Teva Critical Medicines Health Check

Teva Europe 2024 Data Analysis

NPS-TPE-NP-00809

Disclaimer

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

About Teva in Europe

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 deliver quality medicines to help improve health outcomes of millions of patients every day.

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

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In 2022 across Europe…

The company supported **100,000 jobs**

Generated **€2.8B** in labour income

Contributed **€6.3B** to GDP

And saved healthcare systems an estimate of **€5.4B** across these markets

 Teva's 2022 Environmental, Social and Governance Progress Report (available at https://www.tevapharm.com/globalassets/tevapharm-vision-files/teva-esg-progress-report_2022.pdf)

Executive Summary

- Vulnerabilities in the supply chain are increasing the risk of shortages, and restricting the number of therapeutic options available to the patients
- Teva already sounded an alarm bell in its 2023 analysis "The case of Europe's disappearing medicine cabinet"* showing that:
  - **69%** of generics marketed in 2022 **have fewer than 2 suppliers each**
  - **26%** of the generics previously available in 2012, have since **disappeared from the European market**

- This time we're sounding it more loudly! Our latest analysis demonstrates that the European generic medicines market is not in shape to help Europe meet its public health priorities
  - In the mental health therapeutic area, **7%** of the generic products on the Union List of Critical Medicines **disappeared** between 2013 and 2023
  - Meanwhile, over six years (2017-2022) **7%** of generic oncology medicines on the Union List, disappeared
  - For some critical generic medicines, this decrease **is as steep as -43%**
- We need policies in support of a vibrant pharmaceutical industry that will help safeguard European citizens' health

*The full analysis is available on Teva website: https://www.tevapharm.com/globalassets/tevapharm-vision-files/final_for-website_the-case-of-europes-disappearing-medicine-cabinet.pdf

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Does Europe have the medicines it needs to achieve its public health priorities?

Europe has clear public health priorities post COVID19

The **2023 State of Health report** stresses the need to address growing health inequalities across the European Union, as well as increasing unmet medical needs.

The COVID-19 pandemic led to a widening of the gap in life expectancy at birth between 2019 and 2021 across Member States, and the estimates from 2022 show that the gap continues to narrow.

Cancer is highlighted as a key priority area to address.

EU citizens' **mental health** deteriorated following the pandemic. Mental health reforms that cover de-stigmatisation, prevention, treatment and reintegration are needed across all Member States.

"Investments towards resilient and accessible health systems need continuity, underpinned by robust data collection mechanisms"

Is the generic medicines market situation helping to address the public health needs identified?

Source: State of Health in the EU: Synthesis report 2023 (publication December 2023), available at https://health.ec.europa.eu/system/files/2023-12/state_2023_synthesis-report_en.pdf

The EU has also established a Union list of Critical Medicines

REUTERS®


Healthcare & Pharmaceuticals

EU publishes its first list of more than 300 critical medicines, vaccines

By Julia Payne

December 12, 2023 1:23 PM GMT+1 · Updated a month ago

Which medicines are on the list?
A critical medicine is identified by combining two criteria, the seriousness of the disease and the availability of alternative medicines.

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

Is the generic medicines market dynamic helping with the critical need to avert shortages?

 Original article available at https://www.reuters.com/business/healthcare-pharmaceuticals/eu-publishes-its-first-list-more-than-200-critical-medicines-vaccines-2023-12-12/

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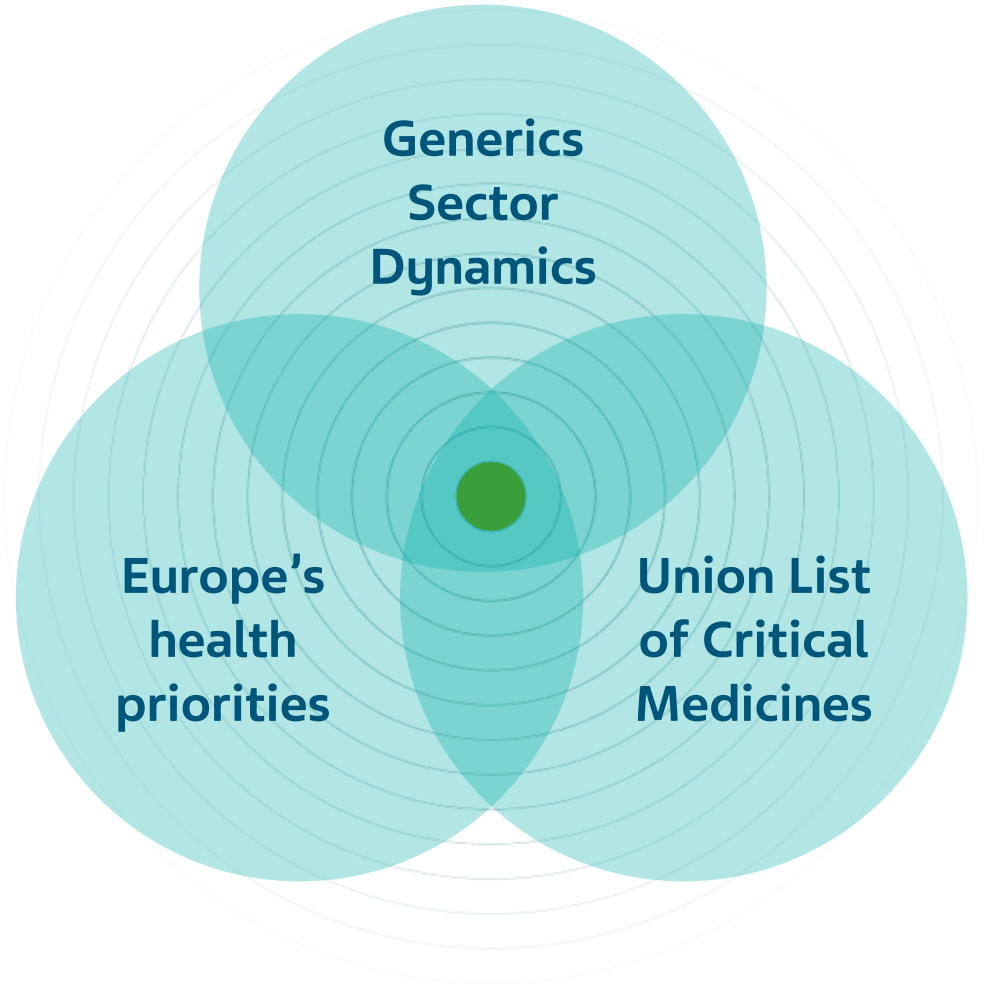
What was the goal of the analysis?

- Understand how the overall dynamic of the generics market in Europe changed between 2013 and 2023, in terms of launches of generic products and withdrawals of generic products
    - Find out when the generics market in Europe starts to consolidation after launch of new generic medicine
    - Assess the European generic market dynamics of medicines on the Union List of Critical Medicines in two selected therapeutic areas
- Identify the area of potential future growth of the generic market in Europe



Main outcomes of the analysis

- Over the last ten years, there's been an **increasing rate of generic product withdrawals (+12%)** while **generic product launches are decreasing (-3%)**
  - Complex and hard-to-manufacture dosage forms such as **long-acting injectables** saw an **86% increase** in the number of generic products over the last 10 years
- Case studies show that **the number of generic products starts to decline 3-4 years** after the launch of new generic medicine

- **Mature generic products** make up most of the Union List of Critical Medicines, however they are **vulnerable to withdrawals** despite containing products that are key to safeguarding Europe's public health
  - In the mental therapeutic area, 7% of products disappeared over the last ten years
  - Among cancer treatments, 7% of products have disappeared in just six years (2017-2022)
- Low-volume products are also observing a decline, such as generic oral liquid antibiotic products (e.g. paediatric syrups). **Between 2013 and 2023, 21%** disappeared from the product segment

 Based on internal analysis by Teva using data from the following source: IQVIA MIDAS® Quarterly Sales data released Q3 2023, Time Period: MAT Q2 2013-Q2 2023, reflecting estimates of real-world activity.

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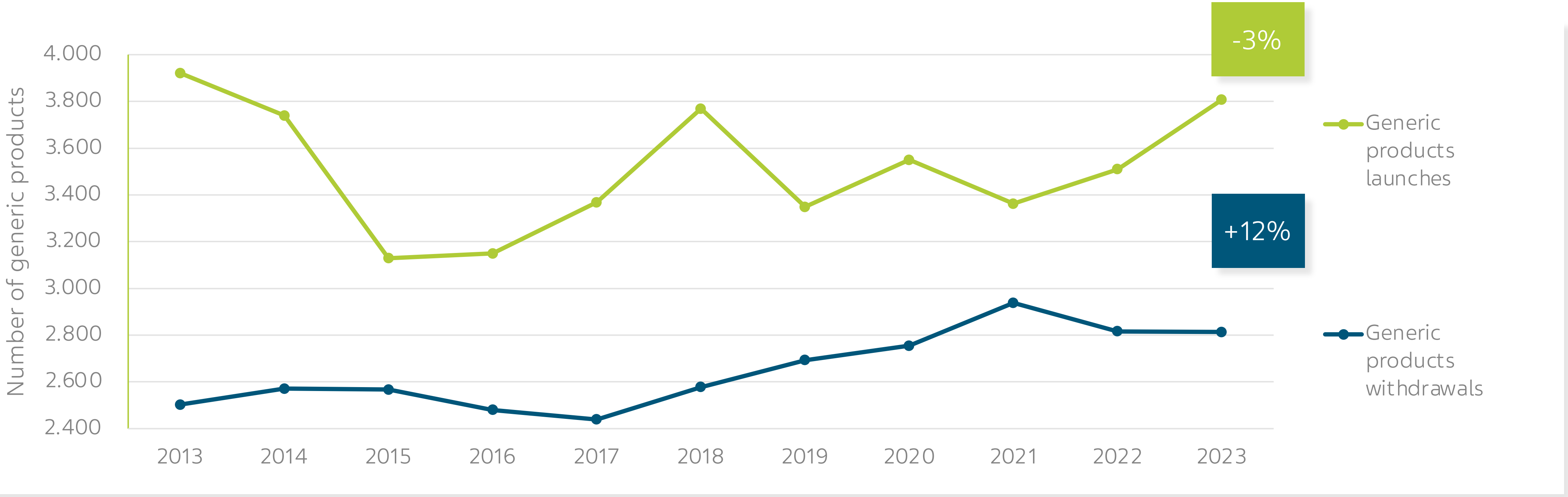
Generic medicines market dynamics in Europe

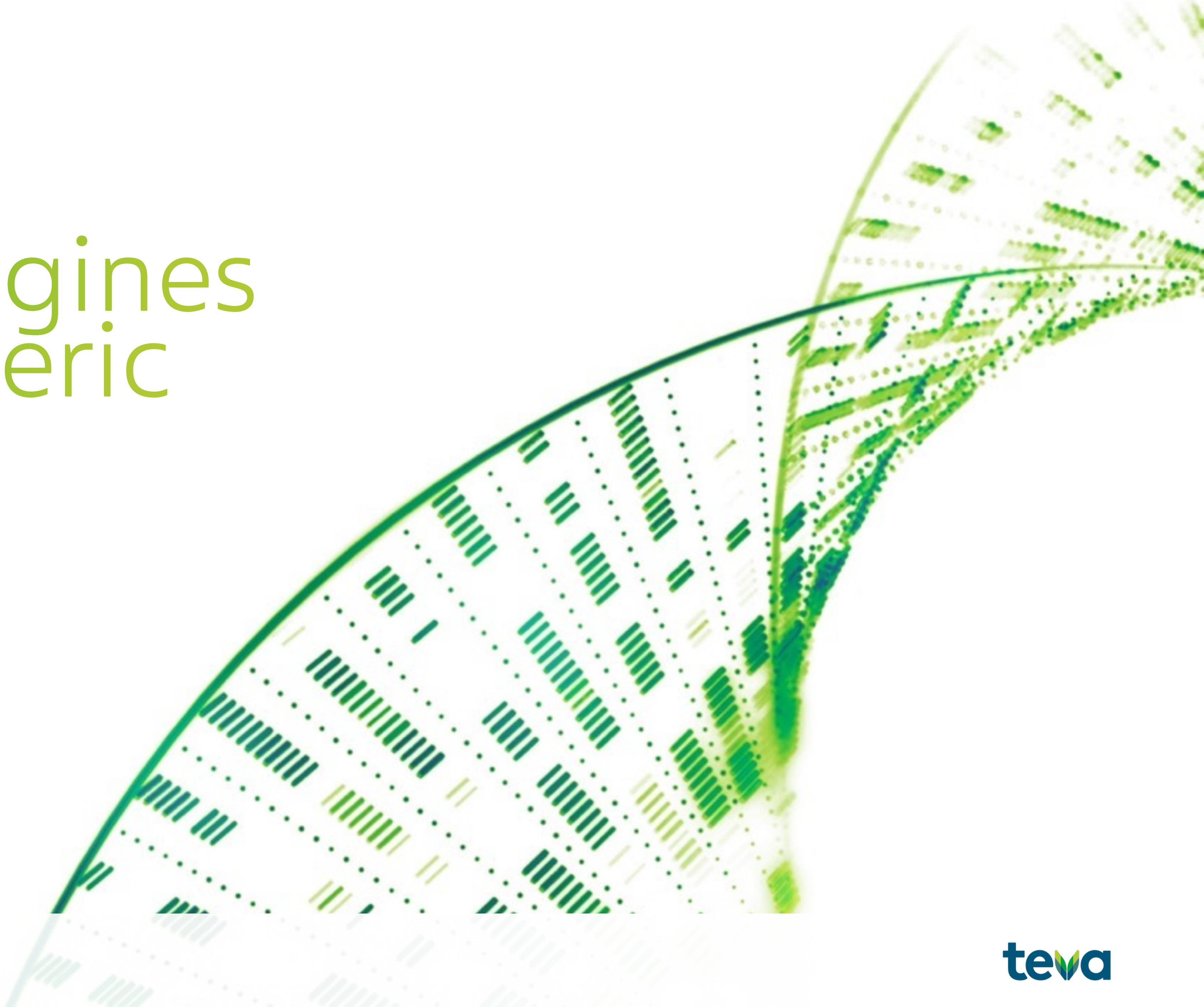
The rate of generic product withdrawals is increasing



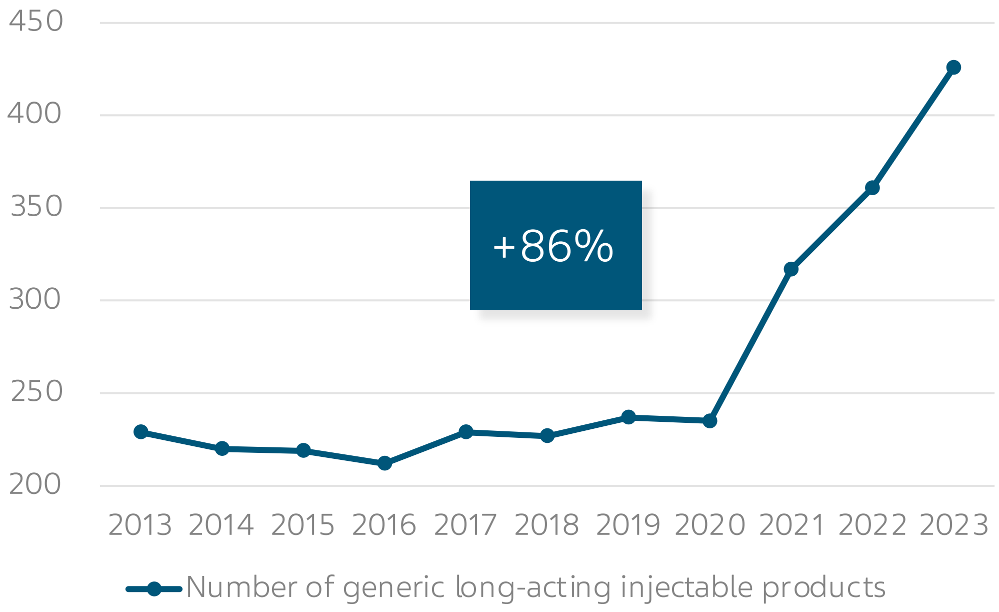
Over the last 10 years, generic product launches are relatively stable **(-3%)** while generic products withdrawals **increased by 12%**

Based on internal analysis by Teva using data from the following source: IQVIA MIDAS® Quarterly sales data released Q3 2023, Measure: count of products with sales of >0 standard unit, Time Period: MAT Q2 2013-Q2 2023, reflecting estimates of real-world activity.

Growth engines of the generic market in Europe



Case study: the growth of generic long-acting injectables



Generic long-acting injectables belong to a group of so-called "complex generics". LAIs allow less frequent administration, a clear advantage in terms of patient compliance and reducing potential side effects like injection-site reactions.*

- Generic long-acting injectables (LAI) is a small but fast-growing group (only 1% of all medicines).
- Over the last 10 years there has been an **86% increase in the number of generic LAI products**.
- Zooming in on the therapeutic groups (ATC level 2) the biggest growth was among **three of them**:
  - Cytostatic hormones (+735%),
  - Hormones of pituitary gland and hypothalamus (+230%)
  - Antipsychotics (+109%)

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*Gonella, A., Grizot, S., Liu, F., Noriega, A. L., & Richard, J. (2022). Long-acting injectable formulation technologies: challenges and opportunities for the delivery of fragile molecules. Expert Opinion on Drug Delivery, 19(8), 927–944.

Complex generics: delivering value to patients

- Complex generics are a group of generic medicines that could have a complex active ingredient, complex formulations, complex route of delivery or complex drug-device combination.
- This makes them hard to develop, hard to produce and hard to get approved by the authorities.
- All of this is requiring a high level of expertise from their manufacturers.

Generics of complex medicines deliver value to patients and the healthcare system on several levels:

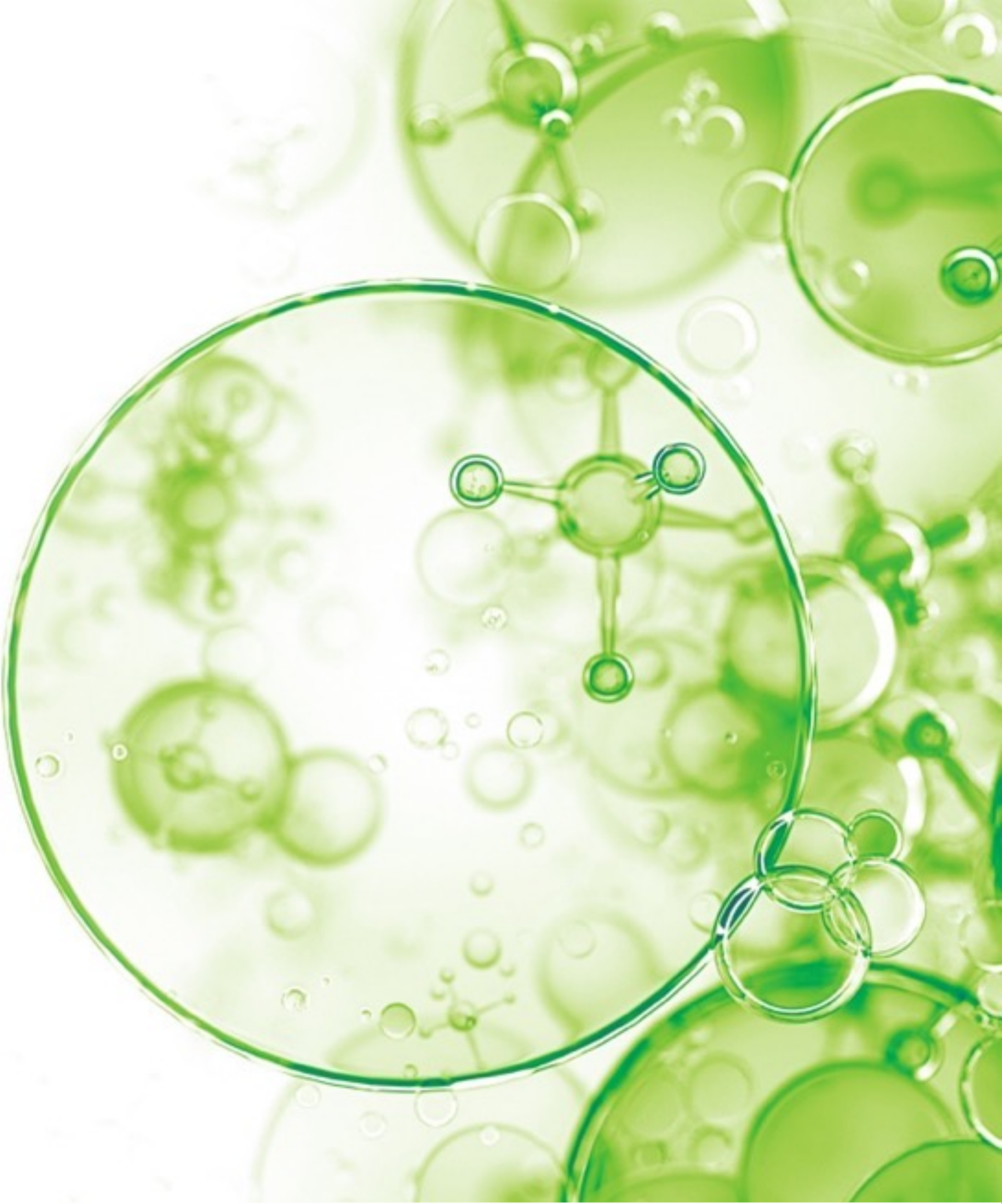
Reducing health inequalities by enabling access to wider population of patients

Improving medication adherence by reducing the financial burden for patients purchasing medicines (i.e. co-payments)

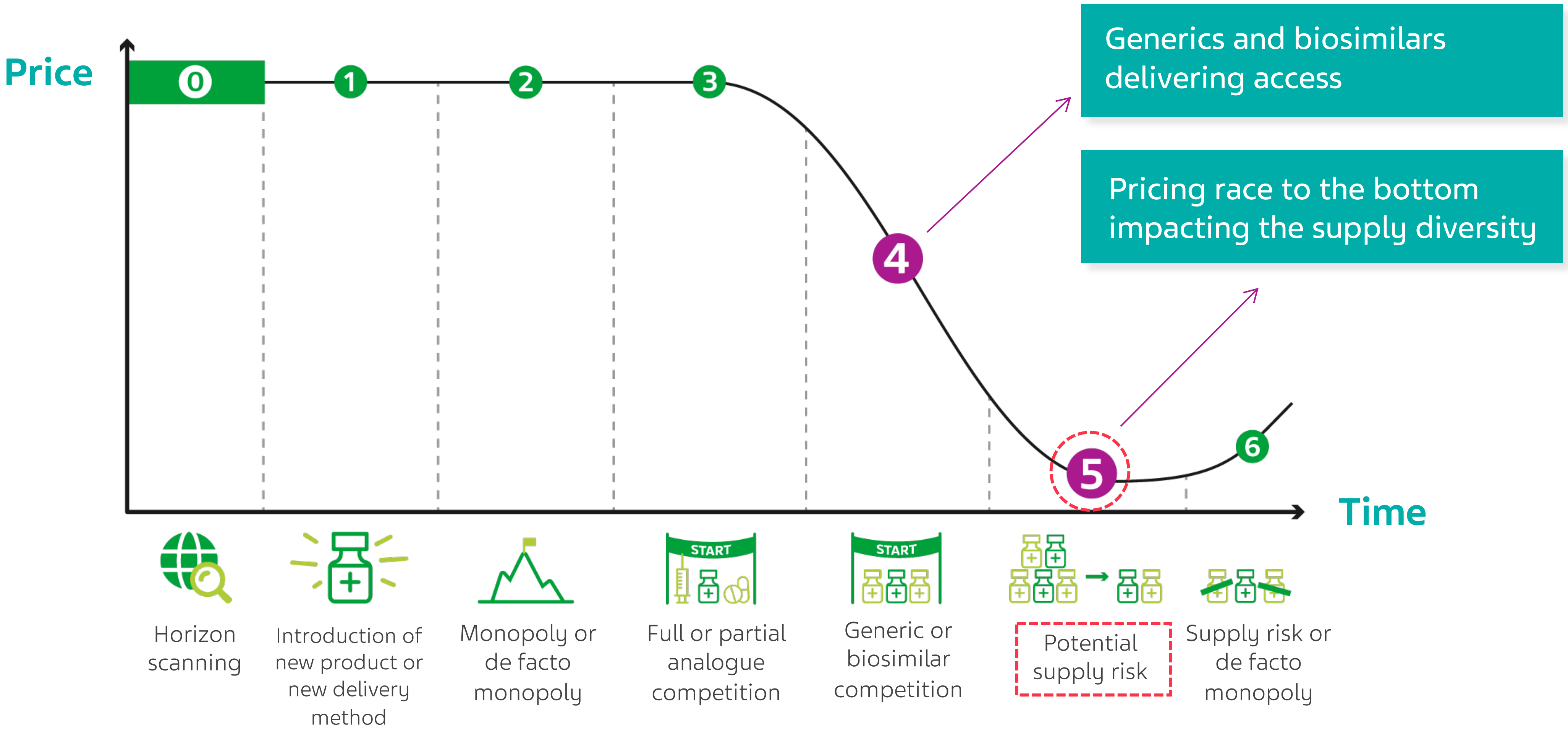
Improving the efficiency and sustainability of the healthcare system through cost-savings

Sources: Zagalo DM, Simões S, Sousa J. Regulatory Science Approach in Pharmaceutical Development of Follow-on Versions of Non-Biological Complex Drug Products. Journal of Pharmaceutical Sciences. Elsevier Inc.; 2022. p. 2687–713. and Medicines for Europe "Value of generic medicines" (available at: https://www.medicinesforeurope.com/wp-content/uploads/2016/07/20151126-EMAC-Value-of-generic-medicines_v7-1.pdf)

The challenge of keeping mature generics in Europe

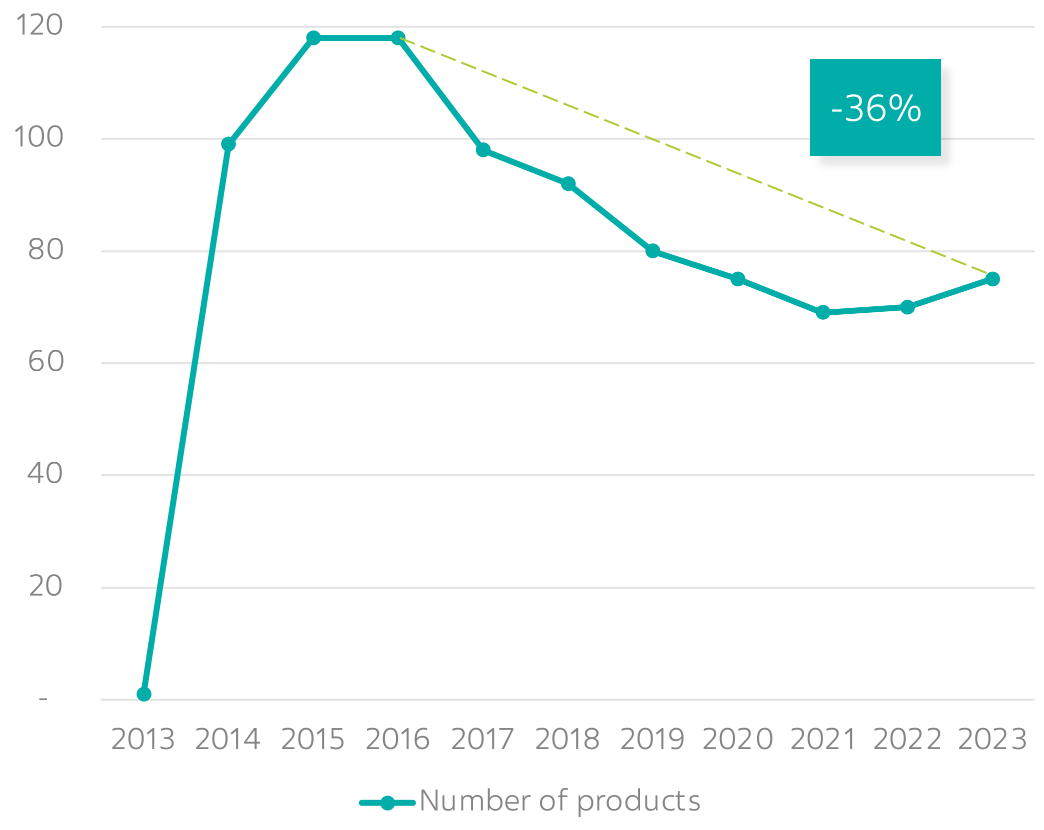


The dynamics of generic product after patent-expiry in market driven solely by price



 Source: Amgros, unpublished presentation at the WHO consultation on strategic procurement on 22 – 23 September 2016 in Copenhagen, Denmark.

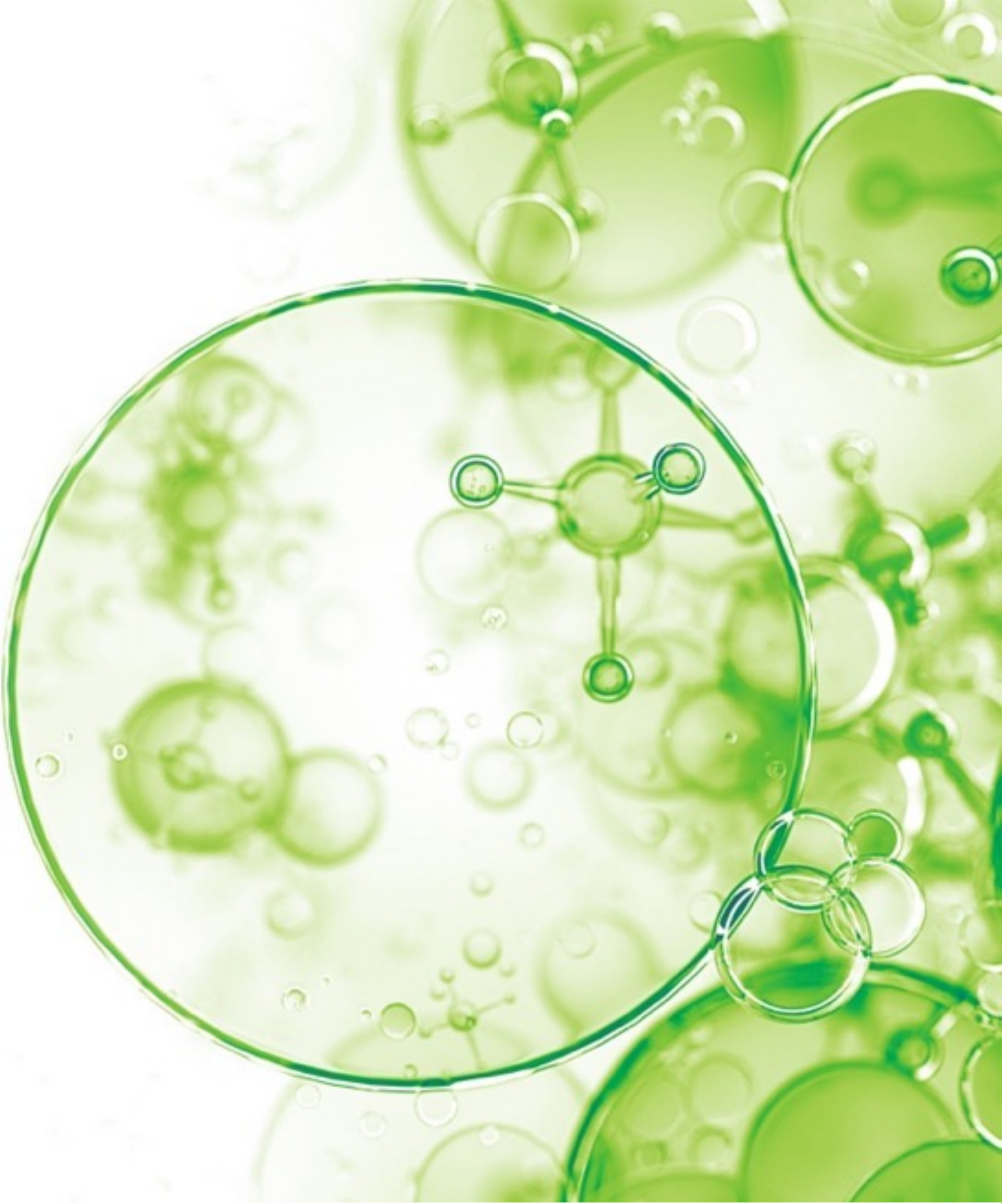
Real world applications: the story of oncology generic medicine launched in 2013



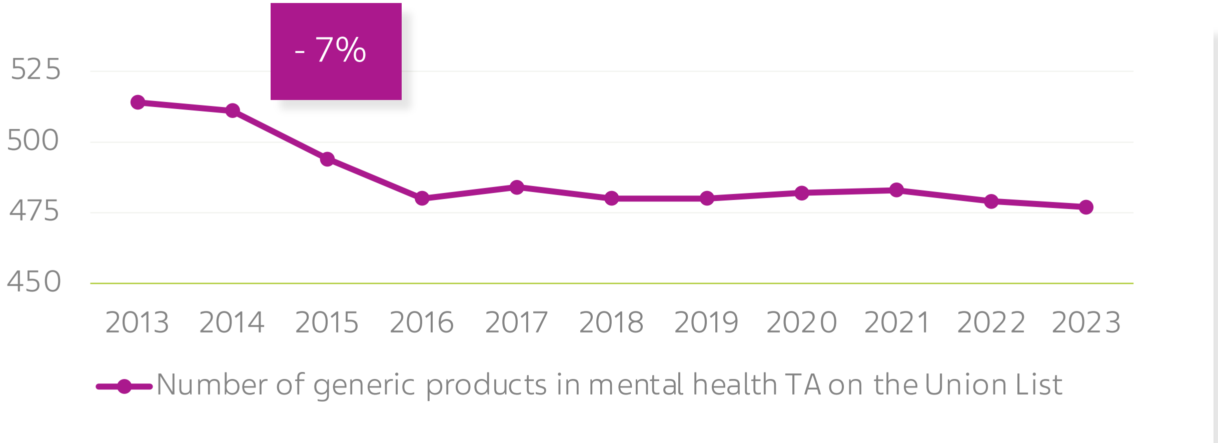
Once the growth peaks three to four years after the initial introduction of the treatment to the generic market in Europe, a wave of withdrawals leads to a consolidation of the product segment.

 Based on internal analysis by Teva using data from the following source: IQVIA MIDAS® Quarterly sales data released Q3 2023, Measure: count of products with sales of >0 standard unit, Time Period: MAT Q2 2013-Q2 2023, reflecting estimates of real-world activity.

Is the generics dynamic currently able to support the Union List of Critical Medicines?

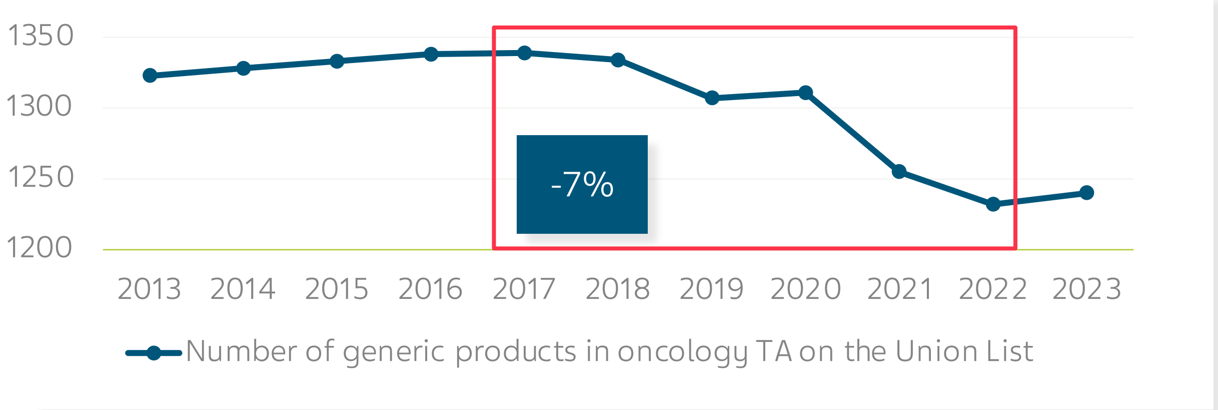


Generic medicines for mental health and cancer on the Union List are disappearing



Mental health TA is defined in this analysis as medicines belonging to ATC classes N05A, N05B and N06A

- In the case of the **mental health treatments** (6 different molecules) we observe that **7% of products disappeared** over the last 10 years.



Oncology TA is defined in this analysis as medicines belonging to ATC classes L01 and L02“

- In the case of **oncology treatments** (31 different molecules) we observe that 50% of the treatments declined. In six years, **7% of the products disappeared.**

 Based on internal analysis by Teva using data from the following source: IQVIA MIDAS® Quarterly sales data released Q3 2023, Measure: count of products with sales of >0 standard unit, Time Period: MAT Q2 2013-Q2 2023, reflecting estimates of real-world activity.

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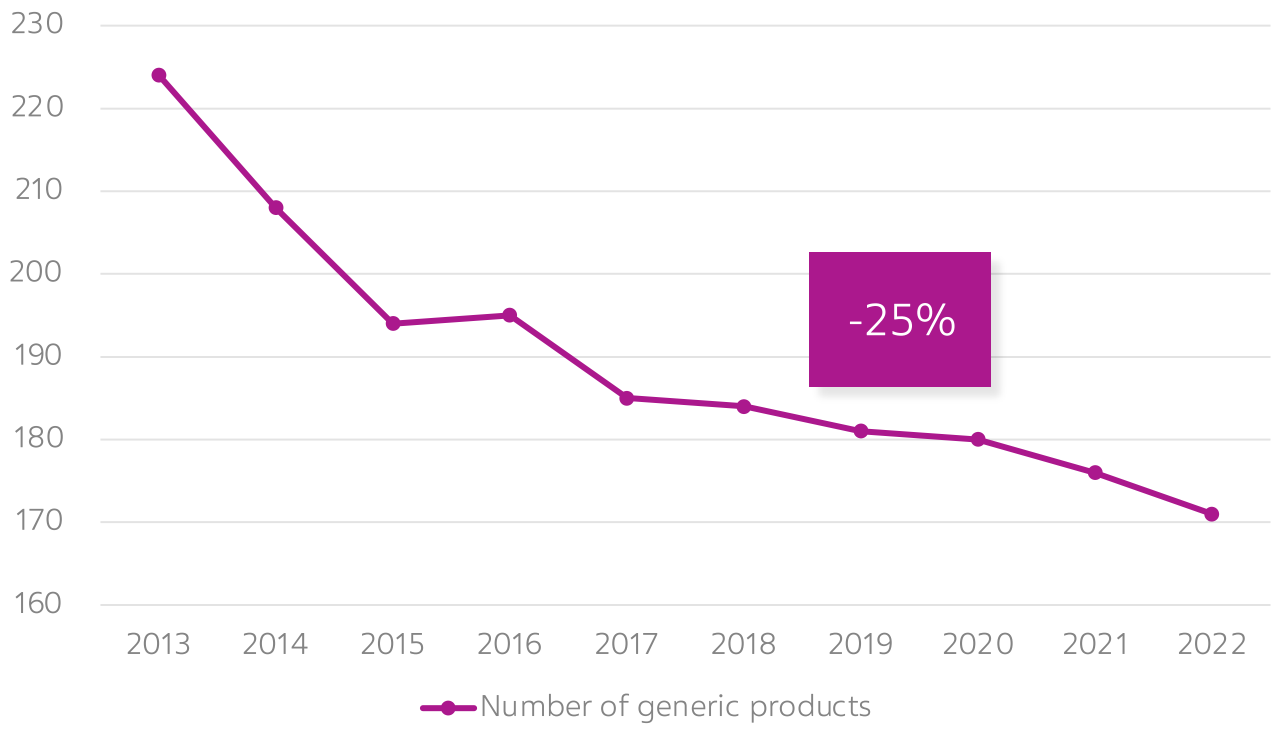
The case of a generic product for the treatment of schizophrenia and bipolar disorder



- The number of products with this medicine have steadily declined since 2013 (-25%).

Based on internal analysis by Teva using data from the following source: IQVIA MIDAS® Quarterly sales data released Q3 2023, Measure: count of products with sales of >0 standard unit, Time Period: MAT Q2 2013-Q2 2023, reflecting estimates of real-world activity.

The case of a generic product for the treatment of schizophrenia and bipolar disorder

	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2023 vs. 2013 %
AT	9	10	10	10	10	9	9	10	10	9	9	0%
BG	12	13	9	8	7	4	4	4	5	5	5	-58%
HR	7	7	7	7	6	6	6	6	6	6	5	-29%
CZ	19	17	15	13	13	12	11	12	12	13	10	-47%
DK	9	7	5	6	7	8	8	7	6	8	7	-22%
FI	11	9	7	8	7	6	6	6	6	6	6	-45%
FR	14	16	17	17	16	14	14	14	14	14	14	0%
DE	19	20	19	18	19	17	17	17	16	15	15	-21%
HU	18	13	11	7	7	5	4	4	3	2	3	-83%
IT	13	13	14	13	15	15	14	14	14	14	13	0%
NL	9	9	8	8	7	6	5	5	6	6	6	-33%
PL	22	20	17	16	16	17	17	16	16	16	16	-27%
PT	13	15	14	15	15	16	15	16	15	15	14	8%
ES	23	24	24	22	23	25	25	23	25	23	23	0%
SE	12	12	11	8	8	8	9	8	8	8	8	-33%
CH	5	5	5	5	5	5	5	5	5	5	5	0%
UK	14	14	15	13	14	12	15	14	13	11	12	-14%
TOTAL	**229**	**224**	**208**	**194**	**195**	**185**	**184**	**181**	**180**	**176**	**171**	-25%

- In **11 out of 15** countries, the number of generic products declined.
- Hungary **(-83%)** and Bulgaria **(-58%)** recorded the biggest loss in the number of generic medicines.

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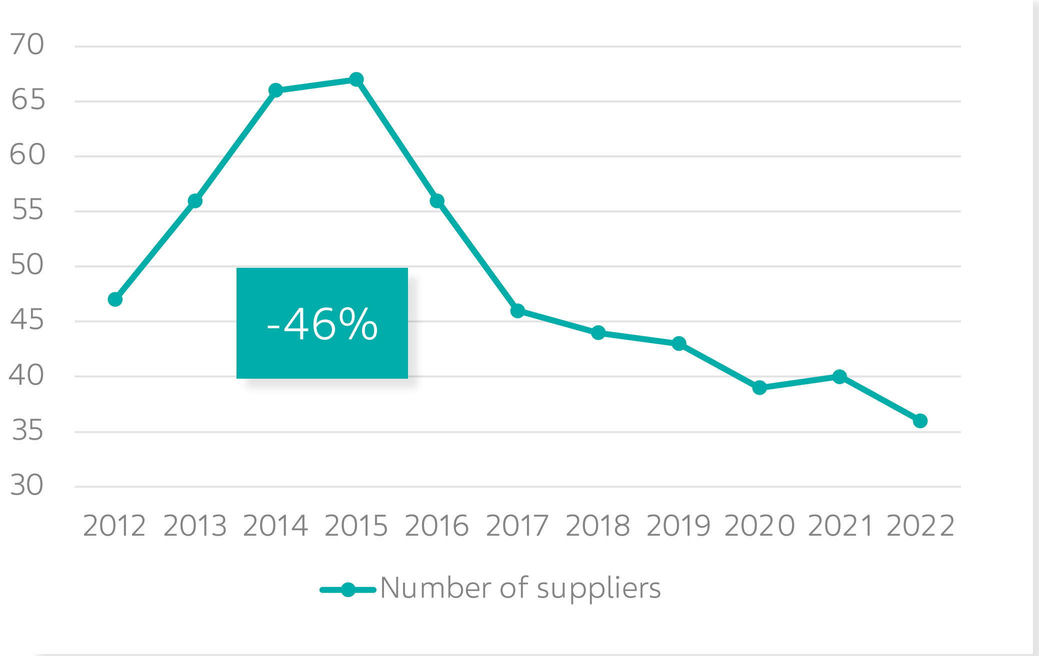
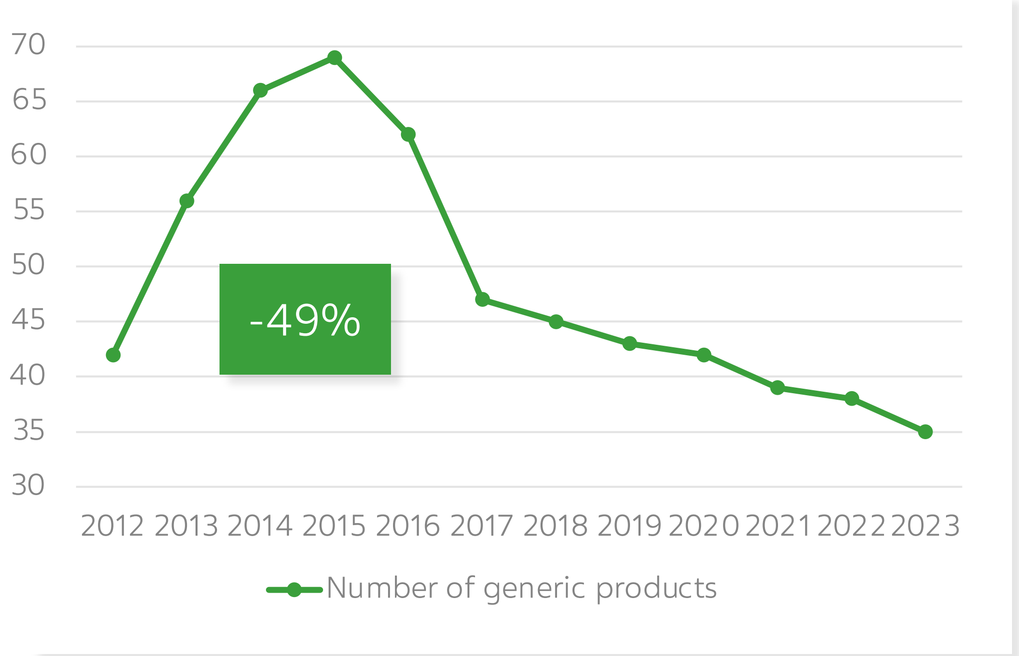
We already demonstrated the relationship between product withdrawals and supplier disappearance



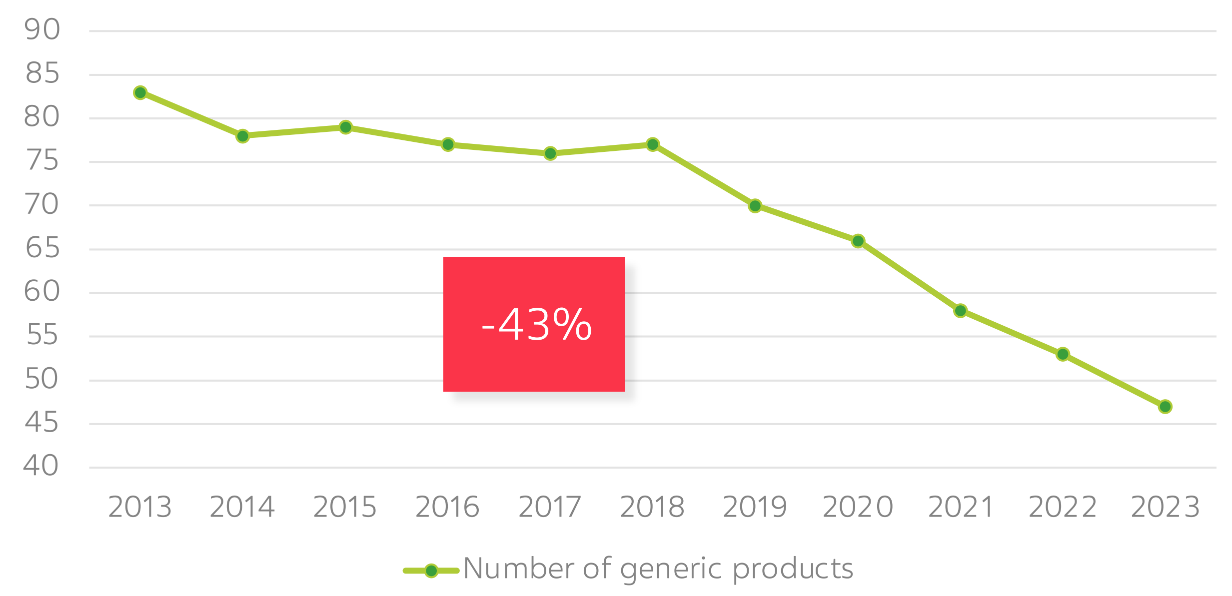


- In Teva's previous analysis "The case of Europe's disappearing medicine cabinet", we demonstrated that one generic oncology medicine had **lost 46% of its suppliers**.

- We can observe the same trend in the number of generic products available, which **decreased by 49%** since 2015.

 Based on internal analysis by Teva using data from the following source: IQVIA MIDAS® Quarterly sales data released Q3 2023, Measure: count of products with sales of >0 standard unit, Time Period: MAT Q2 2012-Q2 2023, reflecting estimates of real-world activity.

Evolution of a generic oncology product to treat breast cancer



- The medicine selected for this case study has seen **a steady decline (-43%).**
- **Since 2018 the decline accelerated**, whilst **39% of products left the product segment**.

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Evolution of a generic oncology product to treat breast cancer

	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2023 vs. 2013
AT	4	4	4	3	3	3	1	2	1	1	1	-75%
BG	2	1	2	2	2	2	2	2	2	2	2	0%
HR				1	1	1	2	2	1	1	1	-50%
CZ	4	3	3	3	3	3	3	3	2	2	2	-50%
DK	2	1	1	1	1	2	2	2	2			-100%
FI	3	3	3	3	3	3	3	3	3	3	2	-33%
FR	8	8	9	9	8	8	6	7	6	7	7	-13%
DE	19	21	21	21	20	19	17	13	11	8	8	-58%
HU	4	3	3	3	3	3	2	2	3	3	3	-25%
IT	5	4	5	4	3	4	3	2	3	3	3	-40%
NL	4	3	3	3	2	2	2	2	2	2	2	-50%
PL	4	4	4	4	4	4	3	2	2	2	2	-50%
PT	5	4	5	5	5	5	5	5	4	3	2	-60%
ES	5	6	5	5	6	5	5	4	4	4	4	-20%
SE	4	3	2	3	3	3	3	3	3	3	2	-50%
CH	2	2	2	2	2	2	2	2	2	2	2	0%
UK	8	8	7	5	7	8	9	10	7	7	4	-50%
TOTAL	**83**	**78**	**79**	**77**	**76**	**77**	**70**	**66**	**58**	**53**	**47**	-43%

- **12 out of 15** analysed countries have **3 generic products or less** on the generic market in Europe
- **9 out of 15** analysed countries have **lost at least half of the generic products**
- **Denmark has lost all the generic products**

In most countries, this generic medicine is tendered focusing only on price.

Based on internal analysis by Teva using data from the following source: IQVIA MIDAS® Quarterly sales data released Q3 2023, Measure: count of products with sales of >0 standard unit, Time Period: MAT Q2 2013-Q2 2023, reflecting estimates of real-world activity.

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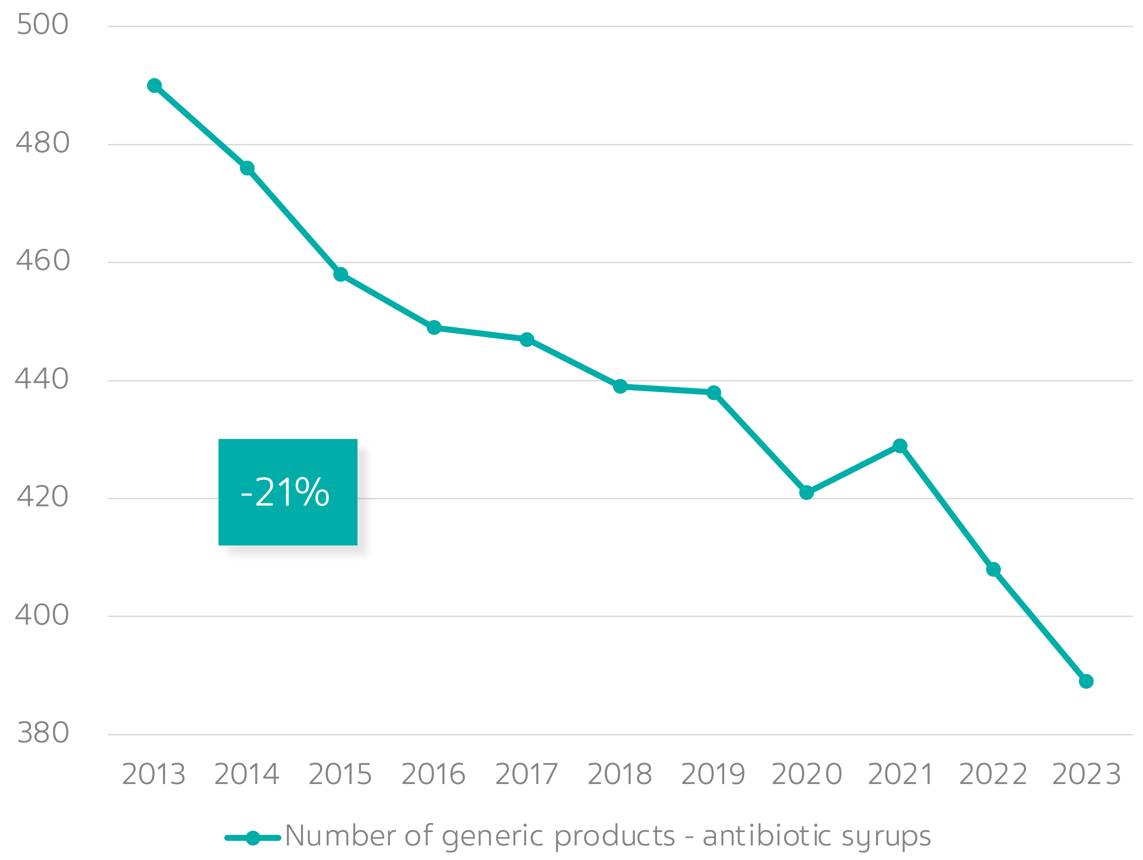
Other generic medicines are also in decline



- The group of oral liquid dosage forms grew steadily until 2018, when the trend **reversed into decline**
- Focusing on a sensitive therapeutic group of antibiotics we see that:
  - Over the last 10 years the number of **withdrawals increased by 38%** and the number of **launches decreased by 5%**
  - This translates to the **loss of 21% of generic oral liquid antibiotic products**

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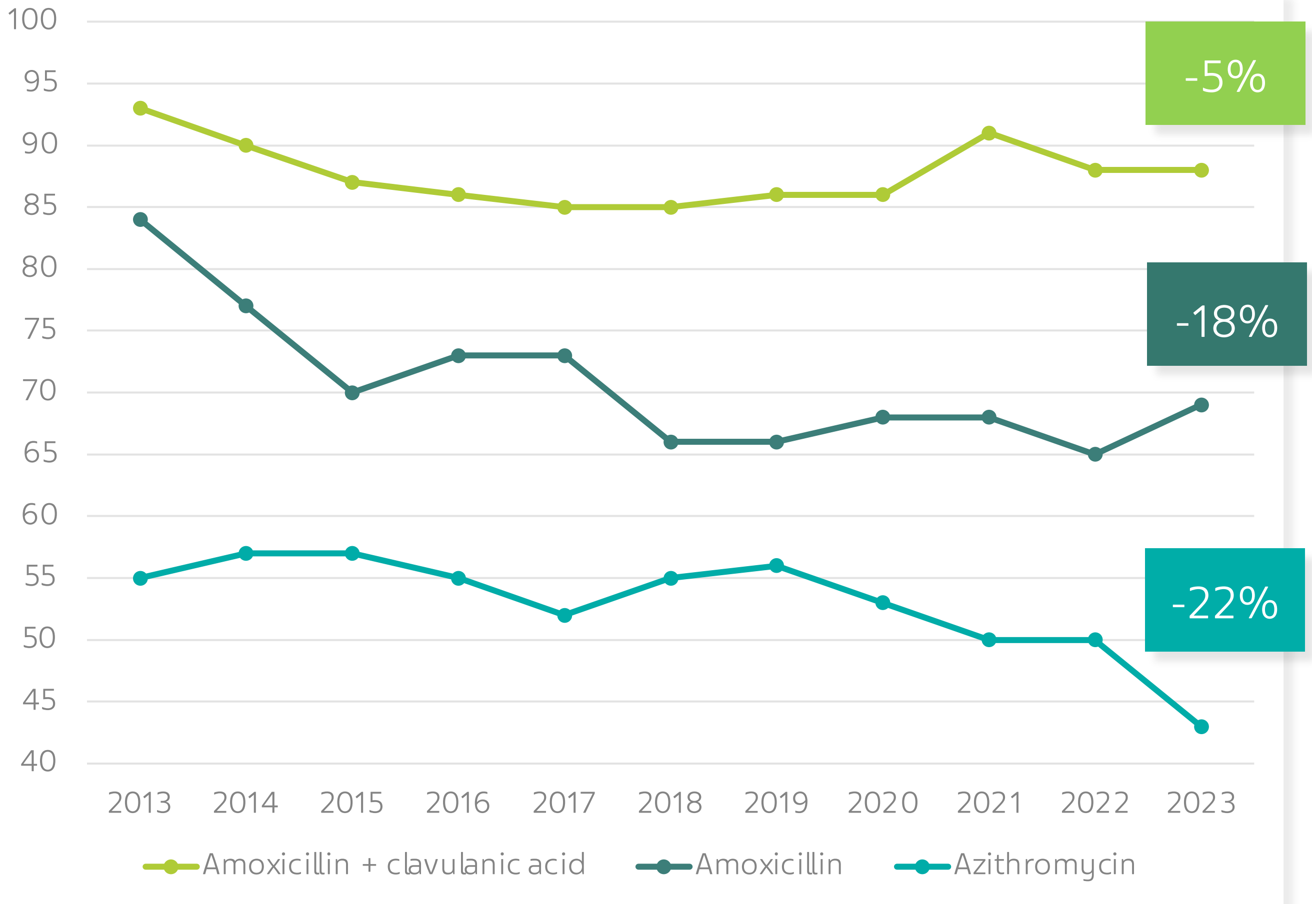
This trend is impacting major generic antibiotic syrups



- Three antibiotics represent more than half of all available antibiotic syrup.
- The three antibiotics have lost 5%, 18% and 22% of the generic products, respectively.

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What is the impact on European patients?

1

- While the number of generics has grown over the years, there is a worrying upward trend in how many of them are discontinued each year.
- We see a gap between launch of new complex generics and withdrawals of mature simple ones.

2

- The generic market in Europe increase comes from complex and hard-to-make generics, notably from innovative medicines which have just lost their exclusivities (patents and other protections).
- However, after only 3 to 4 years we observe the number of generics declining for several reasons, such as the race to the bottom on pricing. This decrease can sometimes reach such levels, that the availability of medicine for patients may be compromised.

3

- Ultimately, this dynamic impacts the products on the Union List of Critical Medicines, notably in areas which have been flagged as key health priorities for Europe such as mental health, cancer and even antibiotics.
- **This has the potential to jeopardize Europe's ambition of supporting its citizens in accessing critical medicines, in areas defined as health priorities.**
  It needs to be addressed.

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What are the solutions?

Teva's recommendation is to develop policies supporting patients' access to medicines

Supporting innovations

Developing a rewarding and ambitious incentive framework, that stimulates the development of new medicines.

Stimulating Access

Warranting legal clarity and predictability for generic medicines developers, to ensure a day-1 launch after the expiry of exclusivity.

Safeguarding essential medicines' sustainability

Introducing multi-criteria, multi-winner tenders and novel pricing practices, while optimizing, simplifying and digitalizing the regulatory framework.

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Contact:

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Methodology

- **Source of data:** IQVIA MIDAS Quarterly Sales Data MAT Q2/2023 combined with secondary desk research
- **Timeframe:** 2012 – 2023
- **Generic competitor population:**
  - Excluding PI competition according to IQVIA-def. „PI“
  - According to IQVIA def. „non-innovative-branded“ & „non-branded“
- **Selected products population:**
  - „launches“: positive sales in one year compared to the previous year
  - „discontinuations“: no sales in one year but in the previous year positive sales
  - The number of products:
    - # count (INN_NFC1*#of competitors*in each market)
  - Critical medicines: as presented in the EMA Union List of Critical Medicines in Decemeber 2023 (available here)

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

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