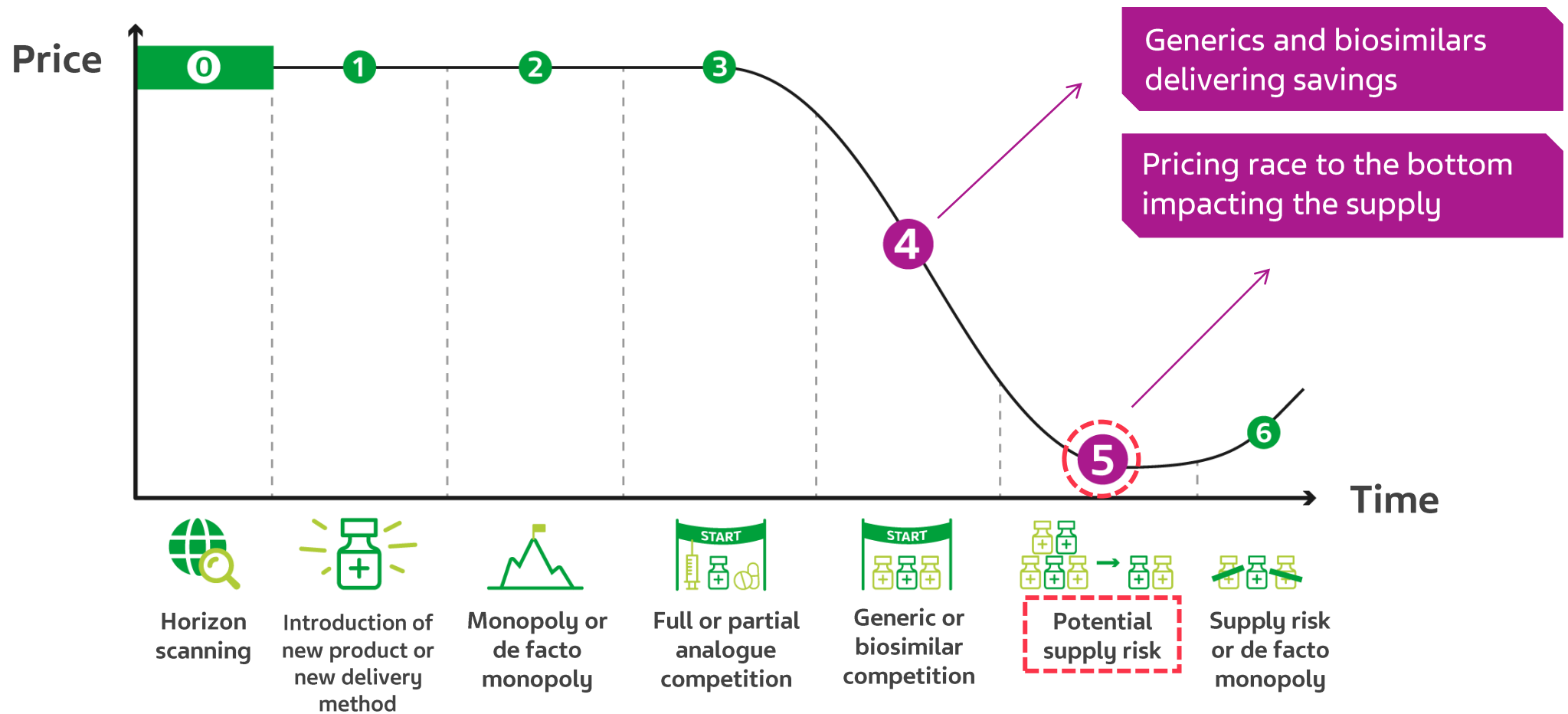
**Volume dynamics (+27%)**  
(n = 104, quarterly 2016 – 2021)



**Value dynamics (-41%)**  
(n = 104, quarterly 2016 – 2021)



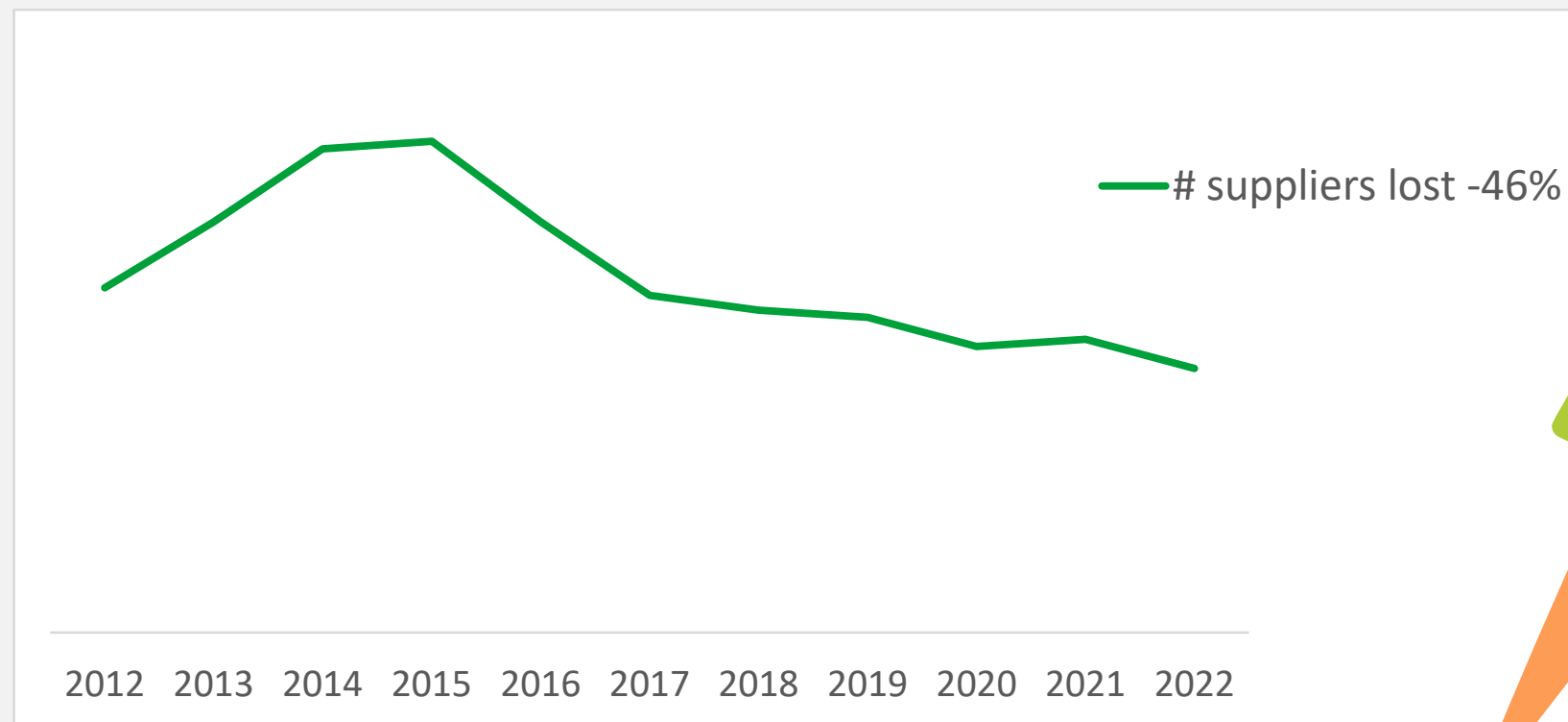
# The natural evolution (and competition) of generics when led by price alone is leading to supply risks, which directly impacts patients



Let's look at a real case in cancer care  
& antibiotics

## Exhibit A: an oncology product to treat ovarian or small cell lung cancer

### Evolution of number of companies on the market



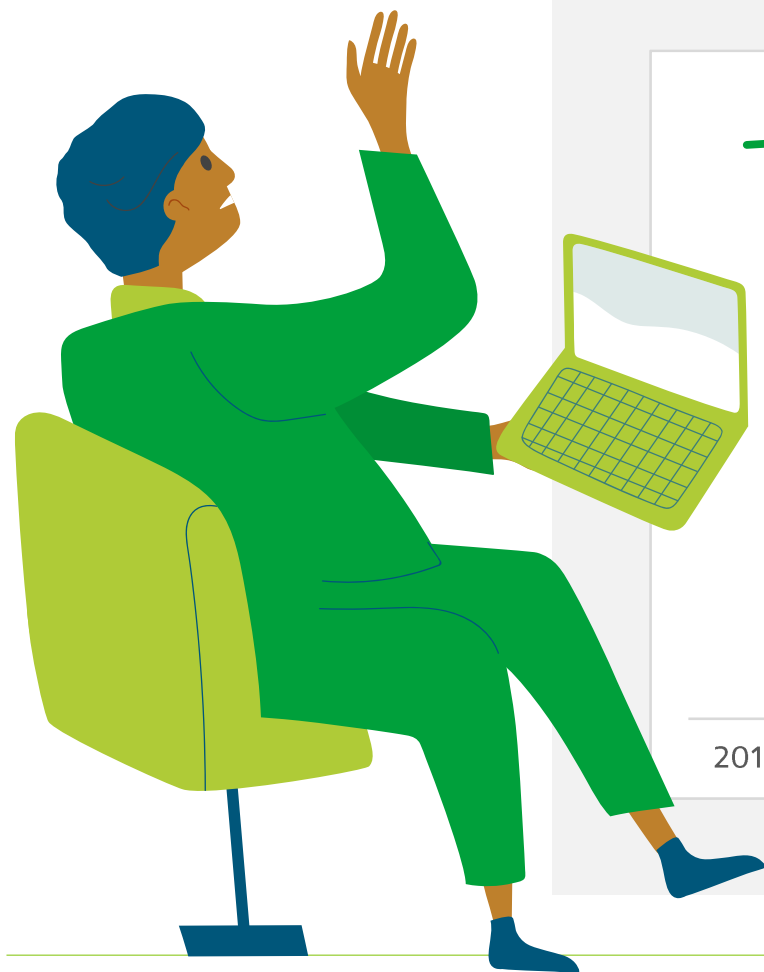
# Exhibit A: an oncology product to treat ovarian or small cell lung cancer

## Details per countries

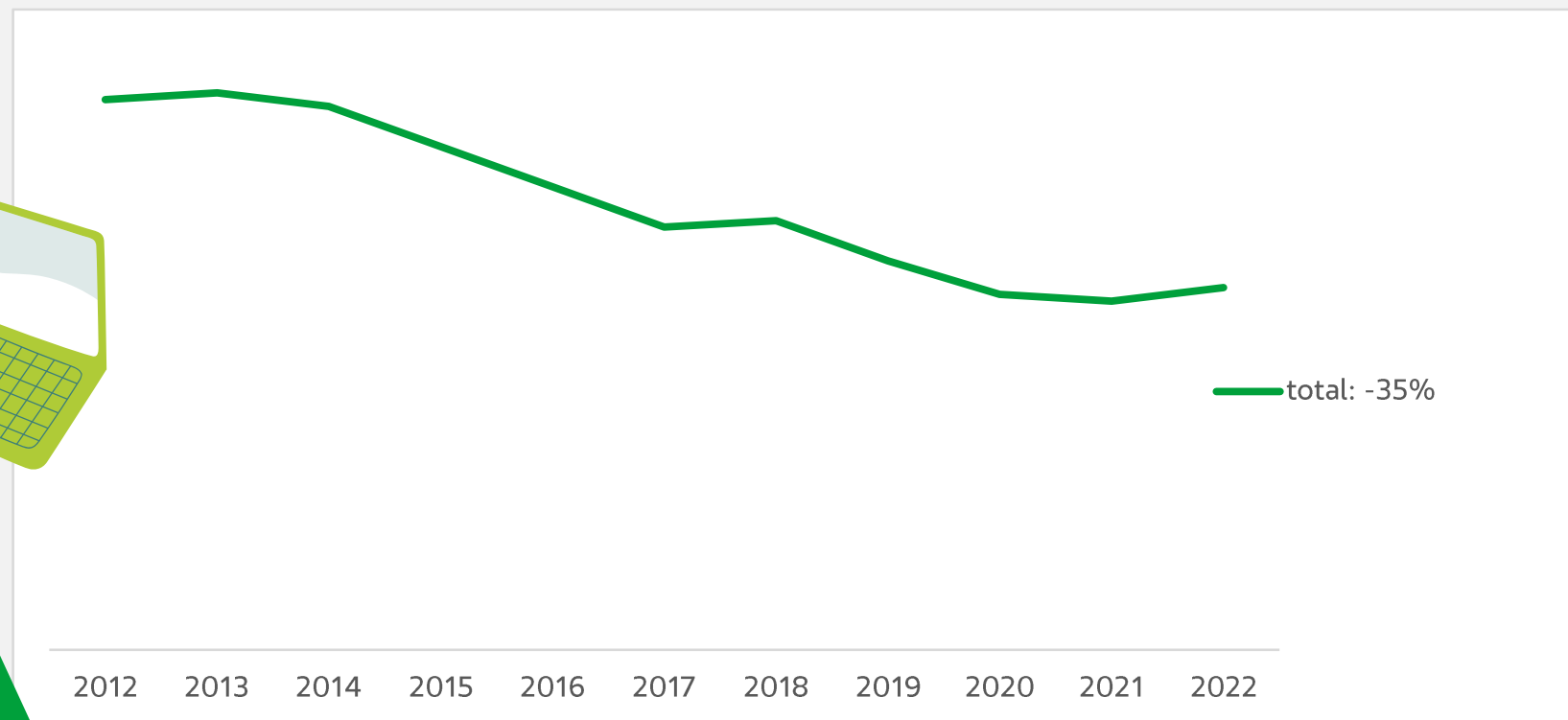
Country	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
EU	47	56	66	67	56	46	44	43	39	40	36
AT	2	3	3	3	3	2	2	1	1	1	1
BG	3	3	4	3	3	1	2	2	2	2	1
HR			2	2	2	2	1	1	1	1	2
CZ	5	6	6	3	3	2	2	2	2	2	2
DK	1	2	3	3	2	1	2	2	1	1	1
FI	1	1	3	3	3	2	2	2	2	2	2
FR	2	4	5	7	7	7	5	5	4	4	4
DE	7	8	8	8	8	8	5	5	4	4	4
HU	2	4	4	4	2	1	2	2	2	2	2
IT	5	5	6	6	4	4	4	4	3	3	3
NL	1	1	3	4	3	3	3	2	2	2	2
PL	4	5	5	4	3	2	2	2	2	2	2
PT	4	3	3	5	3	2	3	3	3	4	3
ES	4	4	4	4	4	3	3	3	3	3	2
SE	3	4	4	4	3	3	3	3	3	3	2
CH				1					1	1	1
UK	3	3	3	3	3	3	3	4	3	3	2

- In 10 years 46% of suppliers of this product have exited the market.
- Leaving just one supplier or two in the majority of the countries studied.
- This product is tendered in most countries focusing on price only.

## Exhibit B: an injectable antibiotic used to treat serious infections



### Evolution of number of companies on the market



## Exhibit B: an injectable antibiotic used to treat serious infections

### Details per countries

Country	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
EU	82	83	81	75	69	63	64	58	53	52	54
AT	4	3	2	2	1	2	2	1	1	1	1
BG	3	3	3	3	2	2	2	2	2	2	2
HR	3	5	5	5	5	5	4	4	3	3	3
CZ	4	4	3	3	3	2	2	2	2	2	2
DK	2	2	2	2	2	1	2	2	1	1	2
FI	3	3	4	2	1	2	2	1	1	1	2
FR	8	8	8	8	9	8	8	8	8	7	7
DE	8	8	9	9	9	7	6	5	4	4	3
HU	3	2	2	2	2	1	1	1	1	1	2
IT	10	10	10	10	9	9	9	7	7	6	5
NL	5	5	4	3	1	1	1	1	1	3	3
PL	6	6	5	5	5	4	6	6	4	4	5
PT	4	4	5	3	3	2	2	2	2	2	2
ES	5	6	6	5	5	4	5	4	4	4	4
SE	3	3	3	2	2	2	2	2	2	2	2
CH	4	4	3	3	3	3	3	3	3	2	2
UK	7	7	7	8	7	8	7	7	7	7	7

- In 10 years 35 % of suppliers of this product have exited the market.
- Leaving just one supplier or two in the majority of the countries studied.
- This product is tendered in most countries focusing on price only.

## And in antibiotics

In 10 years, several antibiotics options have totally disappeared from local countries, for example:



16 antibiotic drugs in  
Poland



11 antibiotic drugs in  
Spain



10 antibiotic drugs in  
France

(Although they remain available elsewhere in Europe)

## And here's one reason why...



In Spain, the price of pediatric amoxicillin was set at 98 cents (\$1.05) for 60 ml in 2003. In 2013, that became the price for 40 ml

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**Half the generic medicines sold in Spain are priced below 1.60 euros per box or bottle**

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From Reuters article: ["Why Europe's drug shortages may get worse"](#)



In Germany, the price that manufacturers receive for the daily therapy dose of a generic drug fell from an average of 12 cents to 6 cents per day.

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From ProGenerika analyses: [Generics in figures: Drug supply under cost pressure \(progenerika.de\)](#)

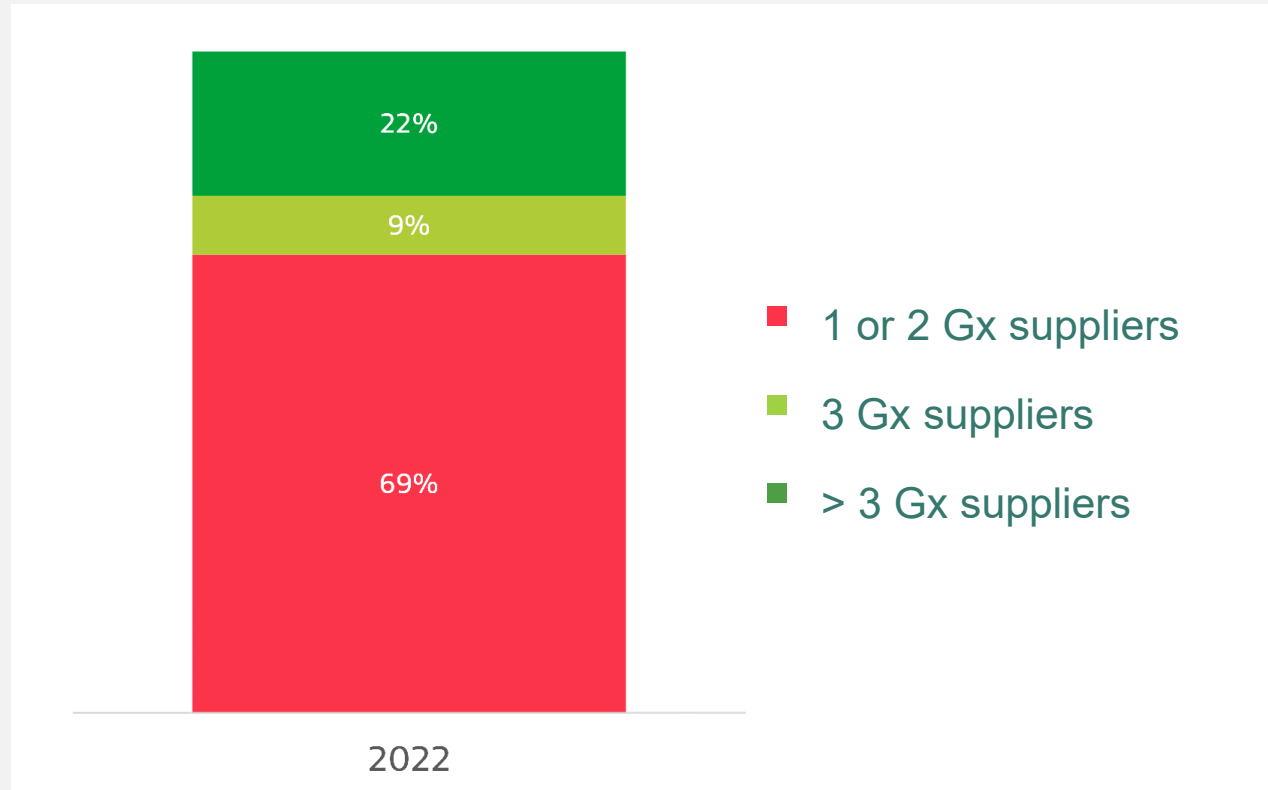
# This isn't isolated by disease

Supplier consolidation is high across the generics market



# The whole market is already highly consolidated – raising issues about resilience and security of supply

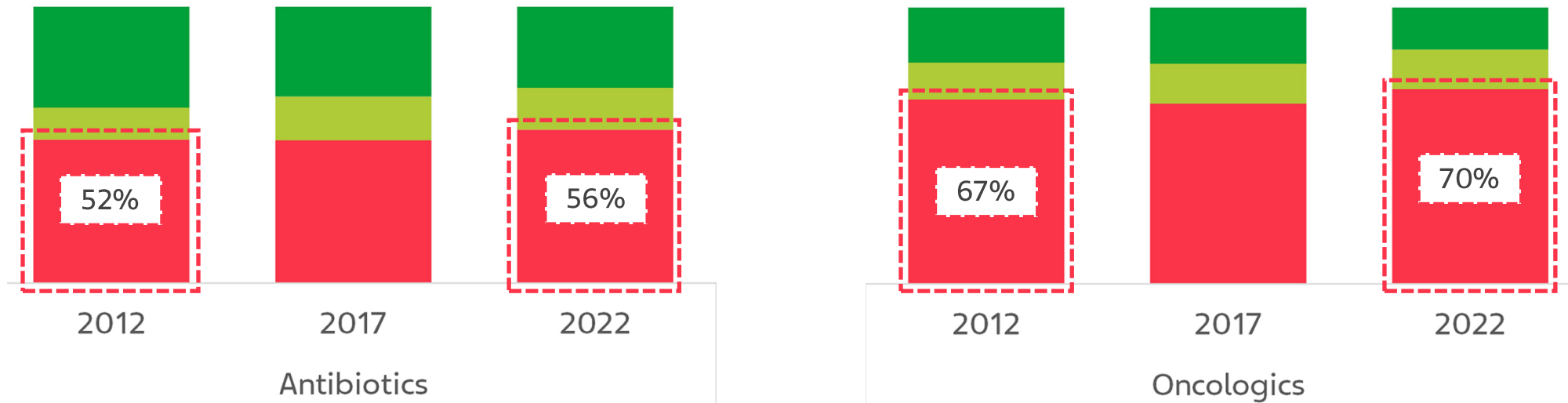
## Number of suppliers per generics market in 2022



In 2022: 69% of EU generics medicines marketed have less than 2 suppliers each

# And in sensitive therapeutic areas the consolidation is increasing

# of Gx suppliers in 2012 on the market 2017, 2022



56% of antibiotics have less than 2 Gx suppliers

70 % of oncologics Gx have less than 2 Gx suppliers

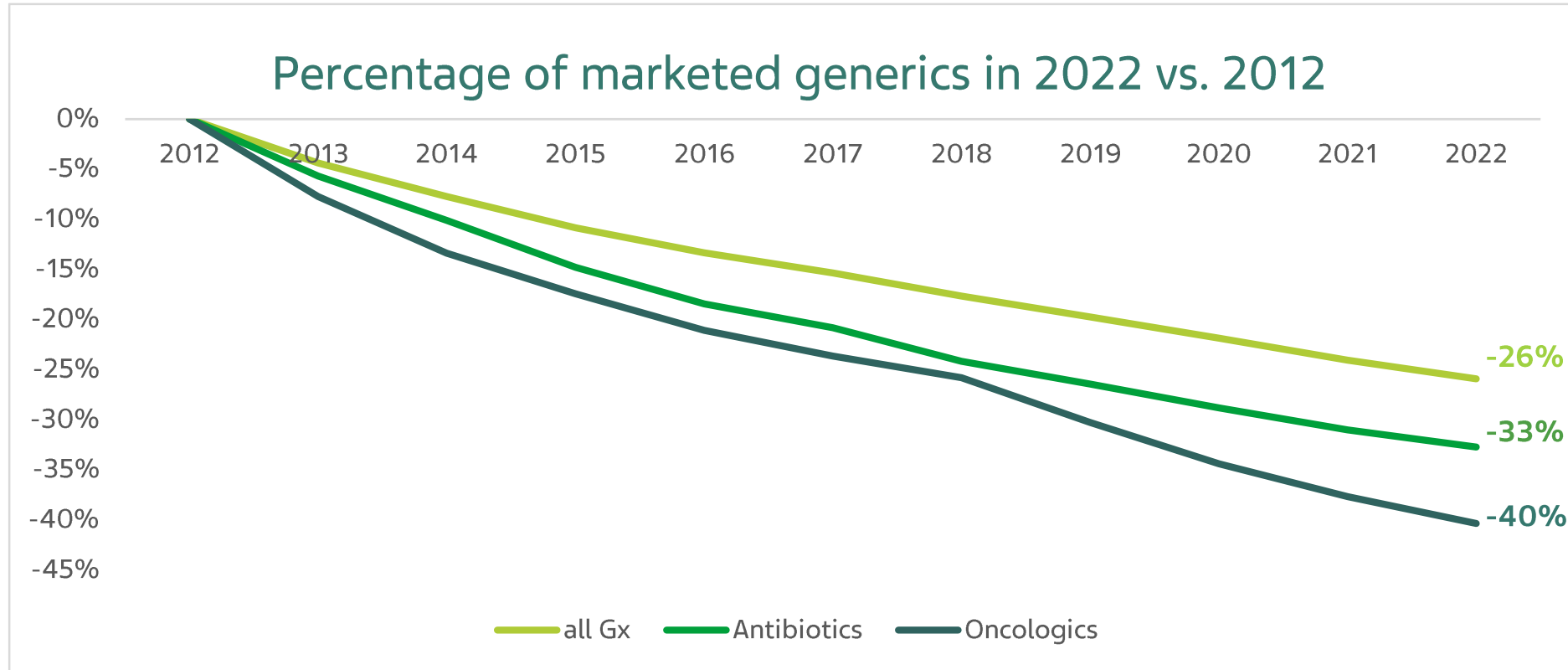
■ 1 or 2 Gx suppliers    ■ 3 Gx suppliers    ■ > 3 Gx suppliers

# From supplier consolidation to medicine withdrawals

Leaving patients with fewer treatment options



# Decrease in suppliers means reduced options for patients



In 10 years 26% of Generics medicines have disappeared from the European markets, 33% for antibiotics and 40% for oncology drugs

And this story is systemic across Europe NOT just confined to one or two diseases or countries – the whole generic medicines cabinet is at risk

Percentage of marketed generics in 2022 vs. 2012 per country

	Antibiotics	Oncologics	all Gx
# of products 2022	vs. 2012	vs. 2012	vs. 2012
	%	%	%
AT	-36%	-47%	-23%
BG	-31%	-54%	-26%
HR	-28%	-34%	-23%
CZ	-40%	-49%	-31%
DK	-27%	-50%	-25%
FI	-40%	-50%	-32%
FR	-17%	-34%	-18%
DE	-48%	-42%	-36%
HU	-38%	-52%	-29%
IT	-20%	-26%	-20%
NL	-44%	-49%	-32%
PL	-34%	-51%	-26%
PT	-38%	-49%	-29%
ES	-34%	-36%	-21%
SE	-34%	-37%	-24%
CH	-29%	-16%	-17%
UK	-32%	-26%	-28%
TOTAL	-33%	-40%	-26%



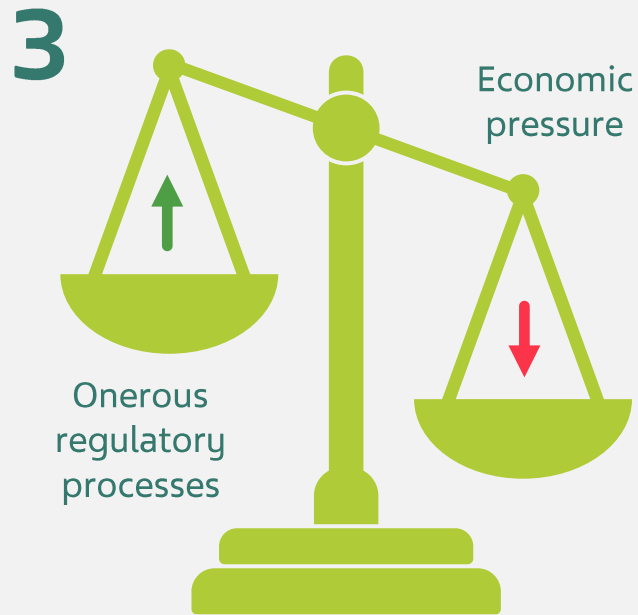
So, what's the answer?



# Let's dare to recognise and address the obvious

**1** Stopping the race to the bottom on pricing is crucial to ensure a sustainable and resilient supply of essential medicines

**2** The current pharmaceutical policy landscape is challenging the sustainability, resilience and diversity of supply, leading to the consolidation of the generic medicines market



- Consolidation of the supply chain both downstream and upstream
- Fewer suppliers in the market
- Increased chance of shortages

**4** Security of supply must be ensured by addressing the root causes of medicines shortages and implementing sustainable economic, regulatory and industrial policies.

**5** Complementary national and EU level policy reforms

# The right answer can only come from complementary local & EU policy reforms

## At national level

- **New pricing models are required**, adapted to countries' pricing systems.\* For example:
  - Automatic price adjustment to reflect inflation
  - Dynamic models based on number of suppliers
  - Delinking from originator price
- **Stop claw back / pay back taxation**

## At EU level

- **Regulatory optimisation & digitalisation**, including in the security of supply provisions in the revision of the pharmaceutical legislation
- **Safeguard security of supply in all policies** including in the new environmental legislations
- **Multi-winner and multi-criteria Tender Guidance**
- **Efficient & competitive funding mechanisms**

**Healthy, competitive, resilient and diversified  
generic supply**

Q&A

# Thank you

## Contact:

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Stefanie Kitzinger, Director Portfolio Europe

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# Annex 1: Methodology

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- **Source of data:** IQVIA MIDAS® Quarterly Sales data released Q4 2022, Measure: USD MNF, Time Period: MAT Q3 2012-Q3 2022, reflecting estimates of real-world activity.
- **Timeframe:** 2012 – 2022
- **Generic competitor population:**
  - Excluding PI competition according to IQVIA-def. „PI“ and „manufacturer“
  - According to IQVIA def. „non-innovative-branded“ & „non-branded“
- **Selected products population:**
  - All generics
  - Generic antibiotics based on IQVIA-definition ATC2 „J1“
  - Generic oncologics based on IQVIA-definition ATC2 „L1“
  - Excluding (2013/2018-2022)-launches
  - Excluding „product-from-whole market-discontinuations (2013/2018 to 2022)“
  - Number of products:
    - # count on Level 1 (INN\_NFC1\_#of competitors) by country
    - # count on Level 2 (per product\* the competition\* in each market) (\*excluding PI; Gx only)
- **Selected markets with available IQVIA data:**
  - AT, BG, HR, CZ, DK, FI, FR, DE, HU, IT, NL, PL, PT, ES, SE CH, UK