



Teva Generics Health Check

European Critical Generic Medicines
Supply Diversity Under Pressure

February 2025

Disclaimer

The analysis presented using IQVIA data was conducted by Teva Pharmaceuticals Europe B.V. independently, and does not constitute an IQVIA position on generic product erosion or market shortages

About Teva in Europe in 2023

Teva is a global pharmaceutical leader with a category-defying portfolio, harnessing our generics expertise and stepping up innovation to continue the momentum behind the discovery, delivery and expanded development of modern medicine. For over 120 years, Teva's commitment to bettering health has never wavered. Today, the company pushes the boundaries of scientific innovation and delivers quality medicines to help improve the health and well-being of millions of patients every day.



The company supported **120,000 jobs**



Generated **€2.8B** in labour income



Teva produces **96%** medicines sold in Europe at European manufacturing sites



Contributed **€5.8B** to GDP

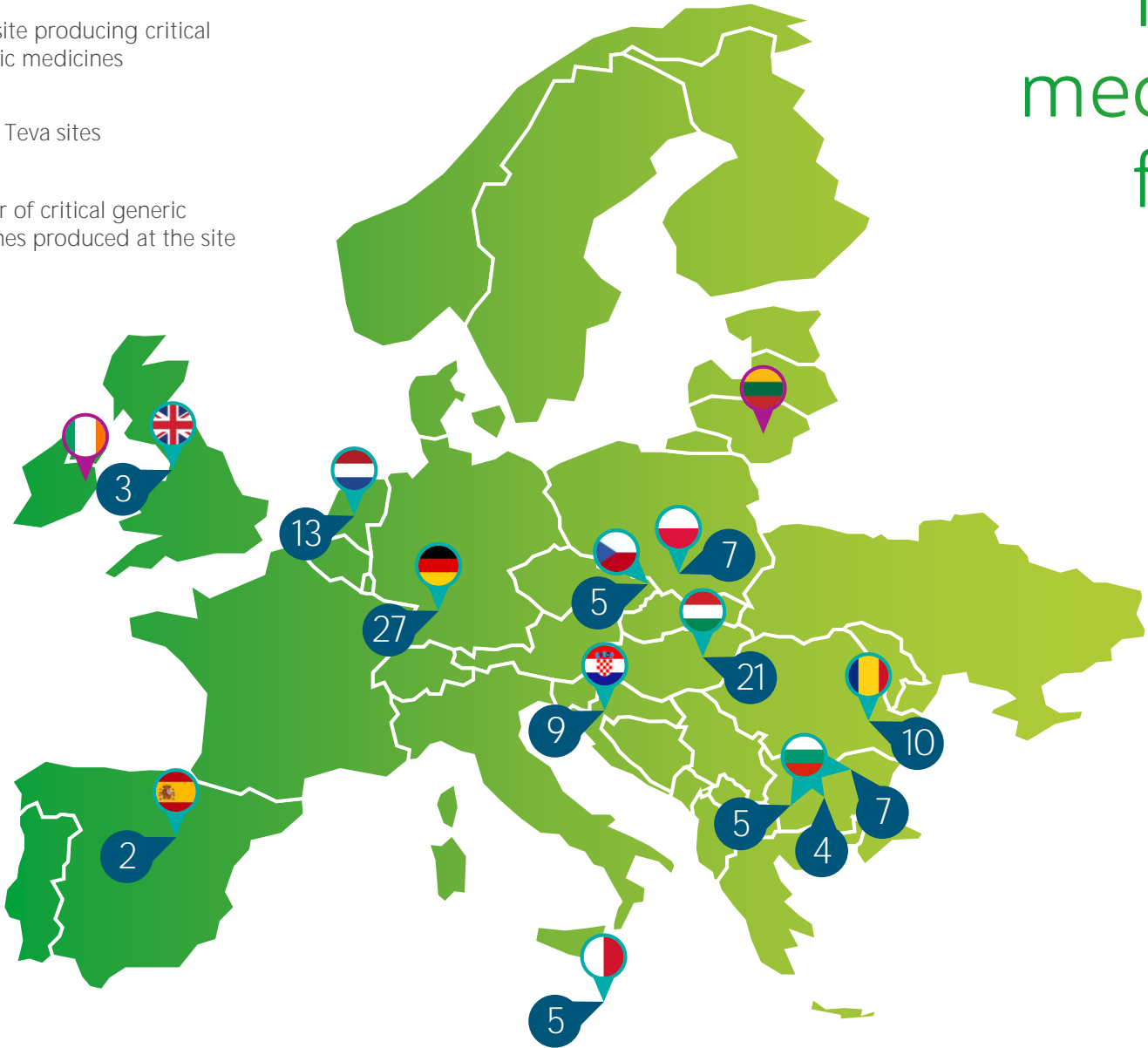
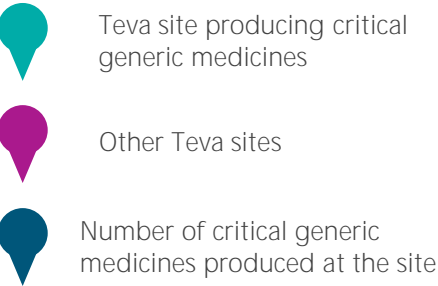


Saved healthcare systems an estimate of **€2.9B**



For Teva's manufacturing in Europe, **40%** of APIs are also produced in Europe

Teva critical generic medicines manufacturing footprint in Europe



of medicines on the Union List of Critical Medicines are supplied by Teva



are produced in Europe across 11 out of 13 Teva manufacturing sites



of critical medicines' APIs are sourced in Europe

4 | *At least one product containing the critical medicine is produced in Teva's European manufacturing site
** At least one product supplied by Teva containing a critical medicine has an API sourced from Europe

In the previous two reports*, Teva has presented data showing that the supply chain of finished medicines is consolidated and critical generic medicines are vulnerable to withdrawals.

Our latest report is focused on assessing the critical generic medicines supplier situation. The new analysis using data from 2014-2024 shows that European generic medicines are under pressure caused by an increase in external costs, combined with price constraints.



Three
times

increase in critical generic products with only 1 or 2 suppliers, compared to all generic products.

83%

of critical generic products are provided by a single major supplier with over 60% volume market share

9%

of critical generic products available in 2014 have completely disappeared

Now is the time to act to save the availability of critical generic medicines



65% of medicines in short supply come from 5 therapeutic classes

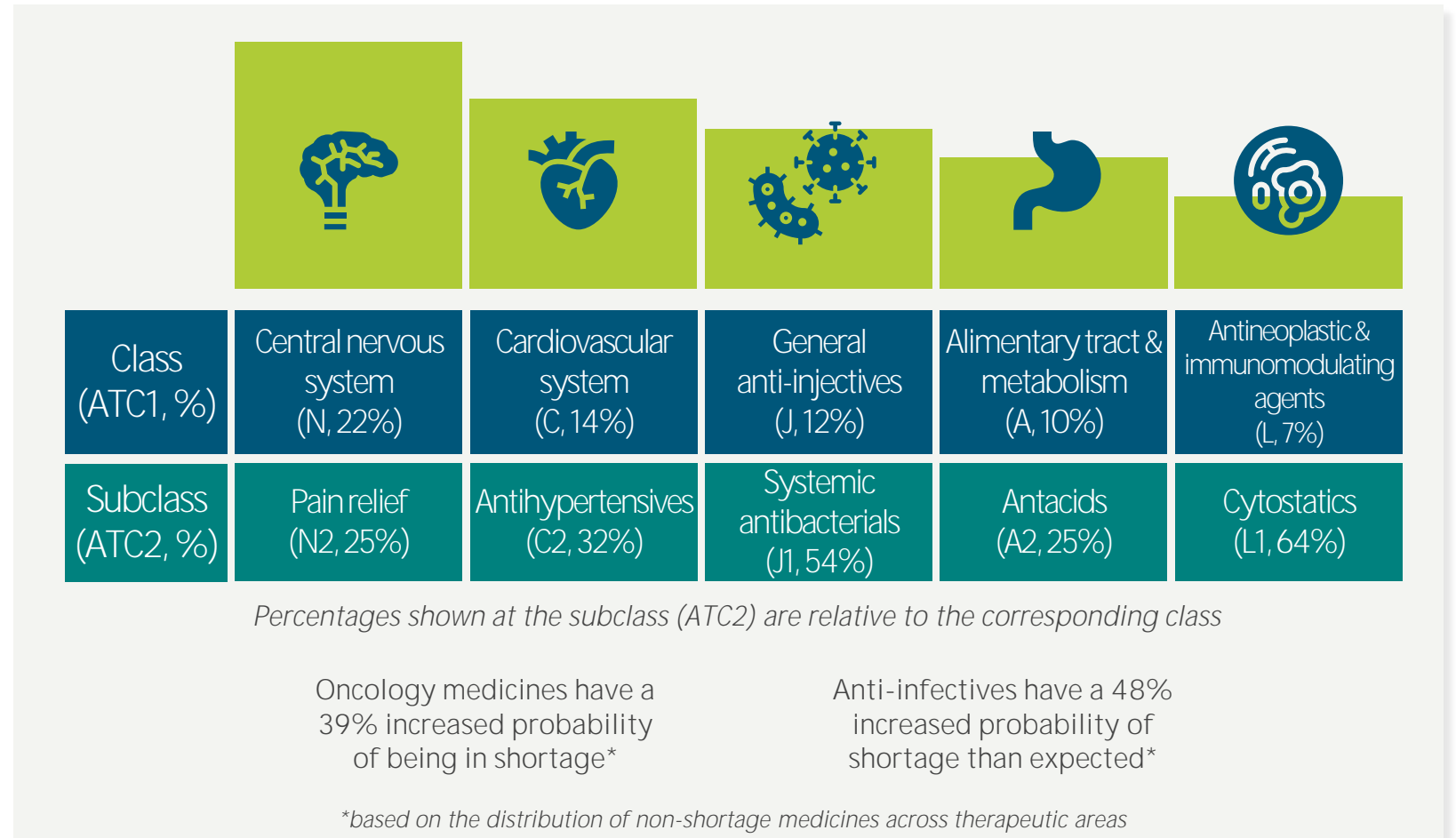
What are the EU Institutions doing about it?
How does Teva contribute to the policy discussion?



Medicines shortages are a problem for many European countries

In December 2021, the European Commission published a study on medicine shortages, which brought three key outcomes:

- 65% of all medicine shortages come only from 5 therapeutic classes
- The root causes of shortages are multifactorial
- Shortages are most concentrated in a handful of countries and often involve older, off-patent and generic medicines



For the last 3 years, Teva has highlighted the unsustainability of the European generic supply chain

2023

Showing for the first time that not only the API supply chain is consolidated but also the supply chain of finished medicines

For example, one oncology product **lost 46% of its suppliers** over 10 years



In 2022, 69% of EU generic medicines marketed had fewer than 2 suppliers

In 2022, **26% of generic medicines marketed in 2012 disappeared** from the European markets - 33% of which were antibiotics and 40% oncology medicines

2024

The rate of generic product **withdrawals increased by 12%** while **launches decreased by 3%**



Critical generics are vulnerable to withdrawals:

- In the mental therapeutic area, **7% of products disappeared** (2013-2023)
- Among oncology medicines, **7% of products disappeared** in just six years (2017-2022)

Teva reports contribute to the policy discussion on the resilience of critical medicines



The actions include the launch of a **European Voluntary Solidarity Mechanism** for medicines, **greater regulatory flexibilities** and the announcement of **EU guidance on procurement** of medicines.



"The inclusion on this list is not an indication that medicine is likely to experience a shortage in the near future. Rather, it **signifies the critical importance of averting shortages for these specific medicines.**"



Bringing together relevant stakeholders to develop joint recommendations on ways to **enhance the security of supply**, strengthen the availability of medicines and reduce EU supply chain dependencies.



"...we will propose a **Critical Medicines Act** to reduce dependencies relating to critical medicines and ingredients, **particularly where there are only a few supplying manufacturers.**"



A key priority of the new Commissioner for Health is to deliver the **Critical Medicines Act** within the first 100 days of the mandate.



What are the goals of this analysis?

Expand on Teva's report Critical Medicines Health Check from March 2024



Compare the supplier situation among all generics and critical generics in Europe between 2014 and 2024



Understand the level of effective critical generic supplier diversity

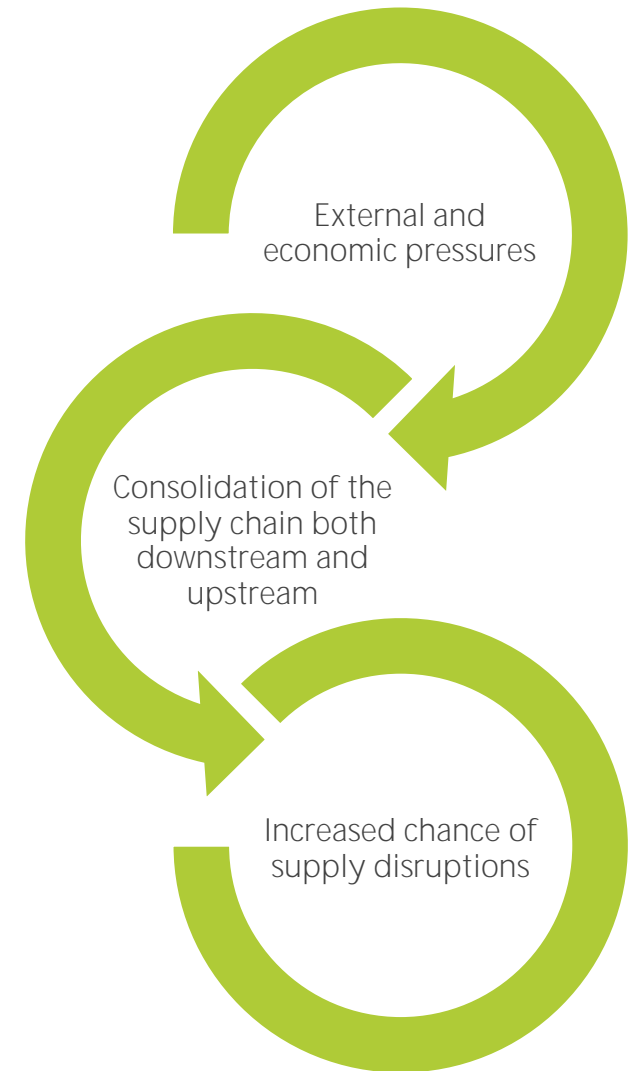


Assess the situation of the critical generic medicines marketed in 2014 compared to 2024



Explore the root causes of the critical generic medicines supply chain consolidation

Use our findings to support Teva's recommendations on security and diversity of supply of critical generic medicines ahead of the Critical Medicines Act expected in 2025





The state of critical generic medicines supply in Europe

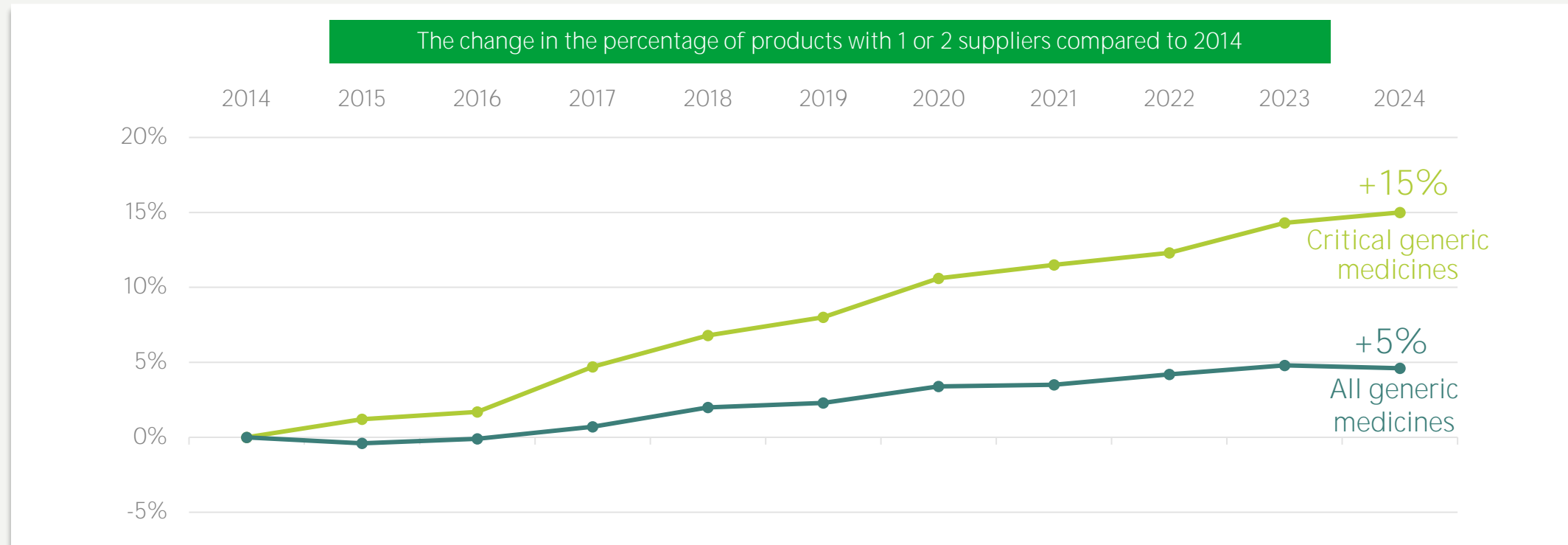


Finding 1

The supply of critical generic medicines is consolidating faster than all generic medicines

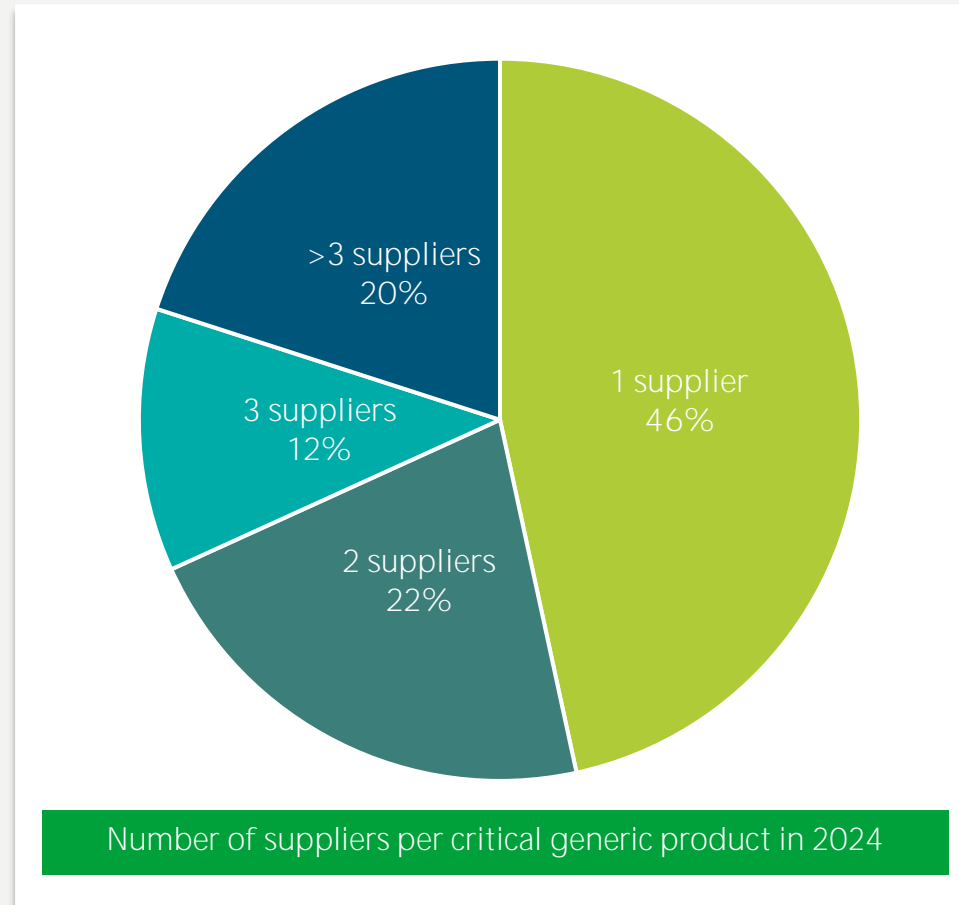


Critical generic products consolidate **3 times** faster than all generic products



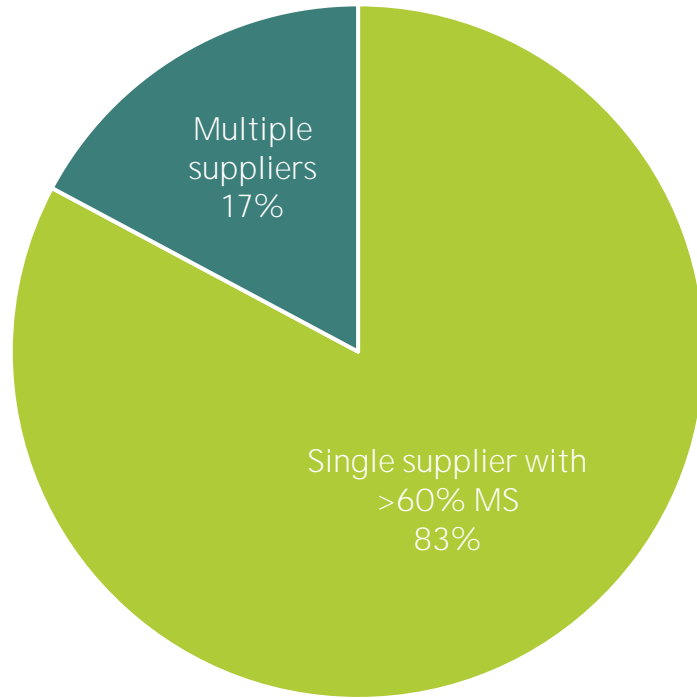
Between 2014 and 2024, the number of critical generic products with only 1 or 2 suppliers increased by **15%**. In the segment of all generic products, this number increased by **5%**.

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



...however, this gives a false sense of how dire the situation of supply diversity really is.

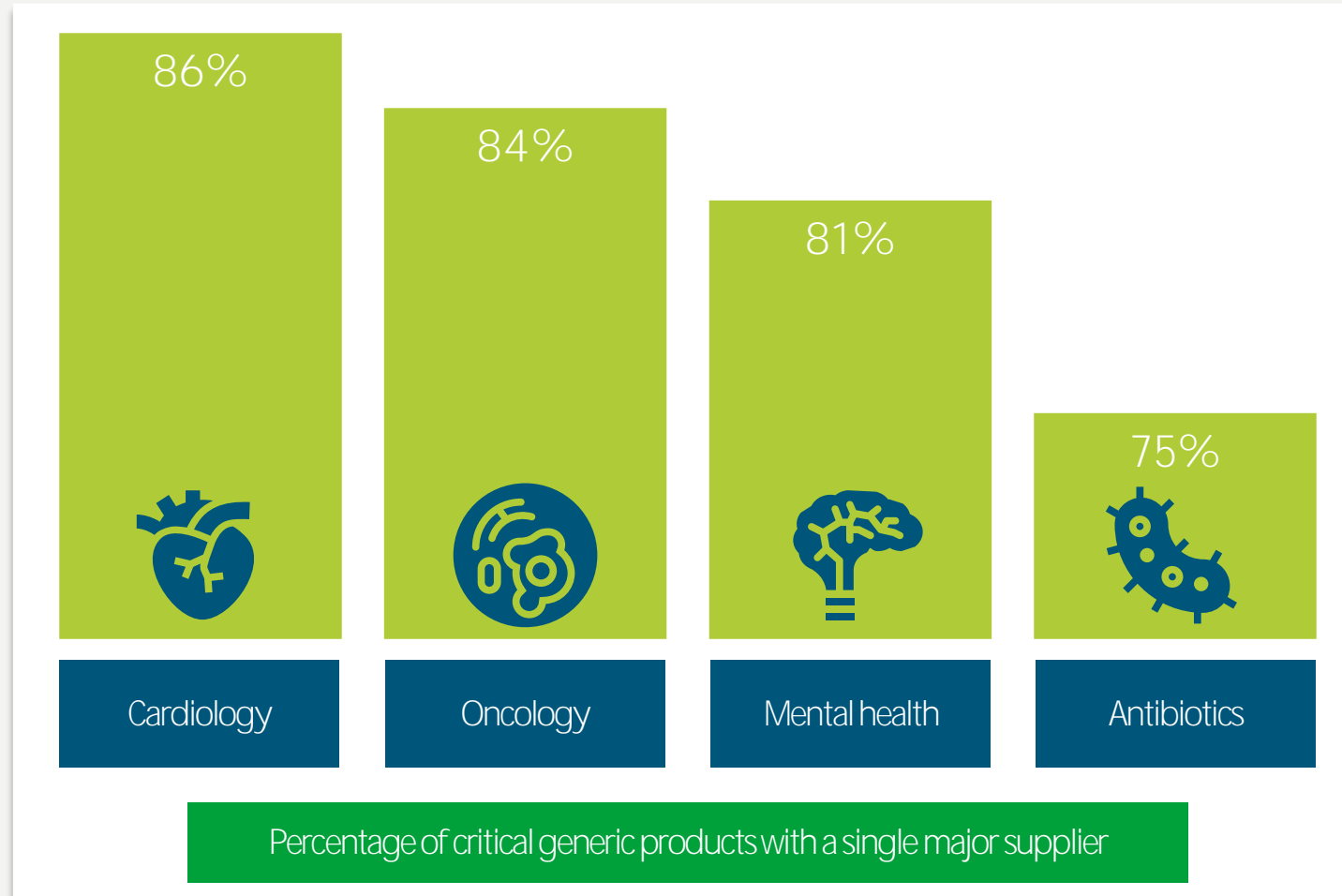
In reality, 83% of critical generic products are provided by a single major supplier



Market share distribution per critical generic product in 2024

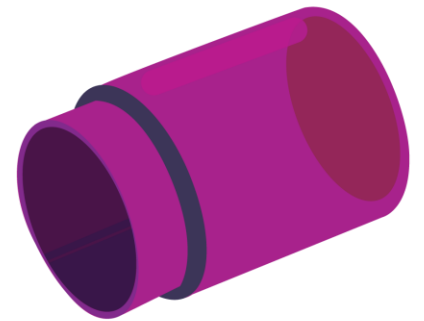
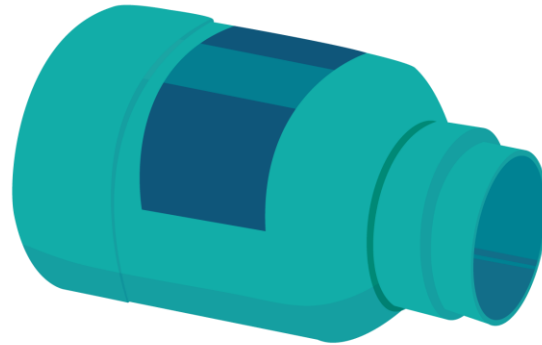
- The level of effective market competition is an indicator of healthy competition.
- When the market relies on a single major supplier with one or more smaller suppliers, in case of supply disruption, the minority suppliers can't step up and fill the gap, as they cannot adapt their production capacity in a short time.

The same pattern can be seen across major therapeutic areas

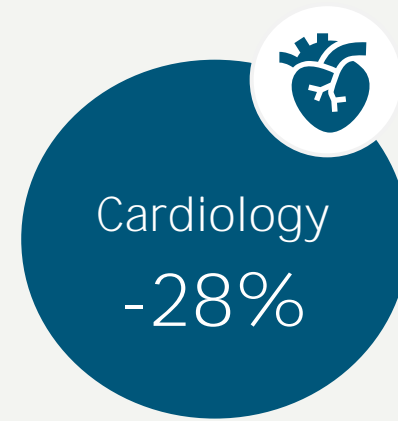
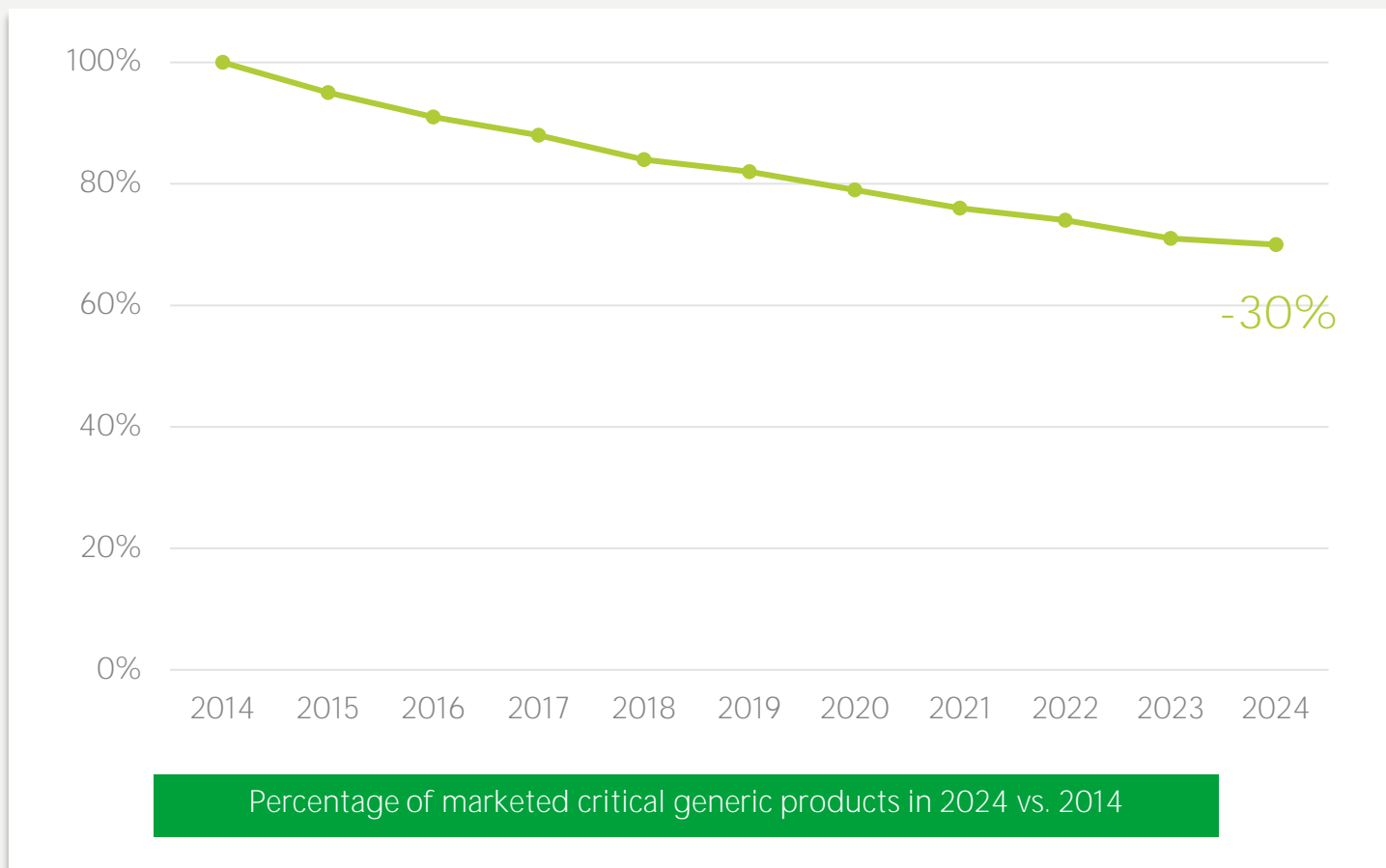
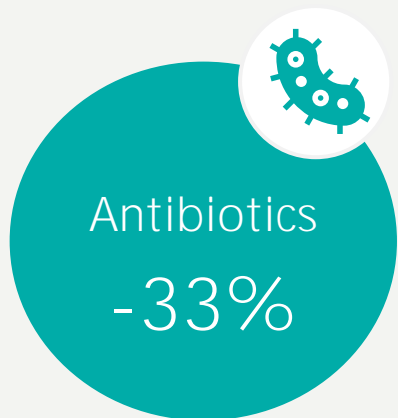
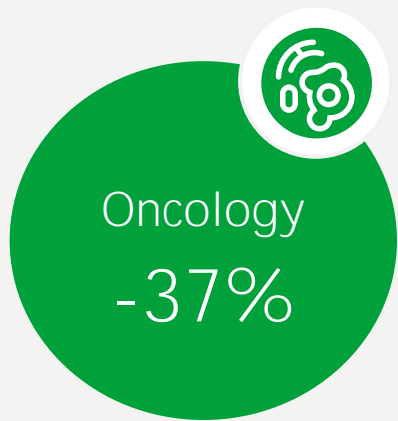


Finding 2

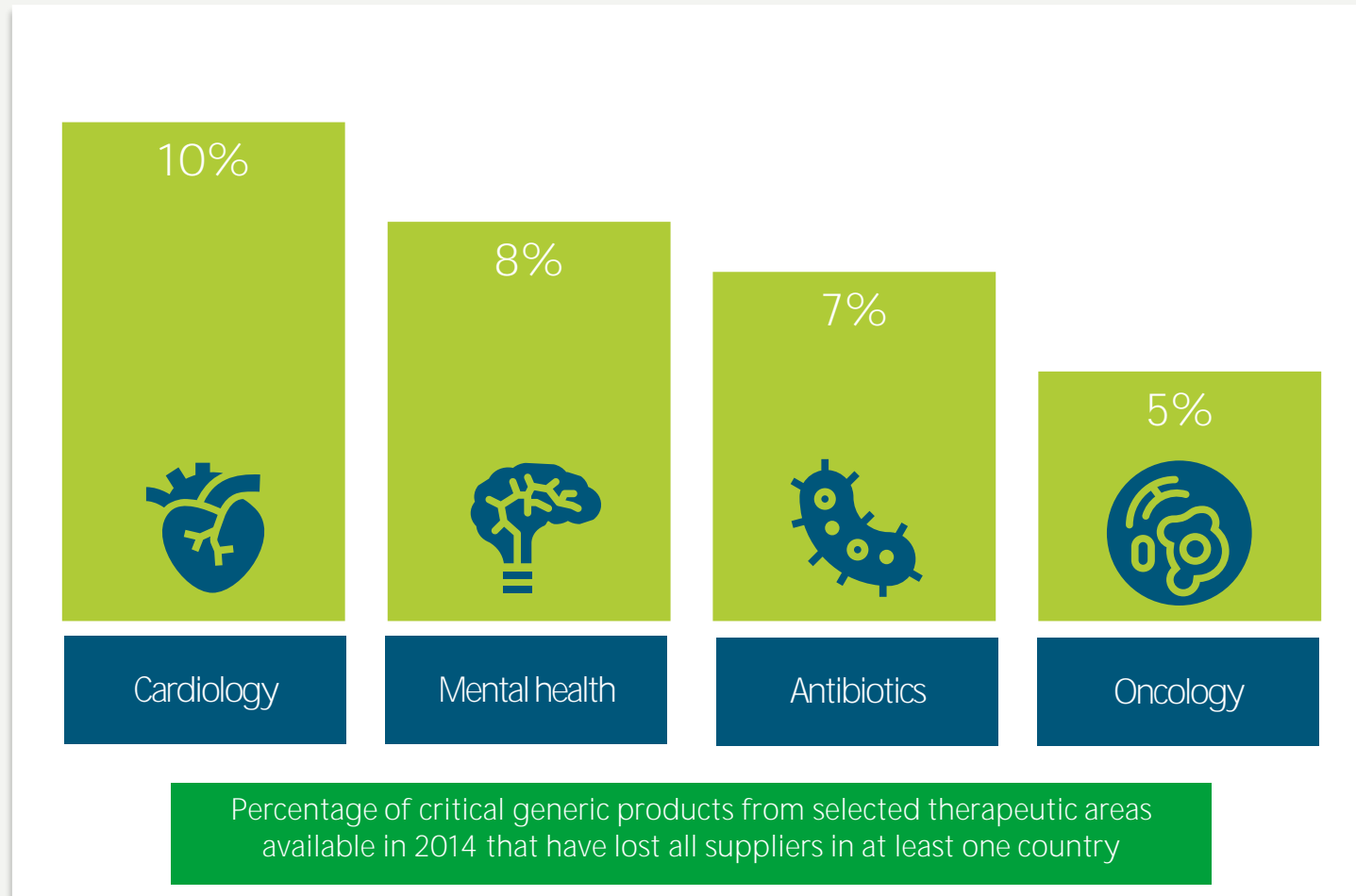
Supplier consolidation
can lead to medicine
withdrawals



30% of marketed critical generic products available in 2014 were withdrawn

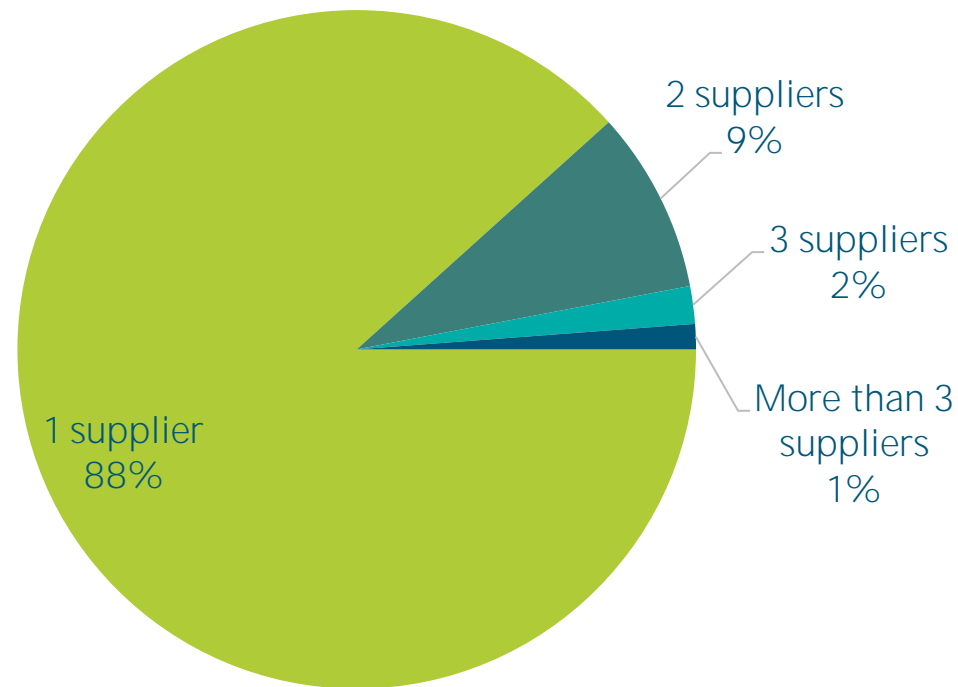


9% of critical generic products available in 2014 have disappeared because there is no supplier



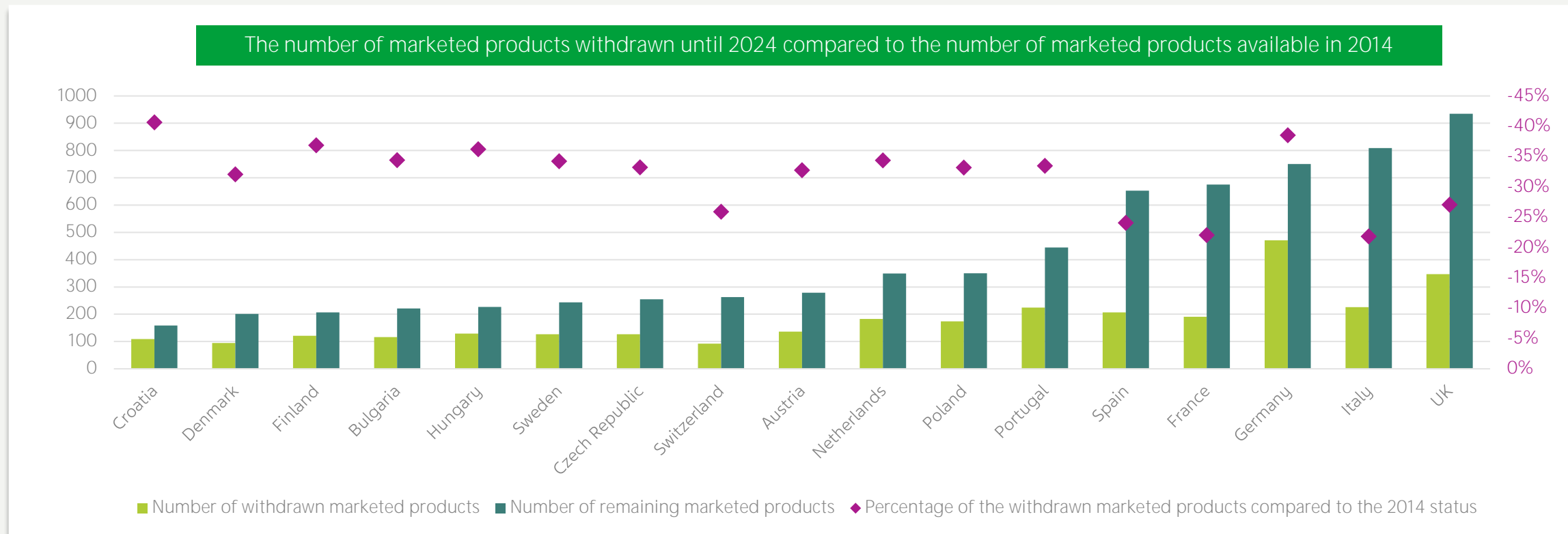
Critical generic products with 1 supplier are in the biggest danger of disappearing

88% of all lost critical generic products had only one supplier in 2014



Number of suppliers in 2014 of critical generics products that disappeared from at least one country

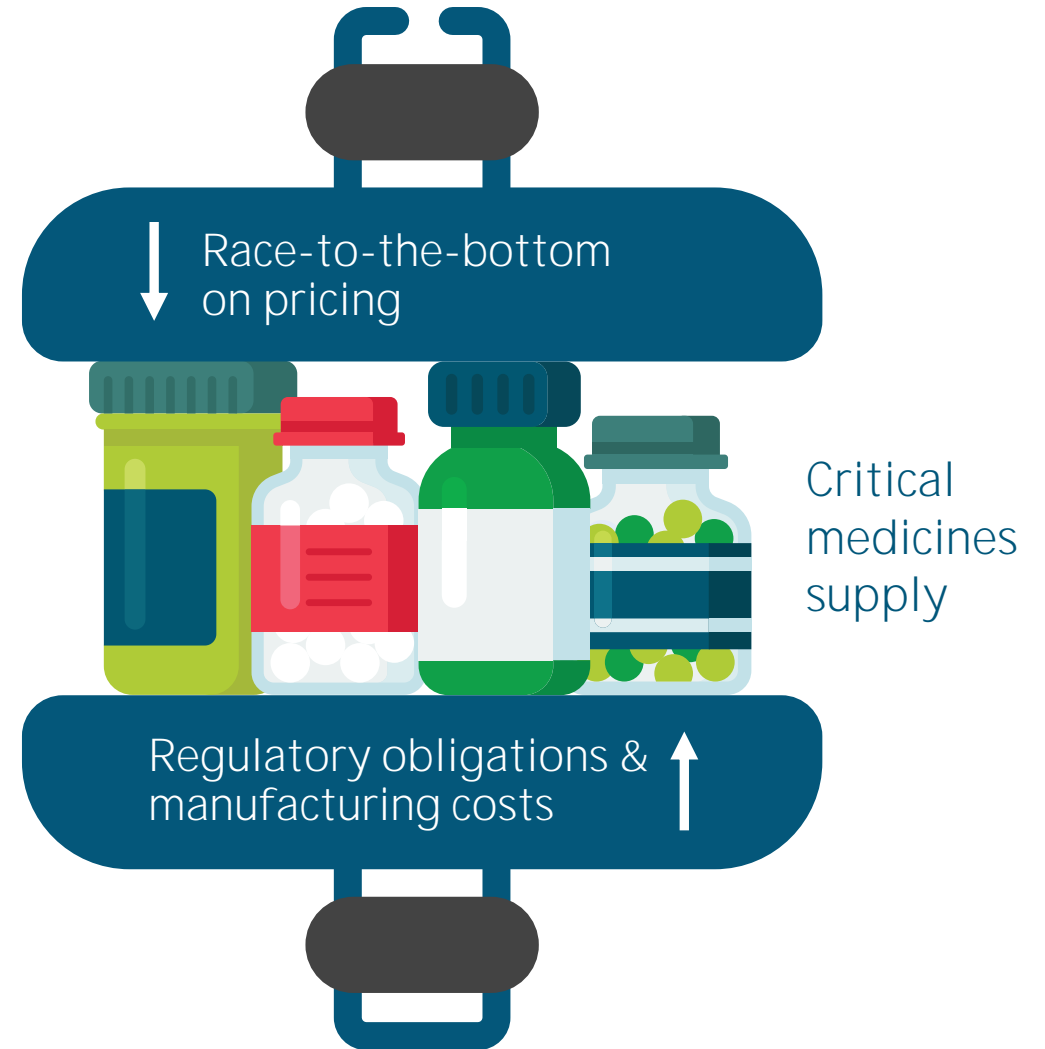
Suppliers are withdrawing their critical generic products in all countries



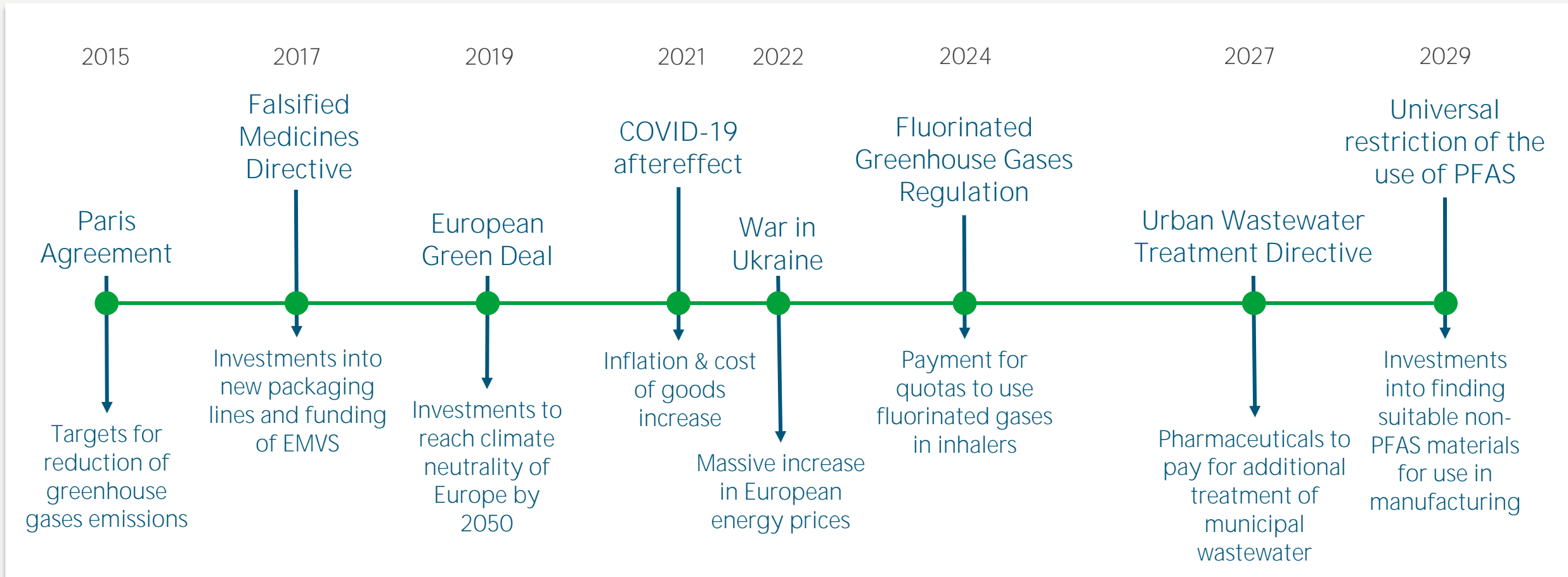
12 out of 17 markets saw a decrease larger than 30%
The majority of these are small European markets

Finding 3

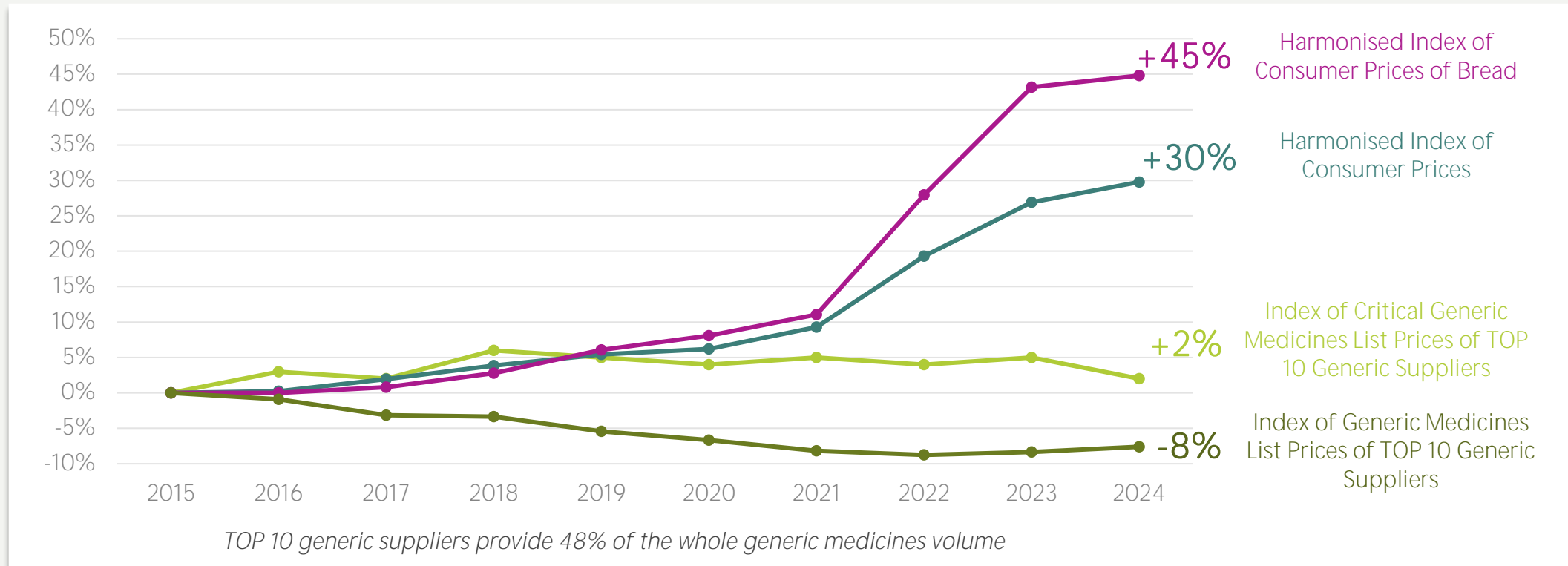
The European generic market is under pressure



International situation and new regulatory obligations, and impact on the cost of manufacturing



The pricing system does not keep pace with rising manufacturing costs



The List Price is further decreased by mandated cost-containment measures outside of the supplier's control, such as mandatory rebates and discounts, and clawback and payback schemes



Solutions for strengthening and diversifying the supply chain



1

Mitigating supply chain disruptions

Support European solidarity mechanism for reallocation of existing stocks

- A fully implemented European Solidarity Mechanism, that enables the reallocation of existing market stocks, as opposed to stocks created through additional safety stock obligations to address localised national shortages.



This will prevent distortion of the Single Market and the undermining of the European principles of solidarity through the proliferation of national stockpiling/safety stock obligations.

- One key enabler for the solidarity mechanism is extending regulatory flexibilities to optimise and simplify the management of mature medicines. This includes full implementation of the electronic patient leaflet, introduction of a common European package, and better use of a digital regulatory framework.

Case study: How uncoordinated stockpiling is putting strain on manufacturing capacity

One month of stockpile in a large European country equals the volume necessary to supply several smaller European countries



Poland + Netherlands + Portugal
+ Czech Republic + Bulgaria +
Sweden + Denmark + Austria +
Finland + Hungary + Croatia

1-month supply volume in France is more than the combined
monthly supply volume of 11 European countries



Poland + Netherlands + Czech
Republic + Bulgaria + Denmark
+ Austria + Hungary

1-month supply volume in Spain is equal to the combined
monthly supply volume of 7 European countries



Poland + Netherlands +
Sweden + Denmark + Finland
+ Hungary

1-month supply volume in Germany is equal to the combined
monthly supply volume of 6 European countries



Portugal + Sweden + Denmark +
Austria + Croatia

1-month supply volume in Italy is equal to the combined
monthly supply volume of 5 European countries

France (29%), Spain (19%), Germany (17%), and Italy (9%) represent $\frac{3}{4}$ of the critical generic antibiotic medicines volume in the analysed European market

2

Safeguarding critical **medicines'** sustainability

Well-defined and realistic sustainable procurement schemes that are designed in collaboration with the industry

- Introduction of multi-criteria and multi-winner tenders, which will reward manufacturers' actions on environmental responsibility, resilience of the supply chain and the overall contribution to the European economy



Develop dynamic pricing practices

Safeguarding critical medicines from the unintended consequences of environmental legislation

- Any legislation with a potential impact on the economic viability of critical medicines must be accompanied by a thorough impact assessment to prevent any future disruptions such as the ones stemming from the Urban Waster Water Treatment Directive.

3

Strengthening manufacturing capacities

Creating a strong environment that will attract private investments and supported by agile public funding schemes

- Supporting strategic projects which contribute to the security of the **EU's medicines supply**, i.e. manufacturing facilities dedicated primarily to feeding an EU demand
- These strategic projects should receive aid such as specific funding opportunities, administrative help, a fast-track approval process and similar.

Public funding schemes to support all types of innovation, including manufacturing processes

- The currently used definition of a first-of-a-kind facility should be extended to cover new or substantially upgraded (e.g. in case of more environmentally sustainable) manufacturing of active pharmaceutical ingredients, finished dosage form, or other critical components (key starting materials, key intermediates).

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Methodology

Source of data: IQVIA MIDAS® Quarterly sales data released Q2 2024

Time-period: MAT Q1 2014 - Q1 2024

Selected markets with available IQVIA data: AT, BG, HR, CZ, DK, FI, FR, DE, HU, IT, NL, PL, PT, ES, SE, CH, UK

Definitions:

- Supplier: IQVIAs field “cooperation”
- Medicine: IQVIAs field “INN”
- Critical medicine: medicines on the EMA Union List of Critical Medicines, version from December 2023 (available [here](#))
- Generics
 - Excluding parallel importers’ competition according to IQVIA’s definition of “PI”
 - Generics per IQVIA definition “non-innovative-branded” and “unbranded”
- Critical generics: critical medicines excluding duplications due to ATC overlaps, vaccines, immunoglobulins, insulins, radiopharmaceuticals, on-patent medicines, off-patent medicines with only innovator, and “other products”
- Product: INN_NFC1
- Marketed product: INN_NFC1 _supplier
- Supplied market: a country with positive sales of a product
- Major supplier: a supplier with a volume market share by Standard Units of over 60% in a specific country
- Major therapeutic areas: oncology – ATC L1 and L2; mental health ATC N5A, N5B, N6A; cardiology ATC C; antibiotics ATC J1

Calculation of the number of products / marketed products:

- $\# \text{ products} = \# \text{ INN_NFC1} * \# \text{ supplied markets}$
- $\# \text{ of marketed products} = \# \text{ INN_NFC1_supplier} * \# \text{ supplied markets}$

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