



Global perspectives on Generics and Biosimilars for IGBA

Presented by:
Doug Long, VP, Industry Relations

February 14th, 2022

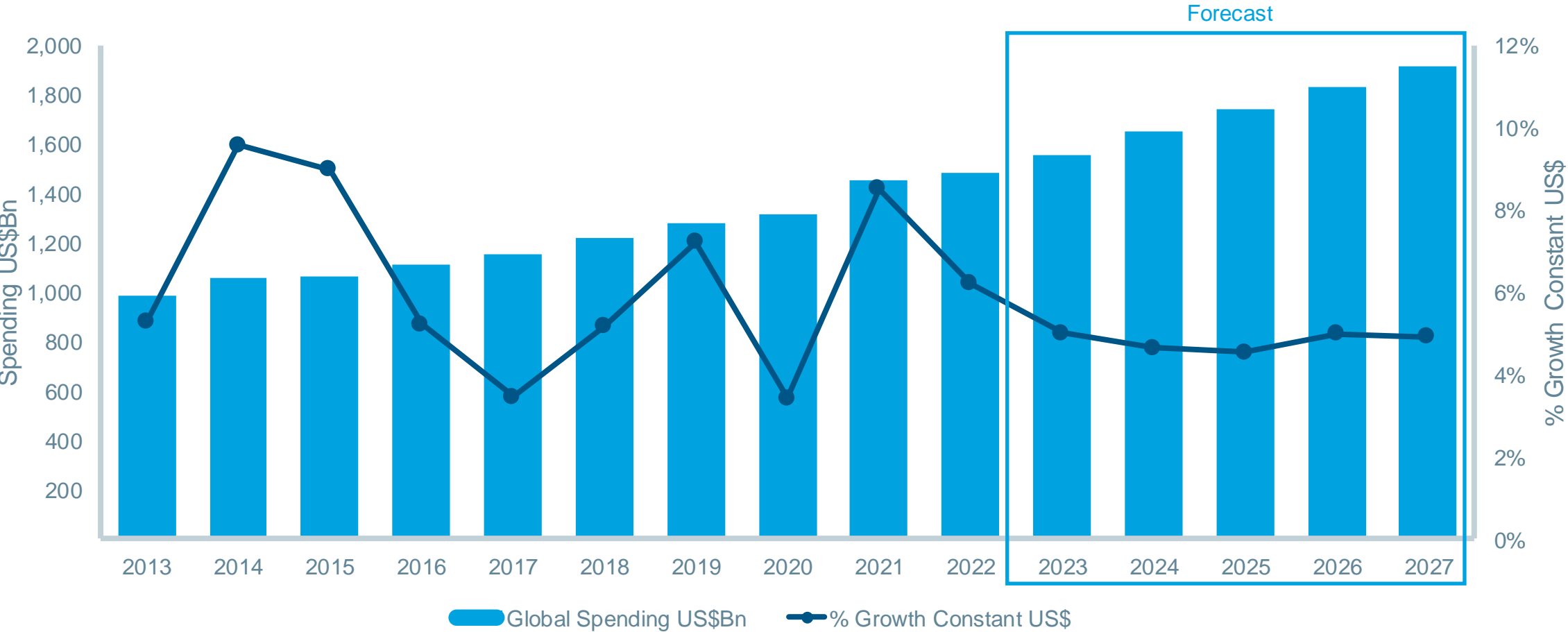


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- + Section II: Global generics market
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- + Section IV: Top 10 corporations by unit and dollar value
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The global medicine market — using invoice price levels — is expected to grow at 3–6% CAGR through 2027 to about \$1.9Tn

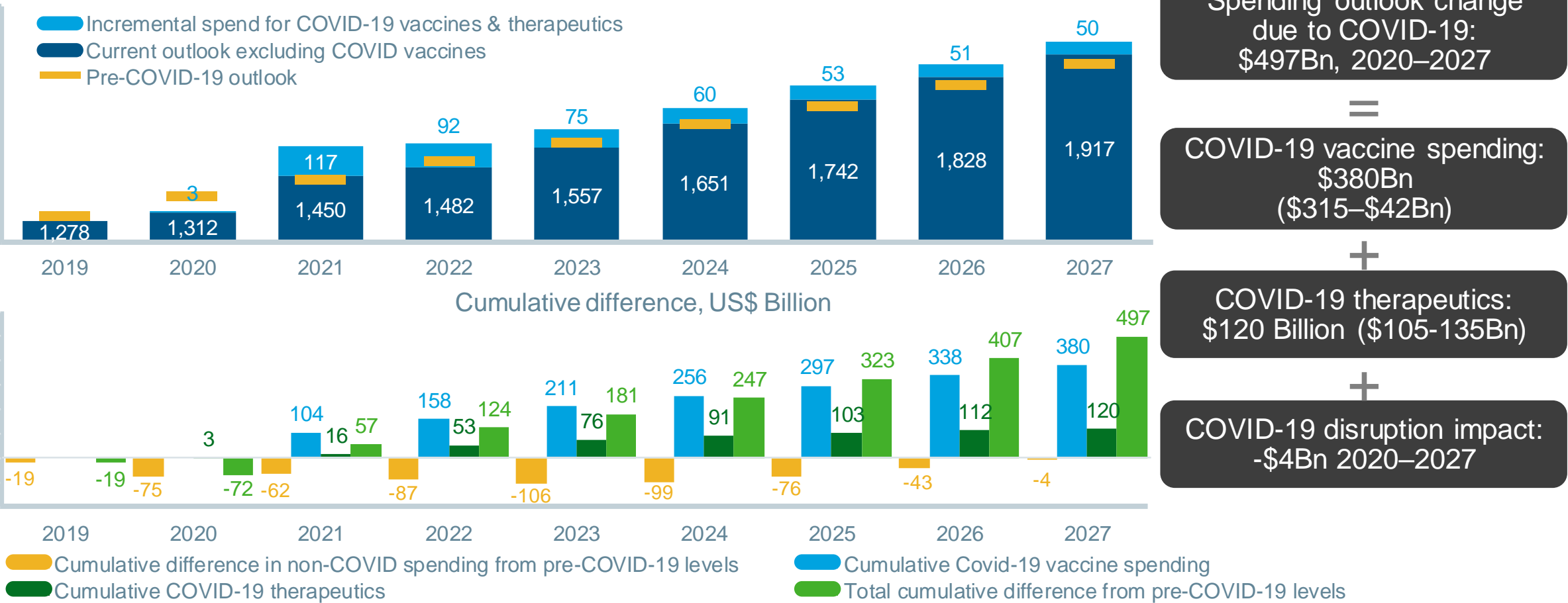
Global medicine market size and growth 2013–2027



Source: IQVIA Market Prognosis, Sep 2022; IQVIA Institute, Nov 2022.
The Global Use of Medicines 2023: Outlook to 2027. Report by the IQVIA Institute for Human Data Science.

Global spending, including COVID-19 vaccines and therapeutics, to exceed pre-pandemic outlook by \$497Bn to 2027

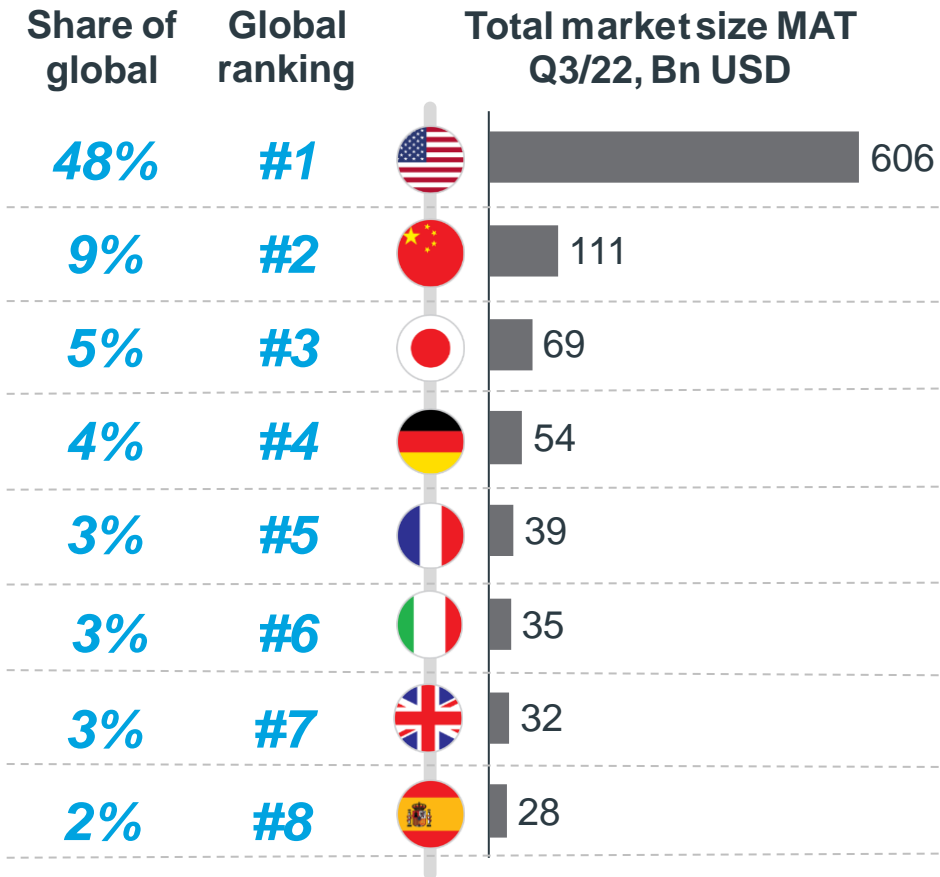
Changes in the historical and projected global medicine spending model due to COVID-19, 2019–2027, US\$Bn



Source: IQVIA Market Prognosis, Sep 2022; IQVIA Institute, Nov 2022.
The Global Use of Medicines 2023: Outlook to 2027. Report by the IQVIA Institute for Human Data Science.

Budget constraints and cost containment measures will shape the global market but are good news of off-patent players

Pricing measures in the Top 8 markets, 77% of global value



(1) SHI Finance Stabilization Act (2) Social Security Finance Bill

Source: IQVIA Thought Leadership, IQVIA Market Prognosis September 2022, MIDAS QTR MAT Q3 2022, Market size listed in USD

Source: IQVIA EMEA Thought Leadership, MIDAS QTR MAT Q3 2022, Market size listed in USD



USA

Inflation Reduction Act (IRA)

- Medicare Part D redesign will shift liabilities to payers which in turn will increase pricing pressure on manufacturers
- Pricing negotiations with Medicare for selected drugs
- From 2025 / 2026 onwards



China

- Pricing pressure from Volume Based Procurement and the National Drug Reimbursement List
- Increasing local competition



Japan

- NHI drug pricing reform implements tougher pricing rules
- From 2022 onwards



Germany

GKVFinStG¹

- Price freeze maintained until 2026
- mandatory rebate increased from 7% to 12%
- free-pricing period reduced to 6 months
- From Jan 2023



France

- PLFSS² 2023 – setting growth of Rx products to 2.4% in '22-'24
- €1.1Bn savings - €900Mn from price cuts and €200Mn from payback scheme



UK

- Voluntary Pricing and Access Scheme (VPAS) potentially requires **>26% payment rebates**
- 2023 onwards



Spain

- Lowest access to innovative medicines across EU4+UK markets
- **2023 elections** creating uncertainty and risk



Italy

- Healthcare expenditure as % of GDP to **fall from 7% in 2022 to 6% in 2025**
- Cost containment remains a priority

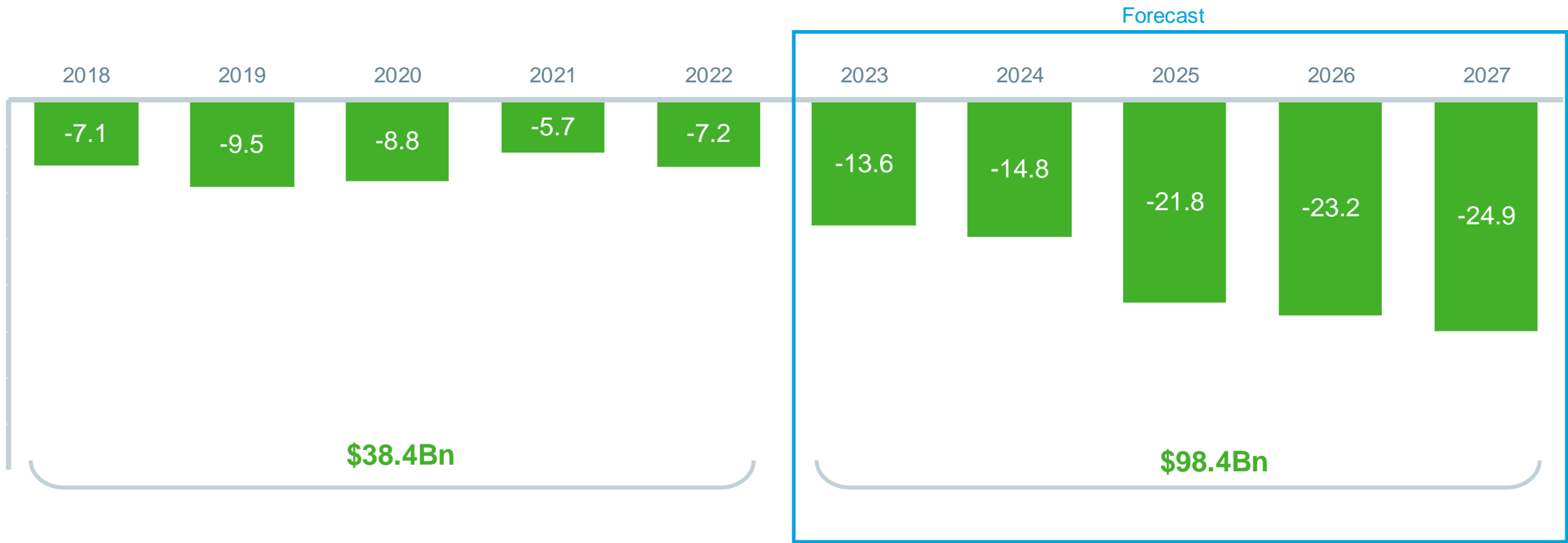


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In the US, the impact of exclusivity losses for small molecules will increase to \$98.4bn over 5 years

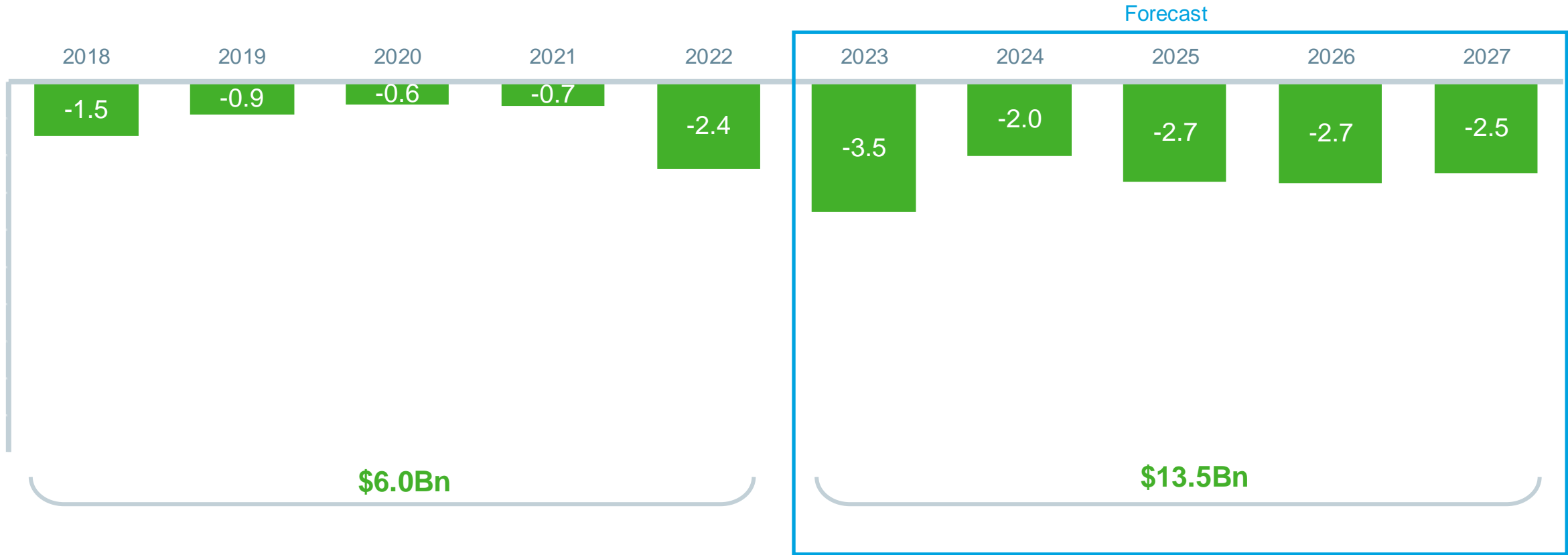
U.S. impact of brand losses of exclusivity 2018–2027, US\$Bn



Source: IQVIA Market Prognosis, Sep 2022; IQVIA Institute, Nov 2022.
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In Europe, the impact of exclusivity losses for small molecules will reach \$13.5bn over 5 years

EU4+UK impact of brand losses of exclusivity 2018–2027, US\$Bn

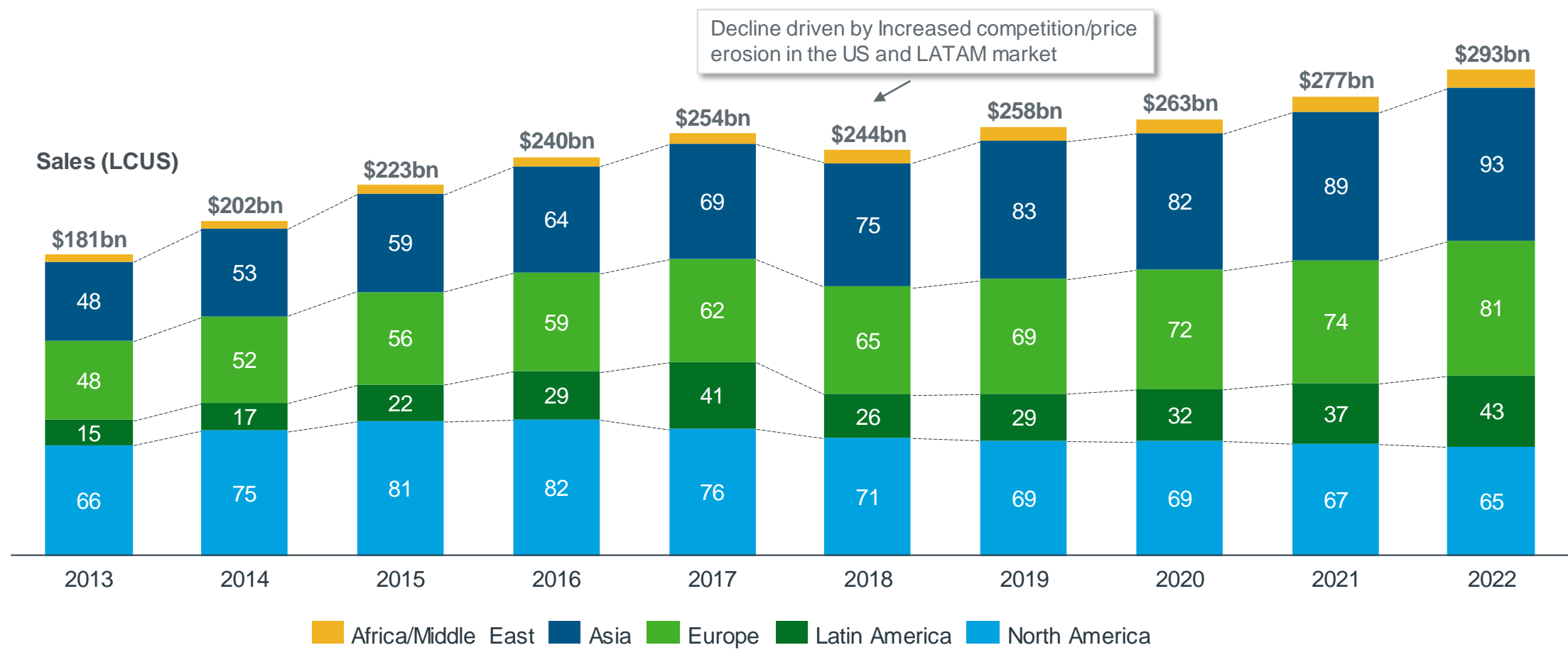


Source: IQVIA Market Prognosis, Sep 2022; IQVIA Institute, Nov 2022.
The Global Use of Medicines 2023: Outlook to 2027. Report by the IQVIA Institute for Human Data Science.



Global generic sales continued to grow in 2022, yet they decelerated in North America

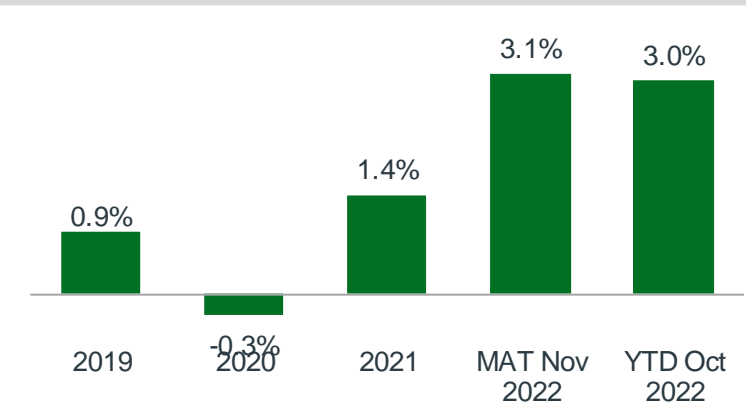
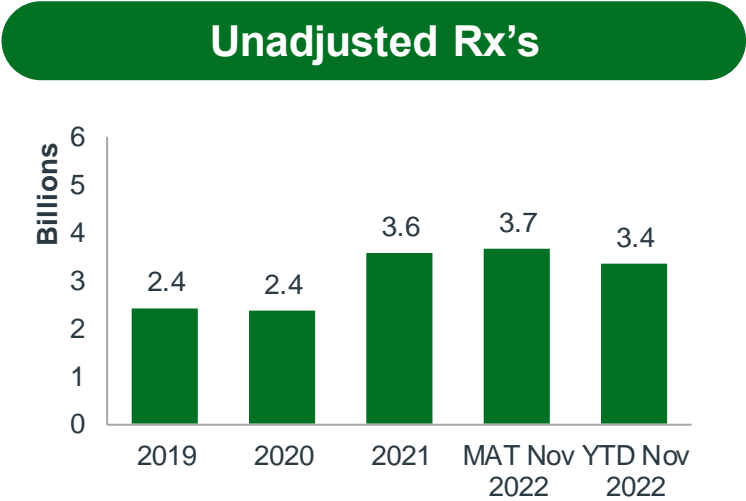
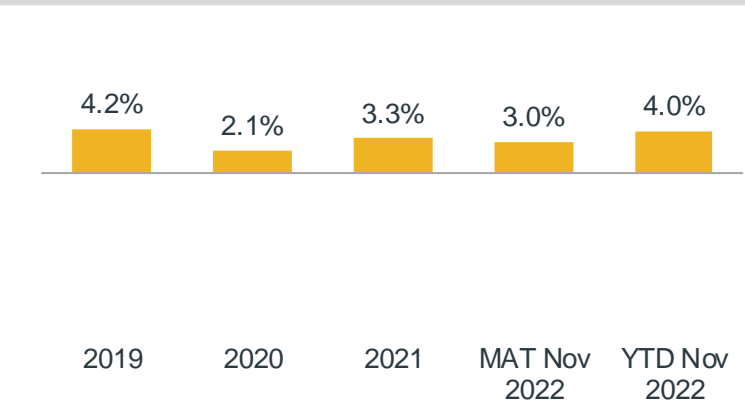
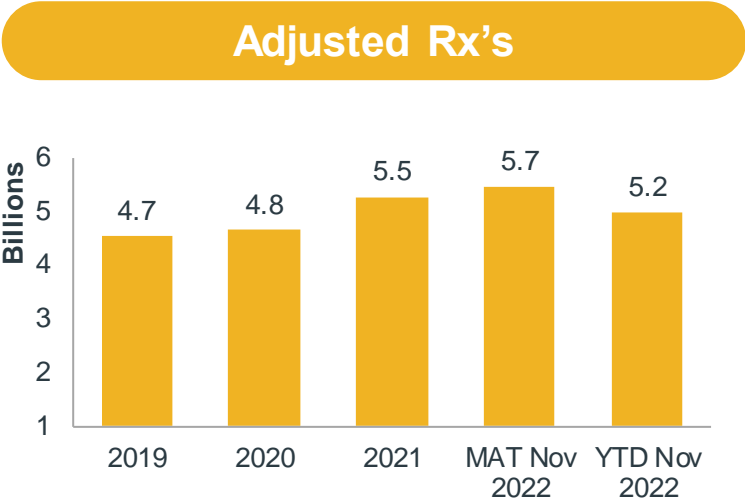
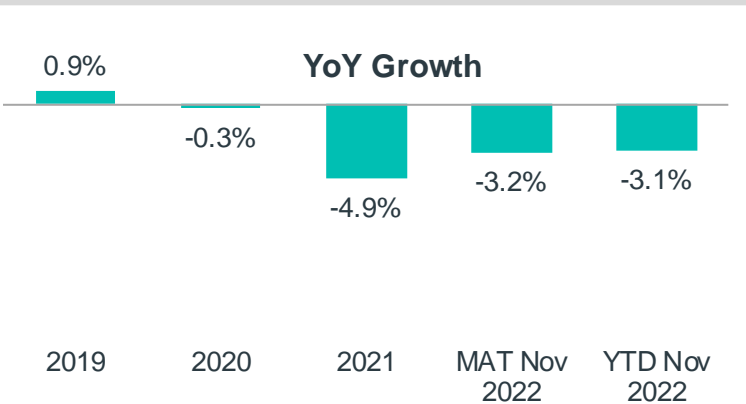
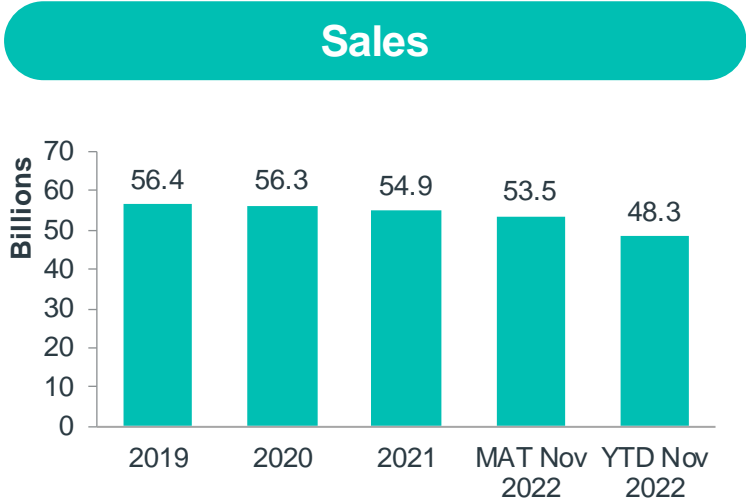
Strong sales are driven by consistent YoY growth in the APAC market



Source: IQVIA GS&AR; IQVIA, MIDAS MAT Q3 2022; Retail and Hospital; Generics Product Class: Generics + Early Entry Generics

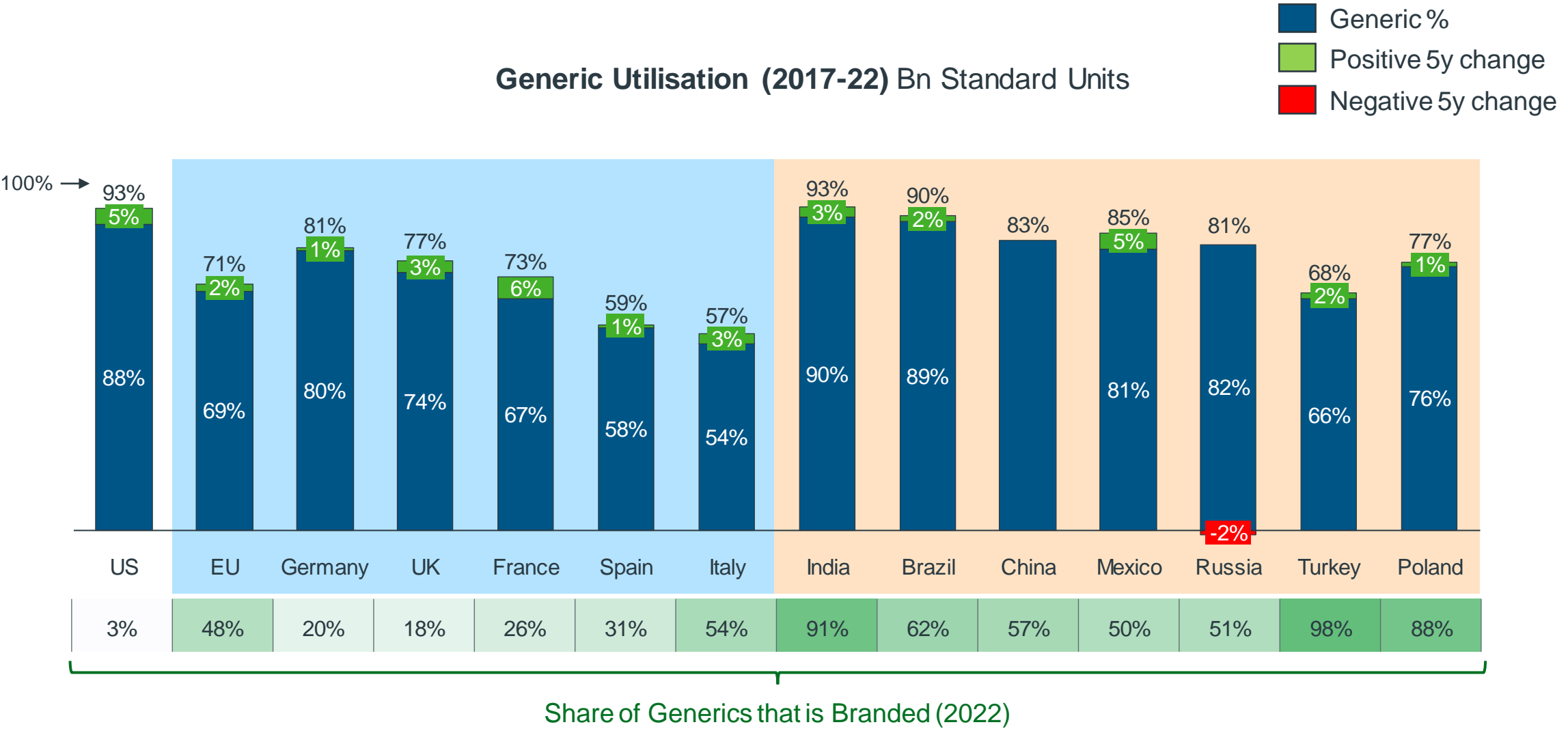
Unbranded Generics sales in the US are negative by Rx's are positive

Unbranded Generics



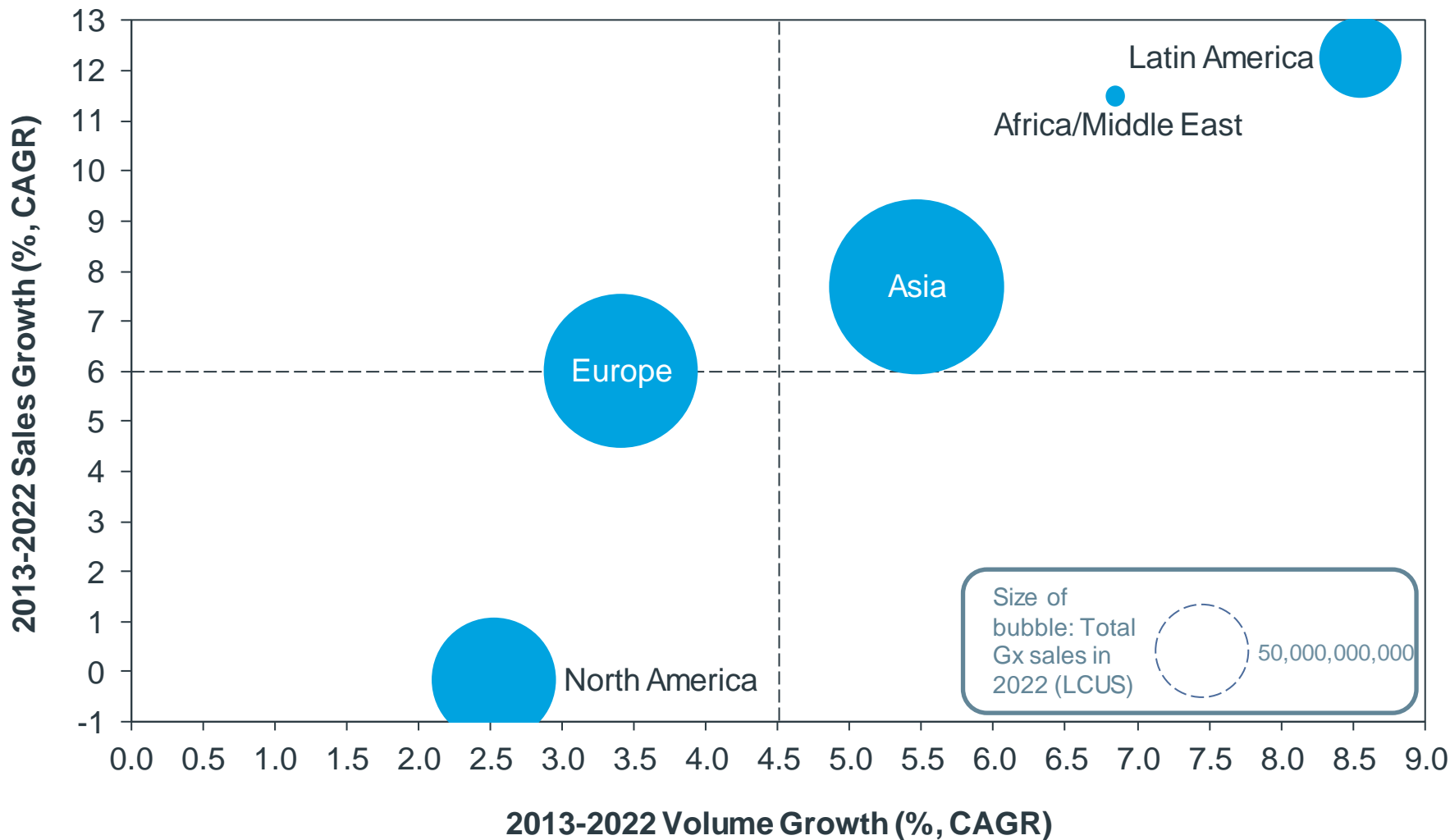
Source: IQVIA, National Sales Perspectives and RxInsights, 2022
Note: Limited to Rx and OTC Insulins; Includes Retail, Non-Retail and Mail

Generic utilisation increased across most major markets, and there are still opportunities for further action in Europe



Notes: Includes Biologics; Excluding Kanpo+TCM, Imaging agents, Hospital Solns., Vx and other non-therapeutics
Source: IQVIA European Thought Leadership; IQVIA MIDAS MAT Q2 2022; Rx only; Innovation Insights, generics defined as Unbranded+Non-original Branded

Latin America, Asia and Africa/Middle East Generic Sales have grown at the fastest rate between 2013-2022



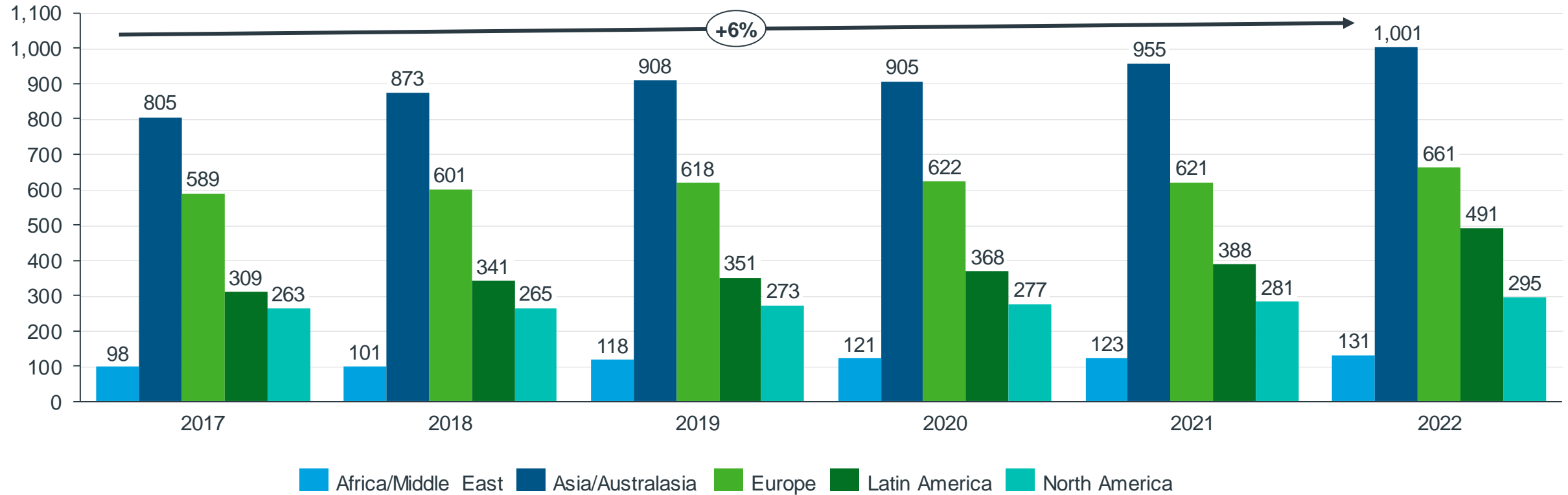
Key Insights

- North America represents a shrinking share of the Gx market, due to rising competition and downward pricing pressures
- Demand shift from brand to generics is fueling growth in the Latin American and Asian market
- Volume and sales growth in Africa/Middle East was second only to Latin America, with a CAGR of 7% and 11%, respectively

Asia dominates in generics unit volume; total generics unit growth reached 6% CAGR in 2022

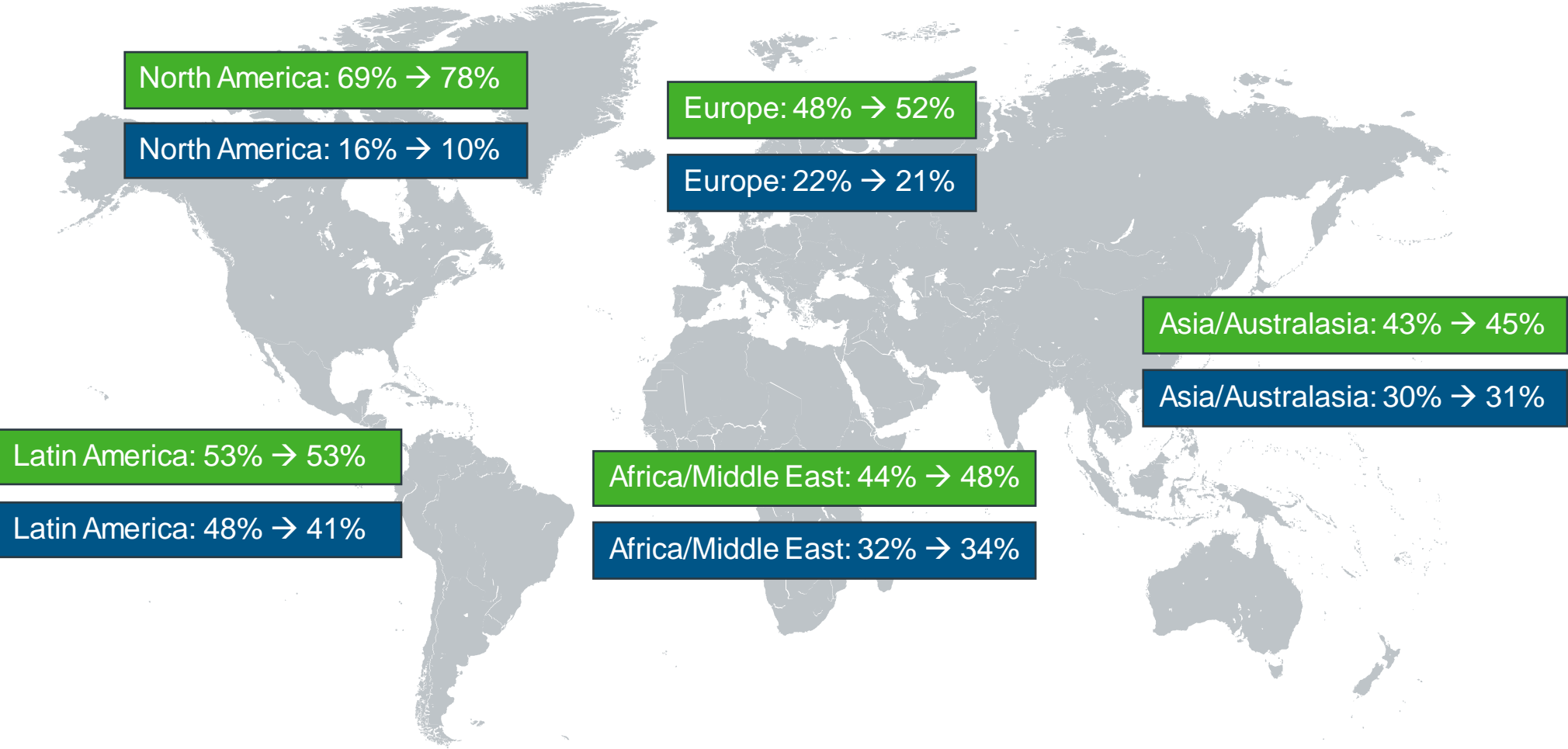


SU, millions



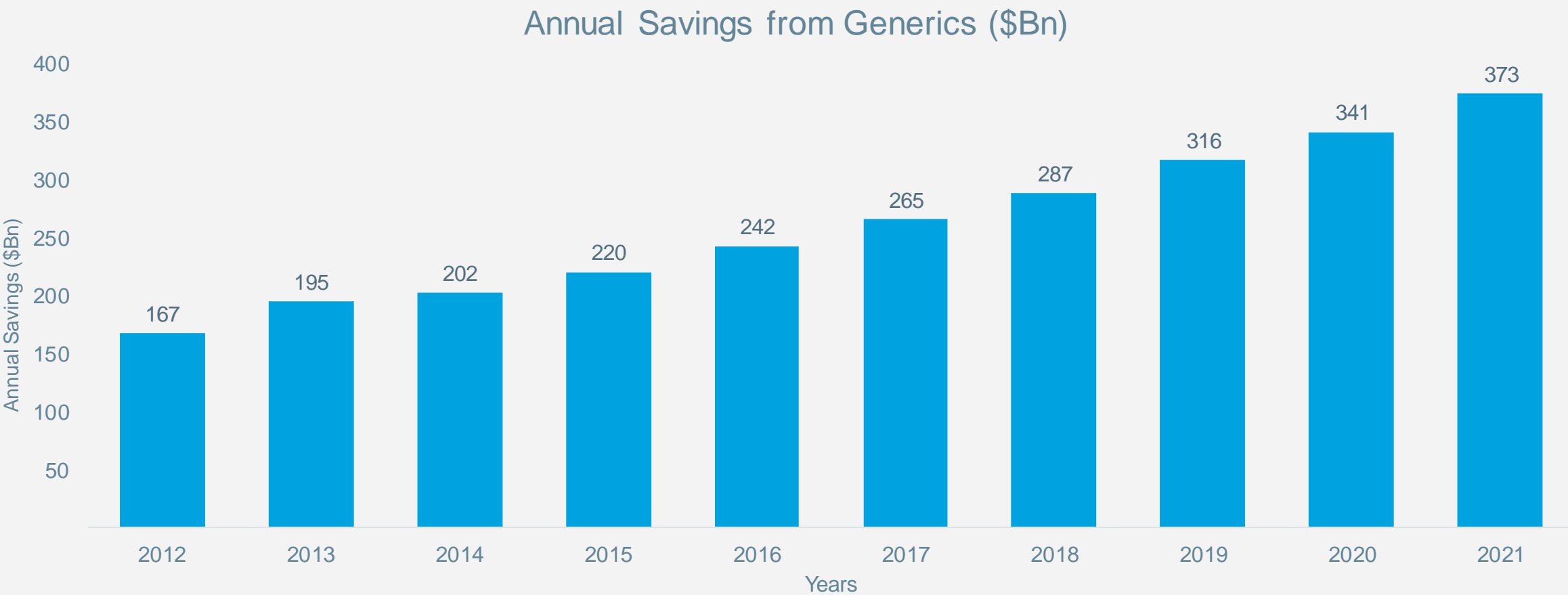
Generics have increased unit, but not value, market share

Generics market share (LCUS, Units), 2017 vs 2022



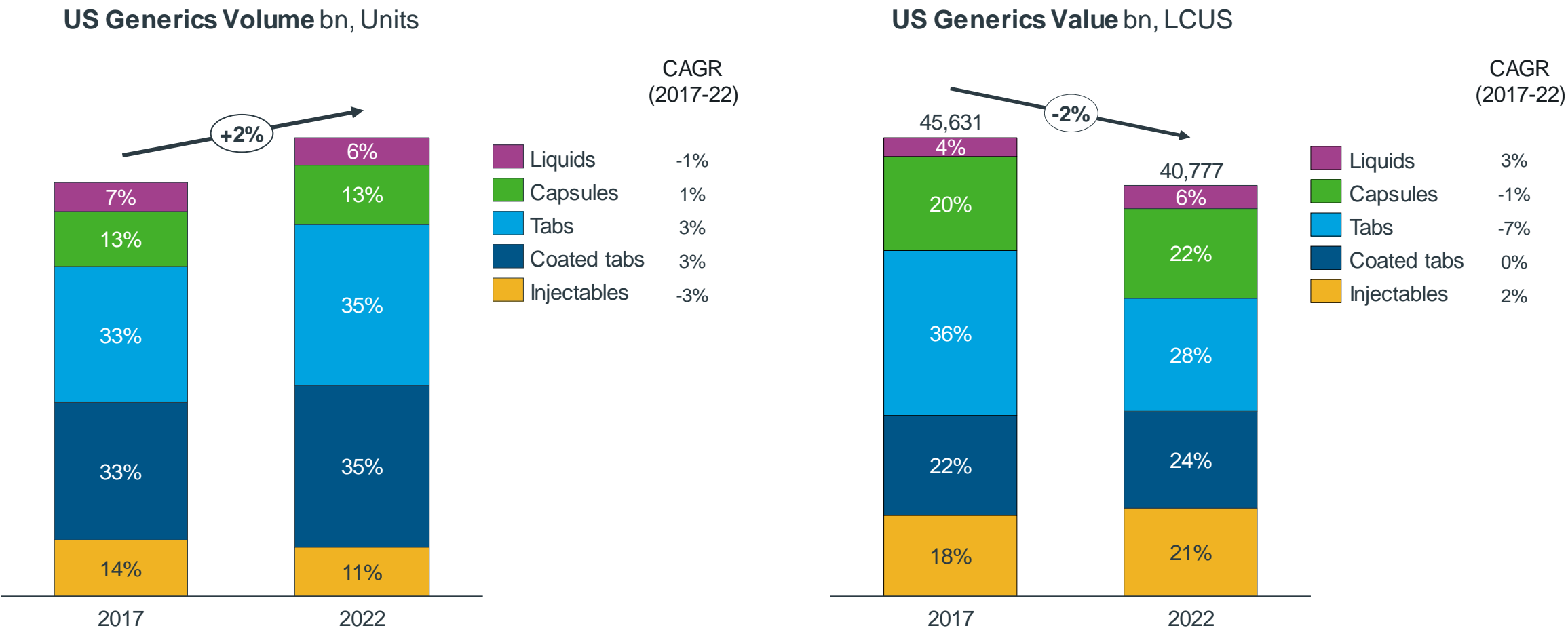
The U.S. healthcare system has saved over \$2.6 trillion in the last ten years due to the availability of low-cost generics

Savings = (Value of generics at pre-expiry brand prices) – (Actual Generic sales)



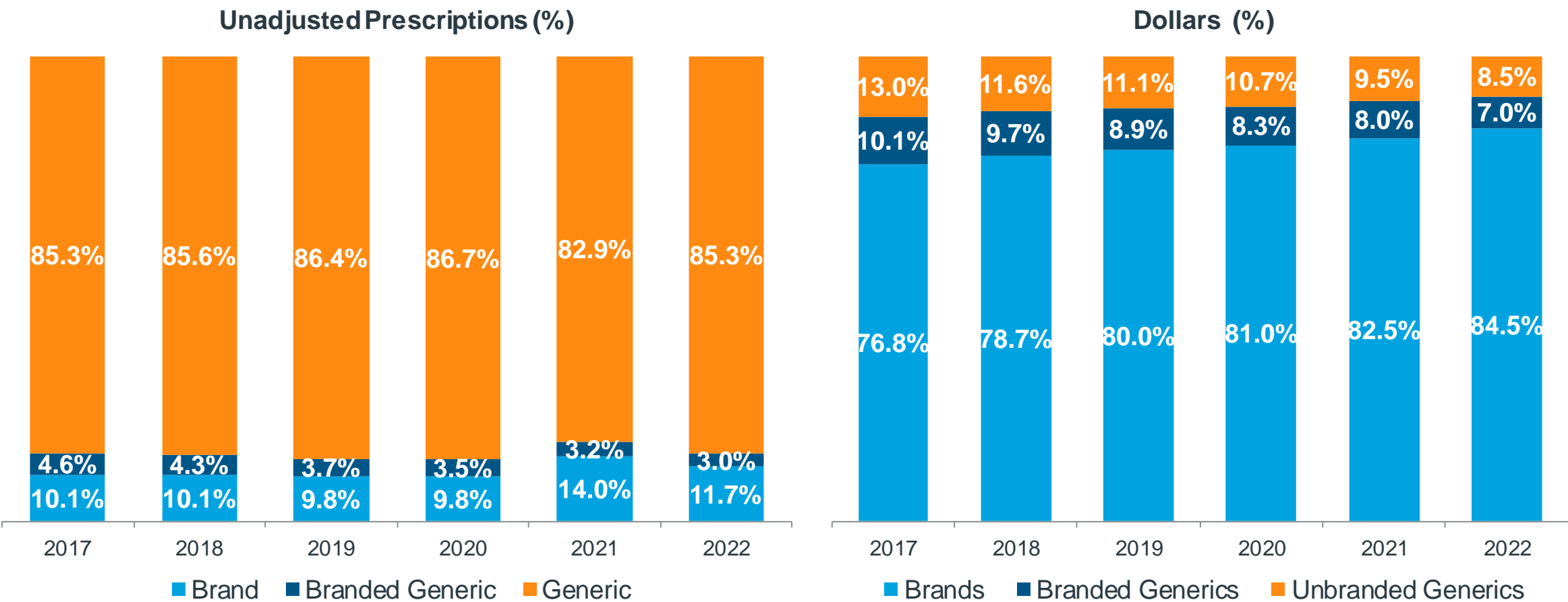
Most Gx volume still in oral solid – 2/3 of volume comes from tablets and capsules

Going forward, value growth increasingly dependent on special delivery systems



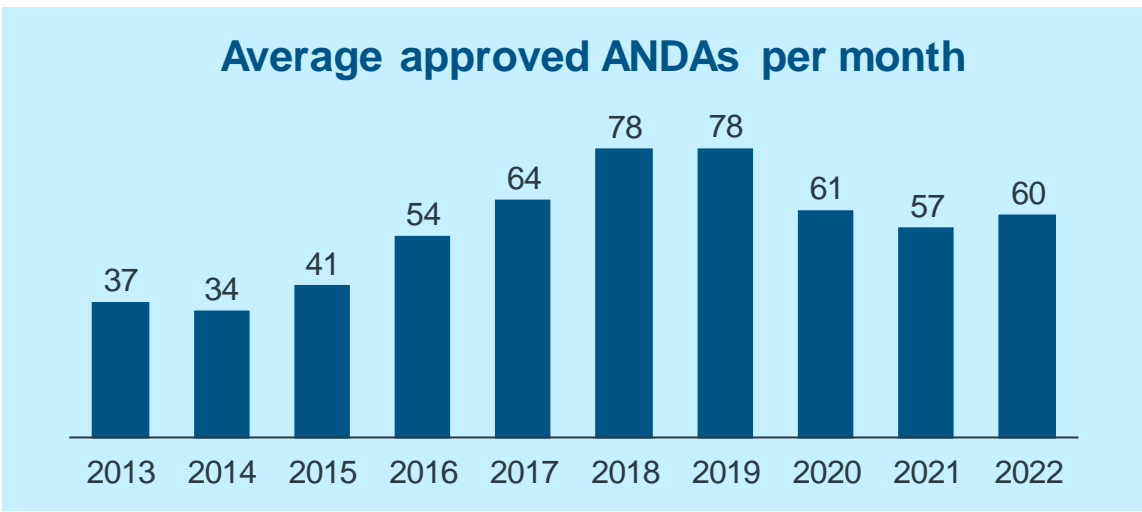
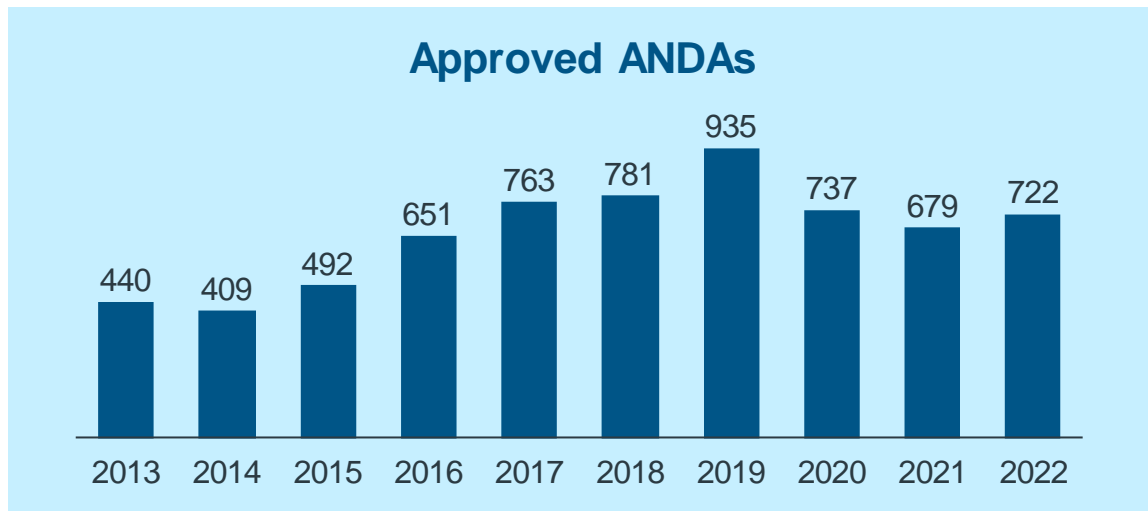
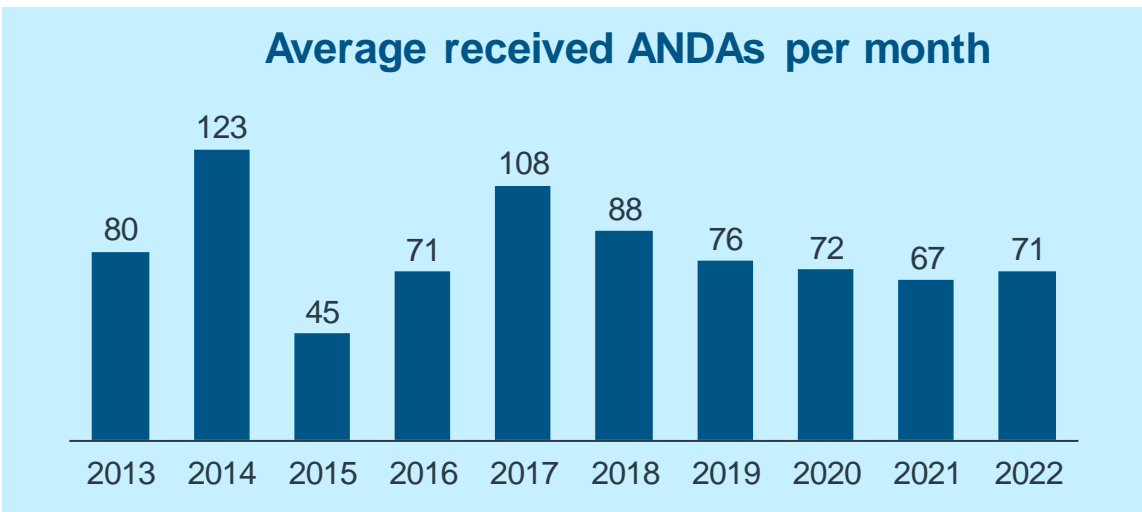
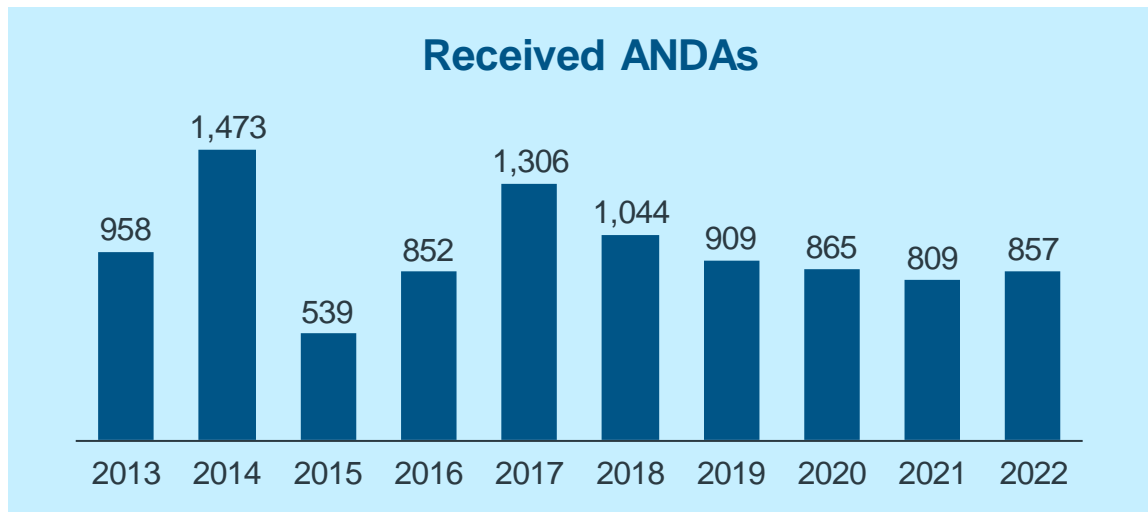
Notes: Excluding Hospital Solutions, Non-therapeutics, Diagnostics, Imaging agents,
Source: IQVIA GS&AR, IQVIA MIDAS MAT Q3 2022; Rx only; NFC123 used for segmentation; Innovation insights

85.3% of prescriptions in the US are dispensed as unbranded generics for 2022 (unadjusted)



ANDA approvals in the US decelerated after COVID-19 but started to increase again in 2022

FDA Fiscal Year Basis

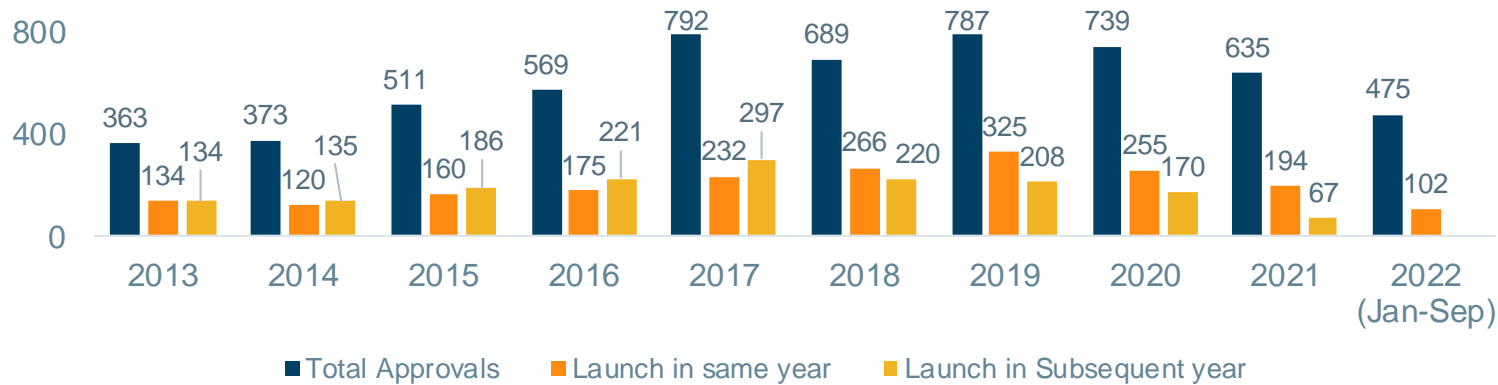


Source: GDUFA approvals, Jan 2023

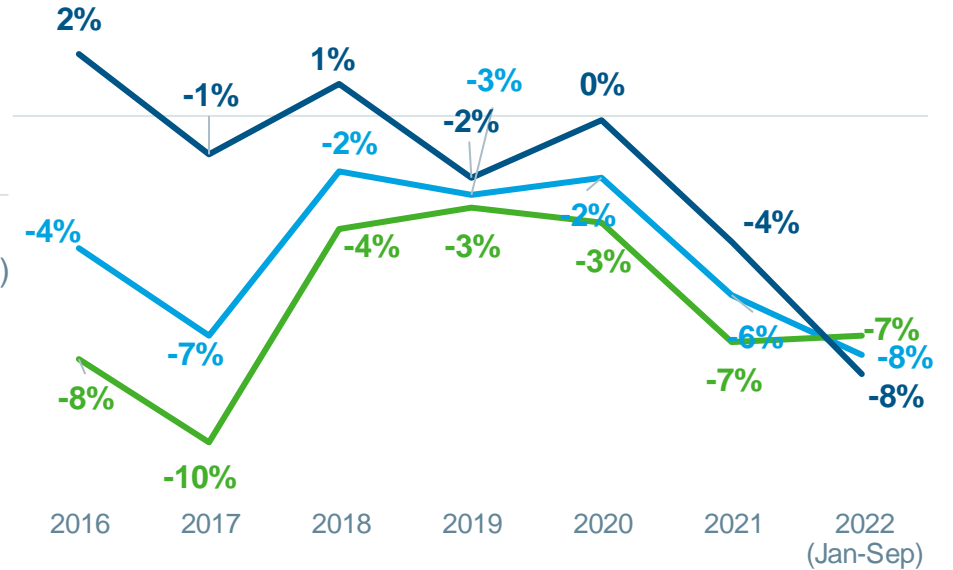
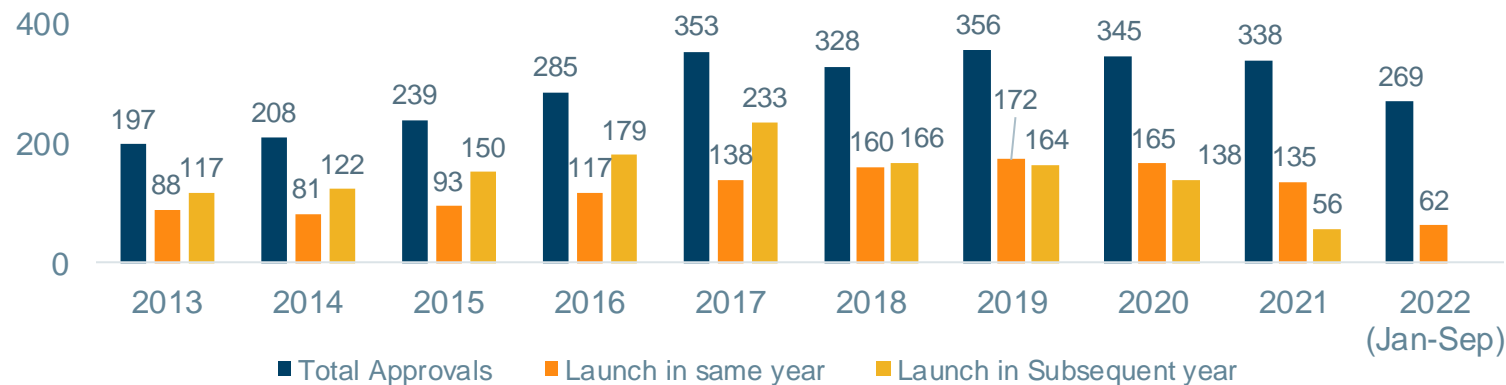
The number of new generic approvals has increased dramatically, contributing to price deflation, but not all approved drugs are launched

Generics Approvals and launches between 2013 and 2022

Total ANDA approvals and Launch



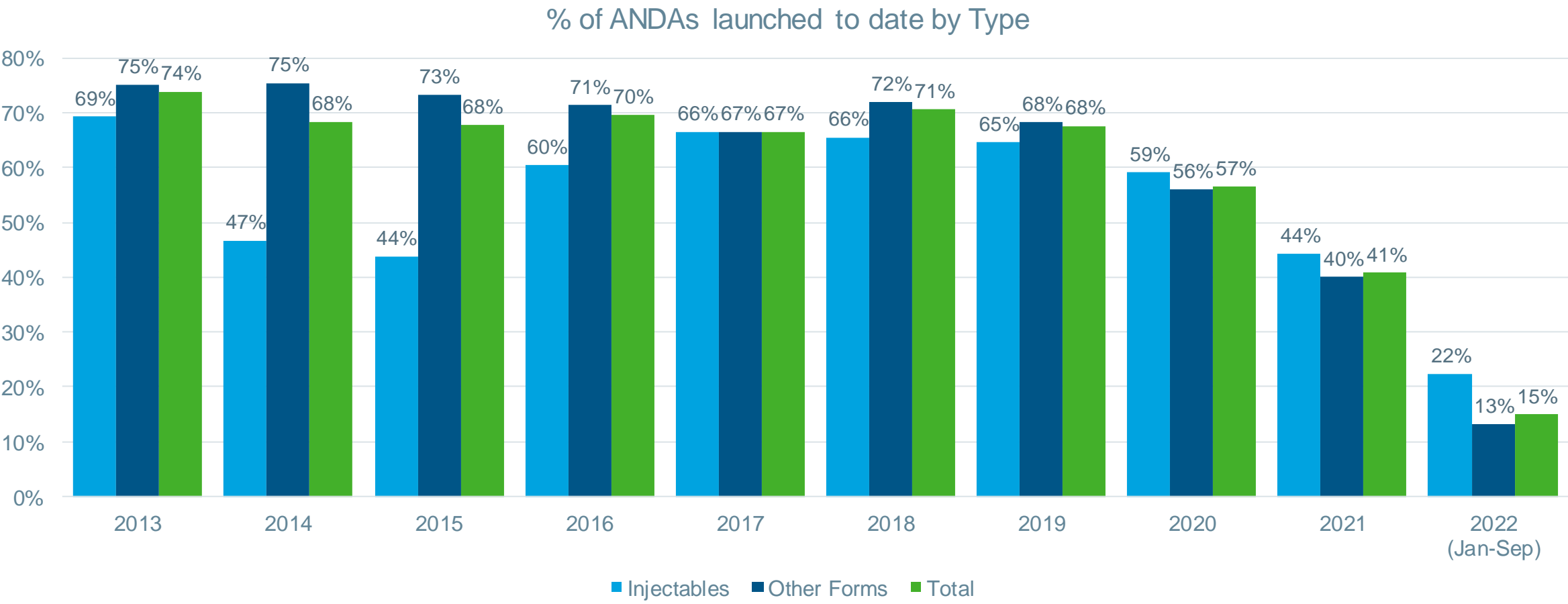
Total Molecule approvals and Launch



- Indicates the total ANDA approvals in a specified timeframe
- Indicates the ANDA that has been approved and launched during the same timeframe
- Indicates the ANDA that has been approved but launched in subsequent timeframe

The share of launched ANDAs in the US continues to decline

Approved injectable ANDAs launched much less often in 2014-2016 but differences narrowed since

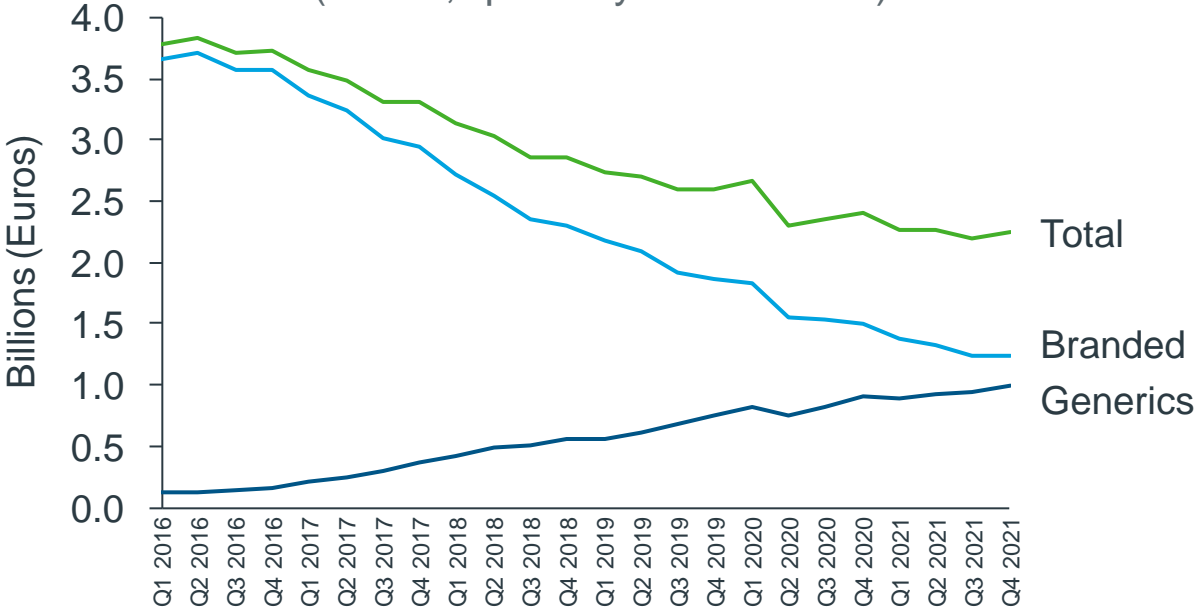




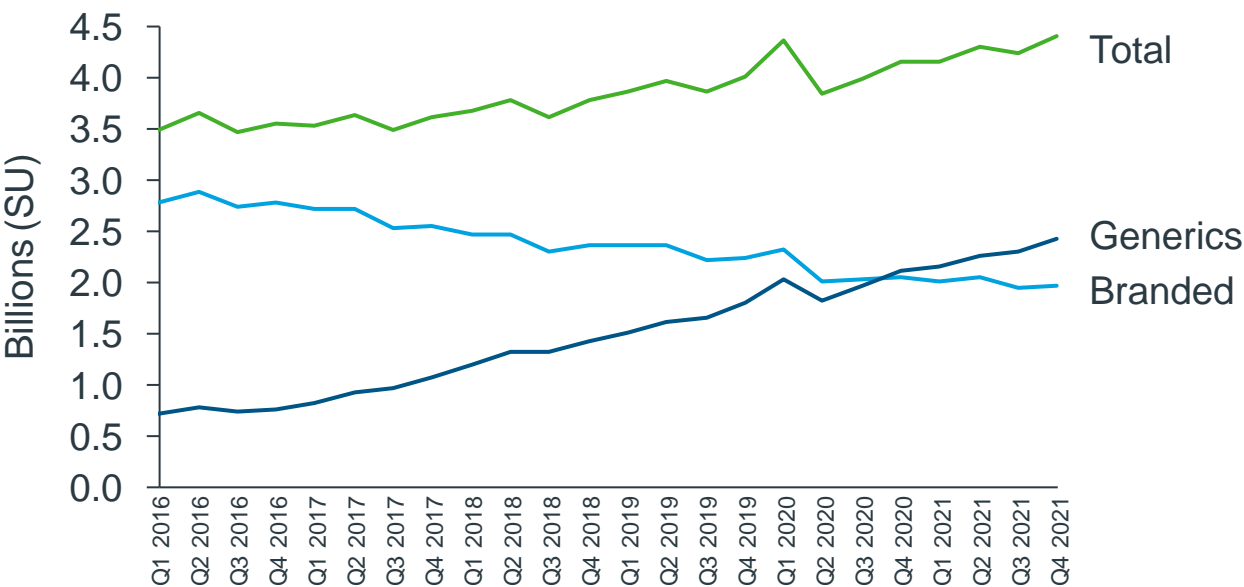
In Europe, a new IQVIA study showed generics reduced costs by 41% between 2016 and 2021, despite a 27% volume growth

Total savings for payers was significant with a CAGR of -8% from 2016 – 2021 products alone

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



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

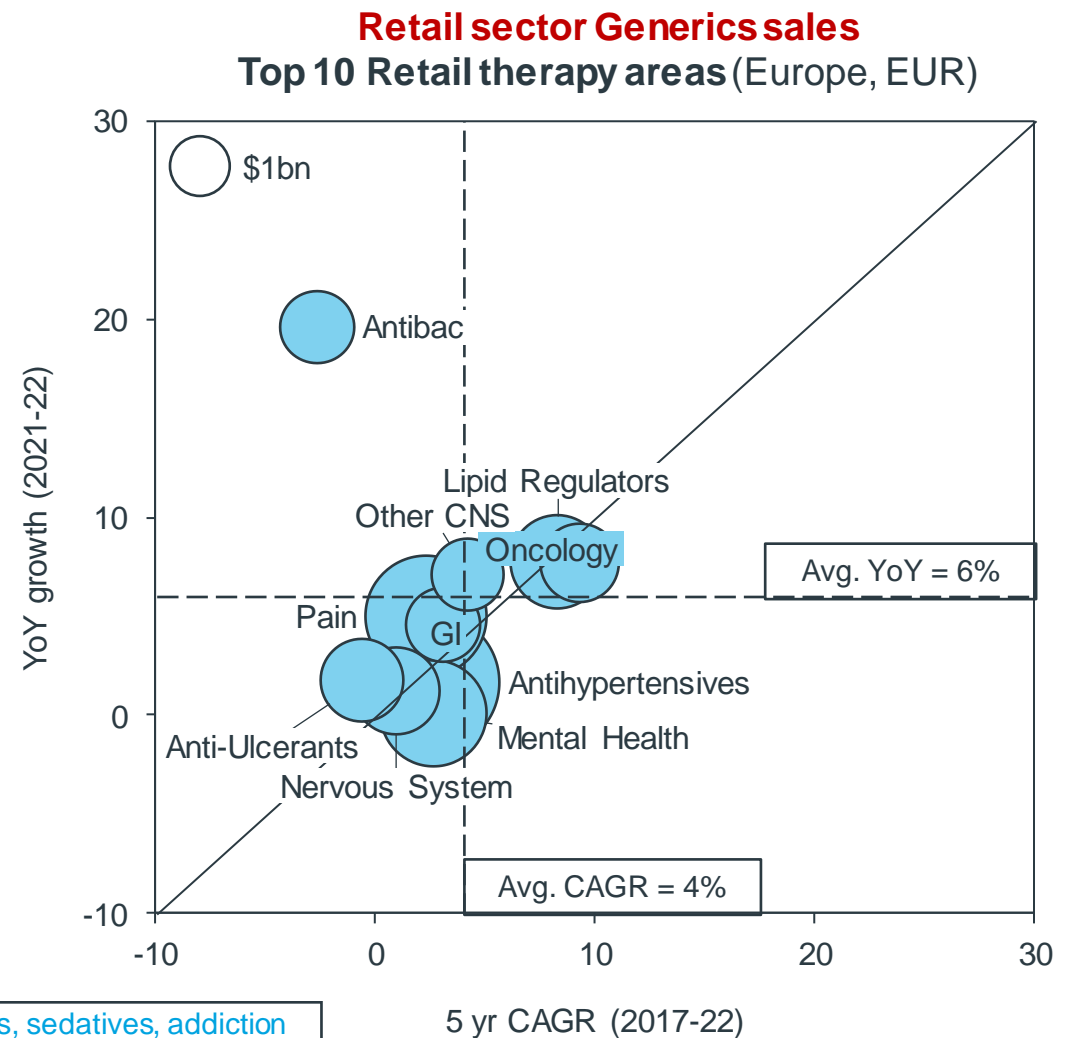
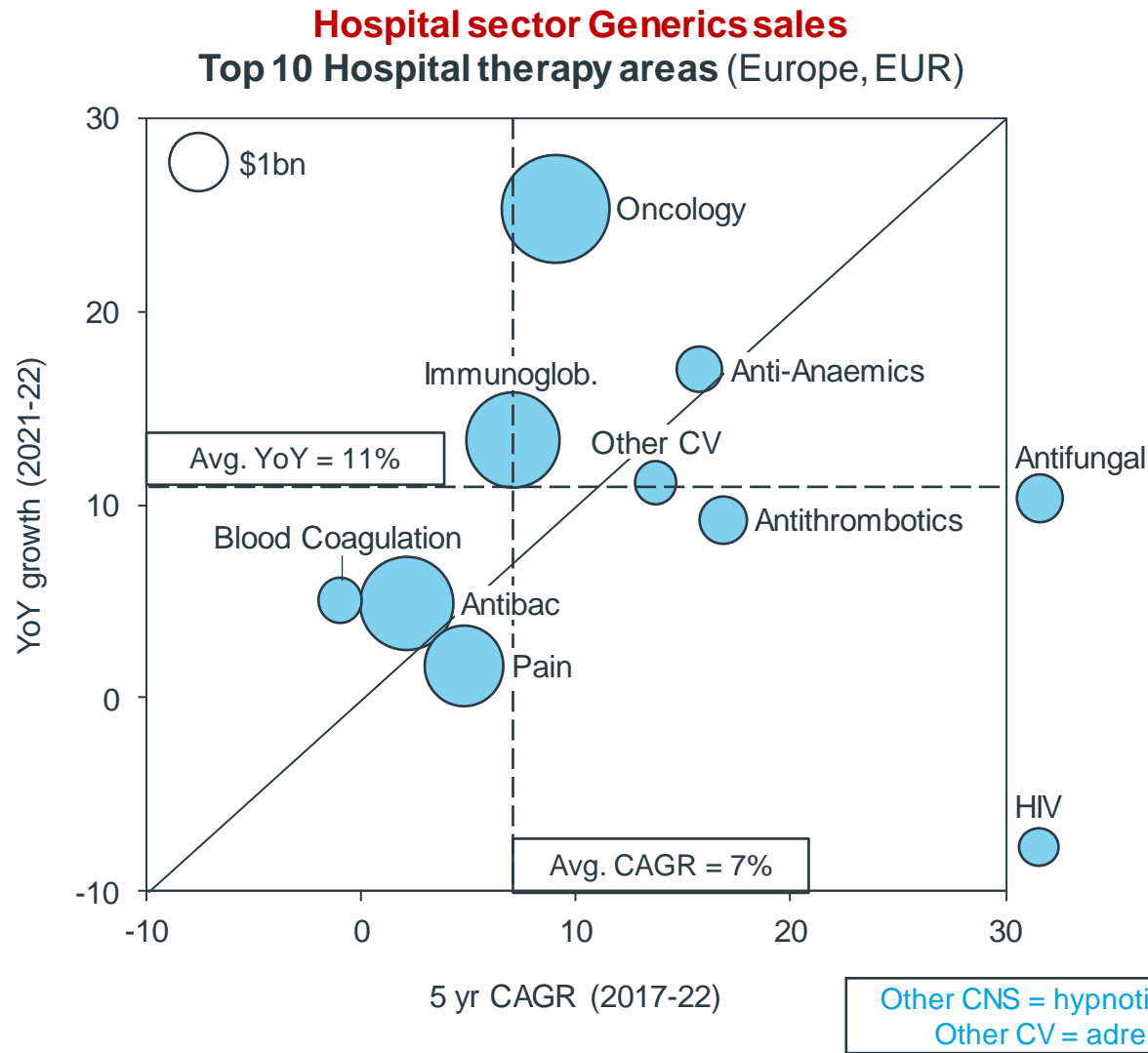


	AUSTRIA	BELGIUM	BULGARIA	CROATIA	CZECH REPUBLIC	ESTONIA	FINLAND	FRANCE	GERMANY	GREECE	HUNGARY	ITALY	LATVIA	LITHUANIA	LUXEMBOURG	NETHERLANDS	POLAND	PORTUGAL	ROMANIA	SLOVAKIA	SLOVENIA	SPAIN	SWEDEN	EU
Small mol (val)	-30%	-41%	-10%	10%	-11%	8%	-39%	-50%	-40%	1%	-10%	-40%	-33%	-48%	-48%	-54%	-12%	-59%	-25%	-45%	-28%	-40%	-50%	41%
Small mol (vol)	44%	50%	76%	28%	56%	62%	101%	-15%	46%	51%	37%	24%	51%	45%	31%	33%	62%	19%	43%	18%	31%	23%	44%	27%

Source: IQVIA Institute, Protection expiry in Europe, 2022
Notes: No available hospital data for Greece, Estonia, and Luxembourg. Table shows growth by country as CAGR 2016-2021.



There is greater growth fluctuation in European Hospital generics than there is in Retail

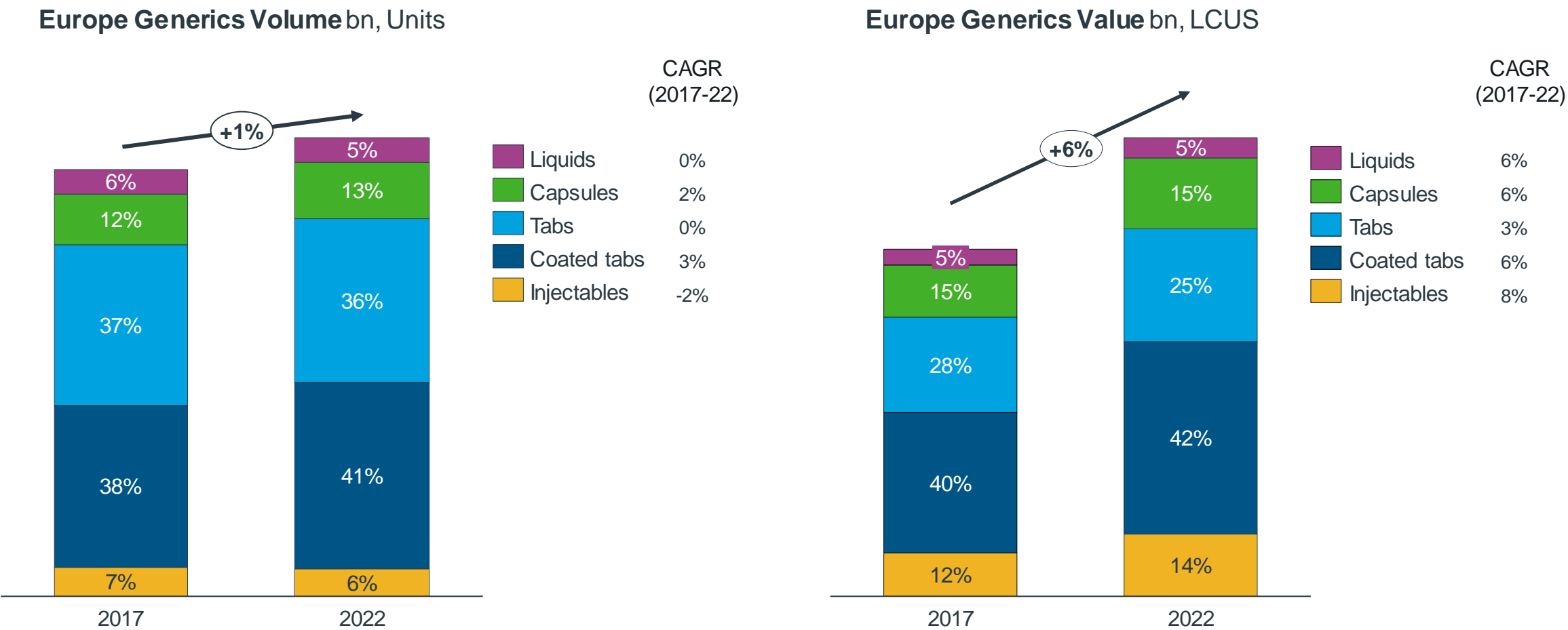


Notes: Generics only (Innovation insights = Unbranded + non-original branded). Rx only. Excluded TAs = hospital solutions, Kanpo and Chinese, imaging agents, vaccines, non-therapeutic agents.
Source: IQVIA EMEA Thought Leadership, IQVIA MIDAS QTR MAT Q2 2022



Similar to the US, most Gx volume is still in oral solid

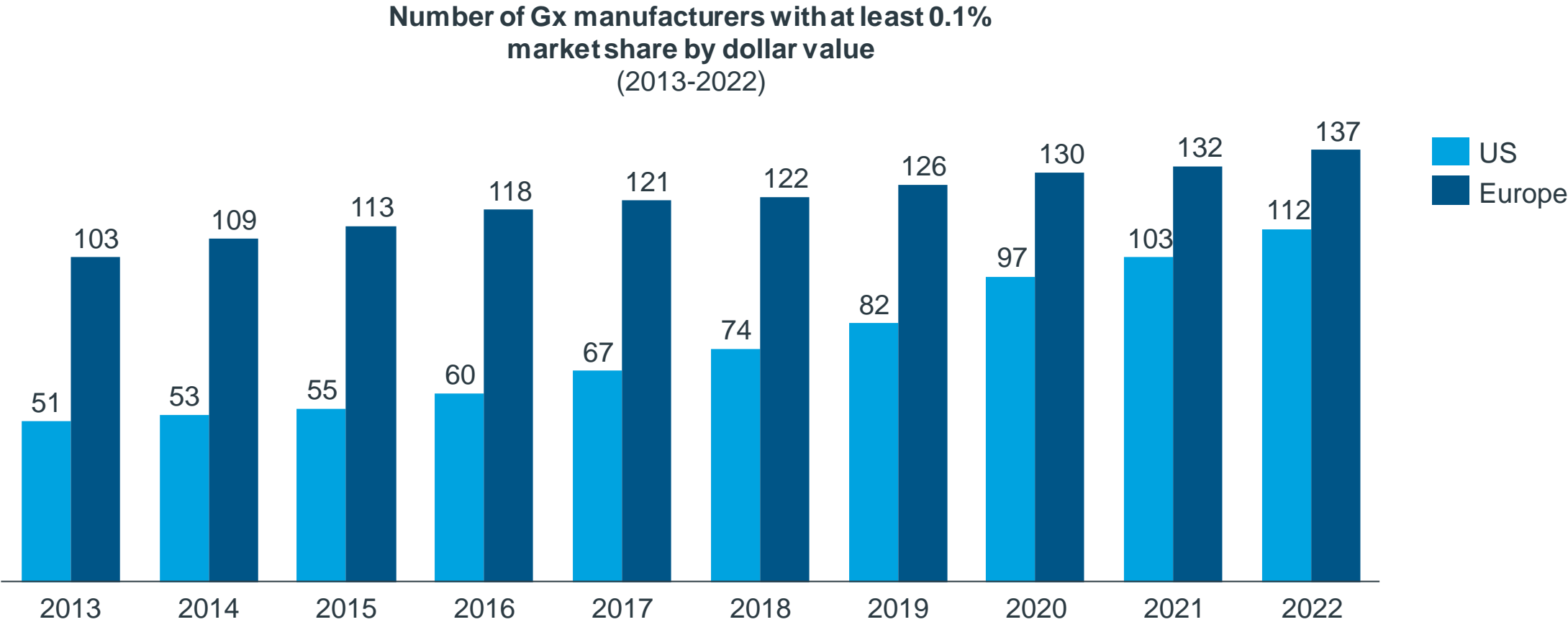
Going forward, value growth increasingly dependent on special delivery systems



Notes: Excluding Hospital Solutions, Non-therapeutics, Diagnostics, Imaging agents,
Source:IQVIA GS&AR, IQVIA MIDAS MAT Q3 2022; Rx only; NFC123 used for segmentation; Innovation insights

Competition is increasing in Europe too, but at slower rate

Growth in the US outperformed Europe, which also saw a 25% increase in MNFs since 2013

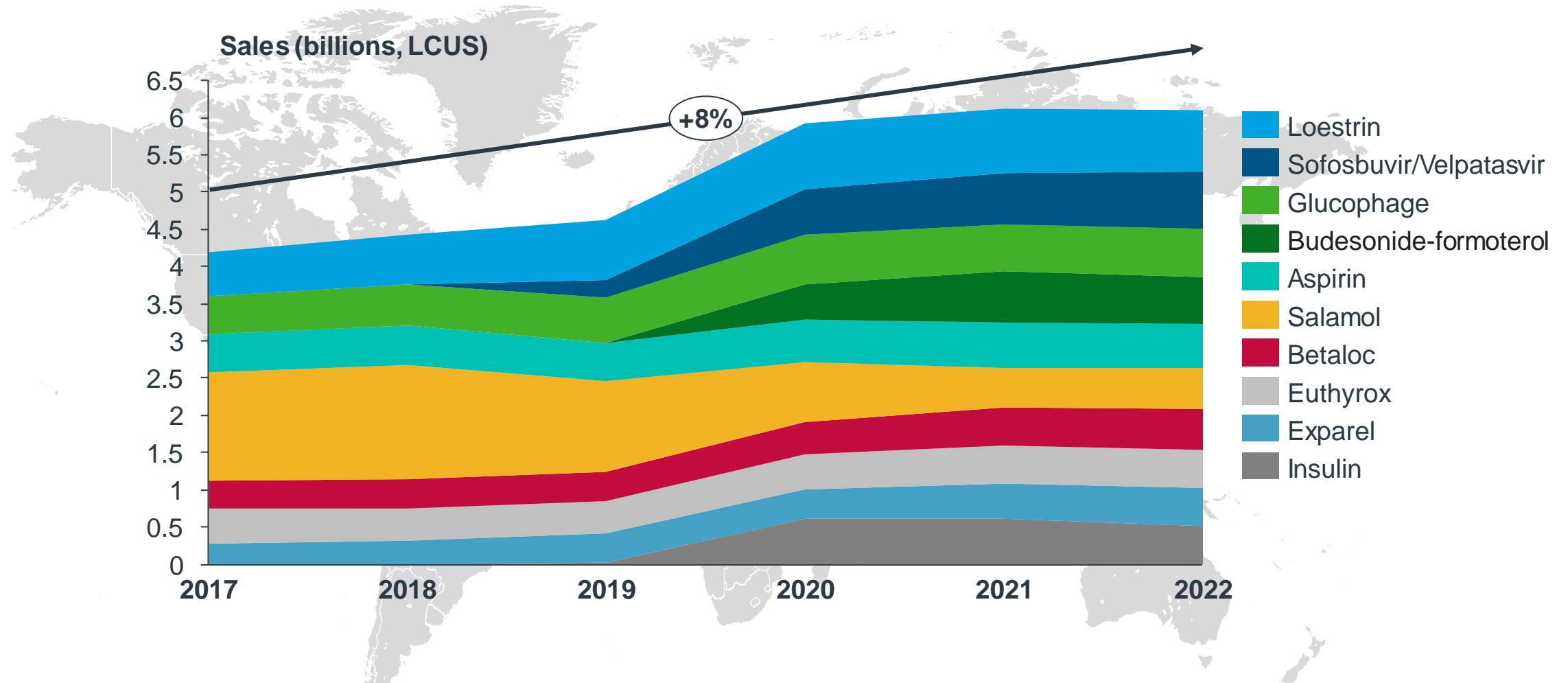


Source: IQVIA GS&AR, IQVIA MIDAS Q3 2013-2022, Rx only, Generics Product Class

Top 10 generic products by value reached \$6.4bn in global sales in 2022, growing at 8% CAGR since 2017



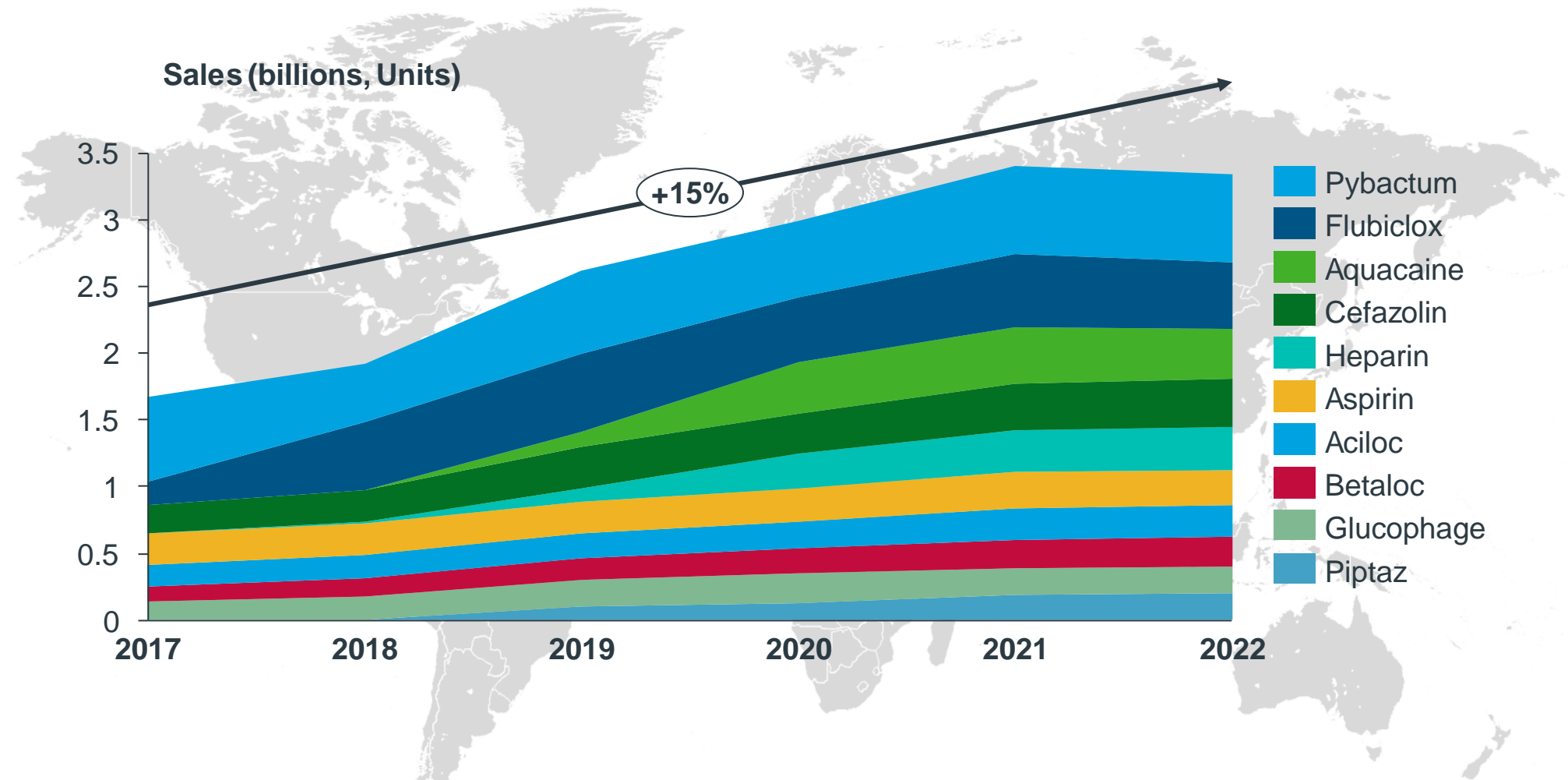
Lo Loestrin Fe dominated global generics sales by dollar value in 2022



Top 10 Gx products volume grew at 15% CAGR between 2017 and 2022



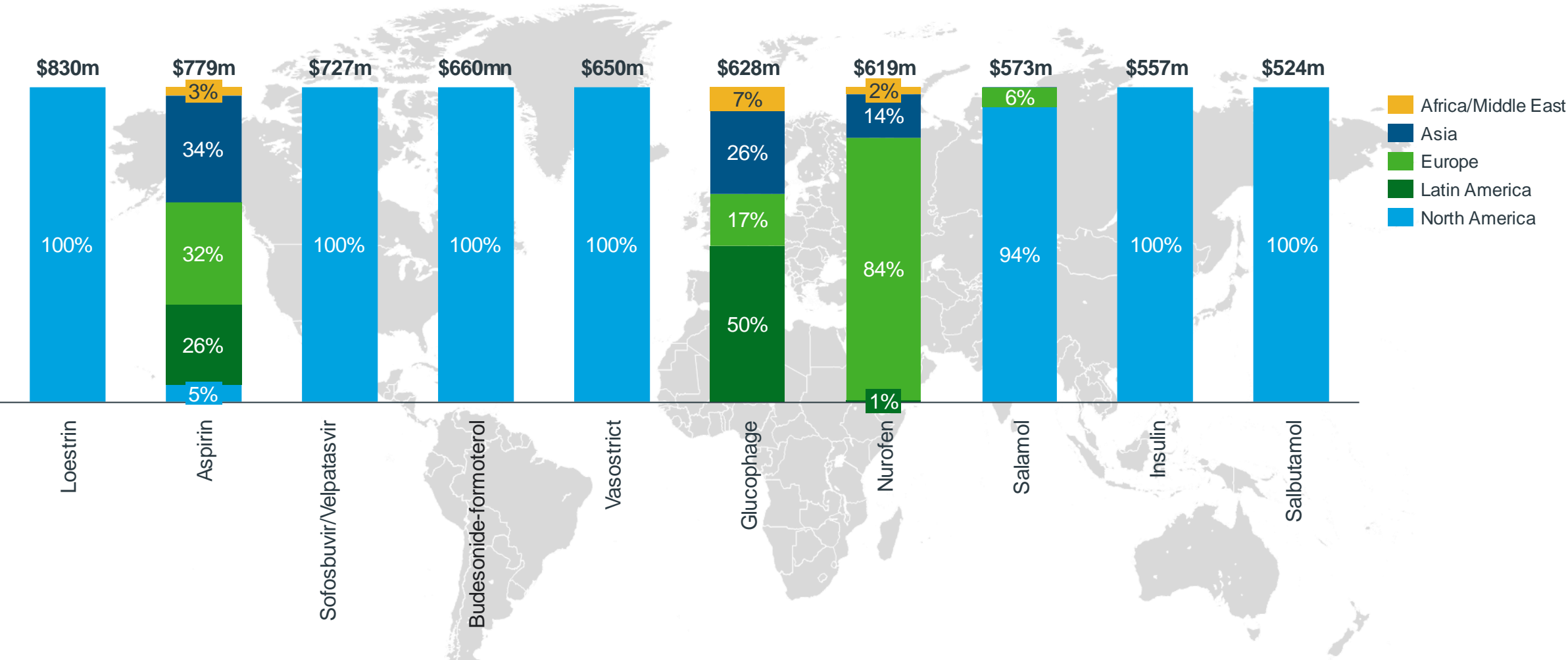
Collectively, they accounted for ~8% of all Gx units sold in 2022





North America remains a key market for best selling products

Top 10 generics by sales (LCUS)

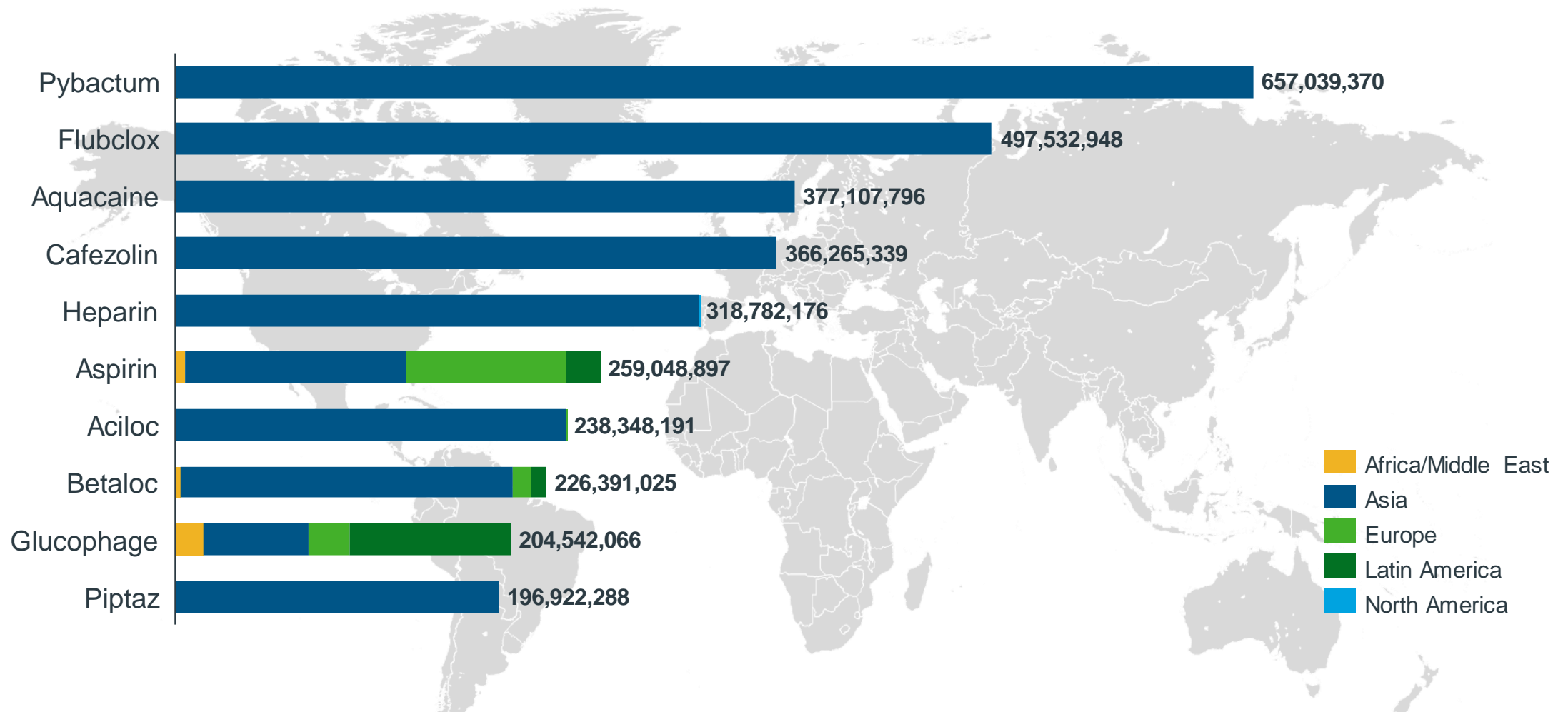


Source: IQVIA GS&AR, IQVIA MIDAS Q3 2013-2022, Generics Product Class

Use of generics varies by geography, with higher consumption in Latin America and Asia/Australasia



Top 10 generics by volume in 2022

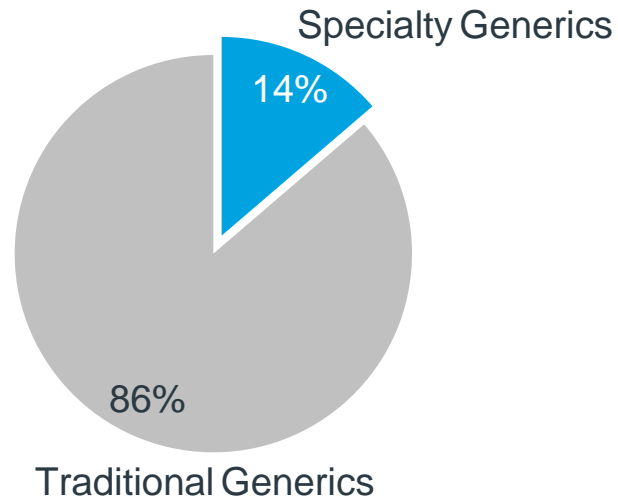


Specialty Generics will become increasingly important in future, driven by Oncology and Immunology

Specialty Gx sales increased at CAGR of 10% between 2017 and 2022

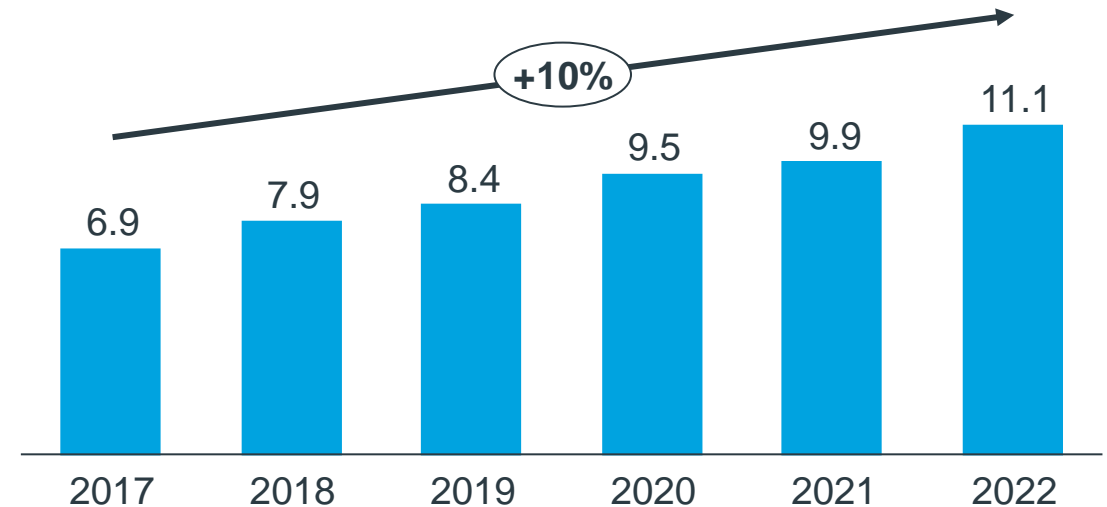
European Rx Generics Market
(\$53bn, 2022)

2017-22 CAGR: 10%



2017-22 CAGR: 3%

Specialty Generics sales (2017-22, bn EUR)



Specialty definition:

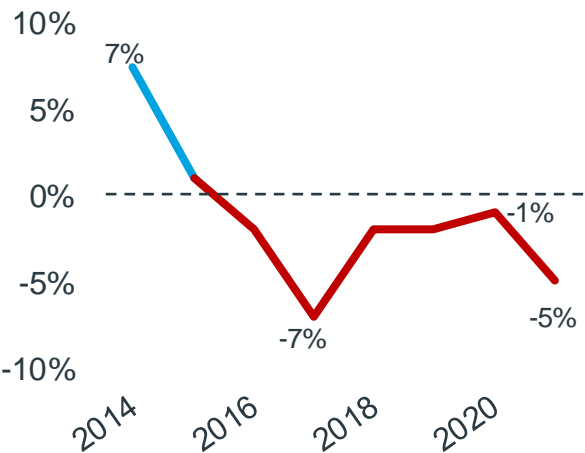
Medicines that treat specific, complex diseases with four or more of the following attributes:

- Initiated only by a specialist
- administered by a practitioner
- requires special handling
- unique distribution
- high cost
- warrants intensive patient care
- requires reimbursement assistance

Strong forces pressure the generics macroenvironment

Powerful buyers

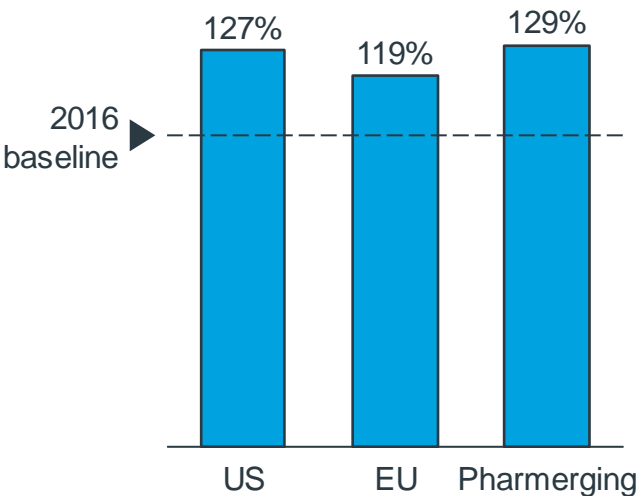
US Generics Net Price Growth



- 90% of US purchasing from top 3 wholesalers
 - WBA
 - Red Oak
 - ClarusOne

Competition increases

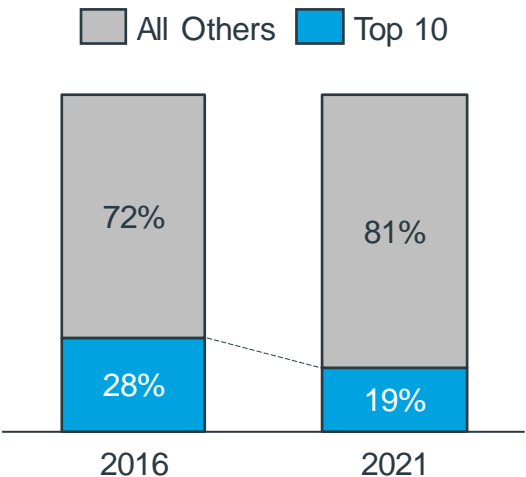
Number of Gx Players in 2021 vs 2016 (>\$10mn sales, Indexed to 2016)



- Rapid increase in competition in the US compared to Europe
- This is driving fragmentation
- Manufacturers seek growth in Pharmerging

Fragmentation

Market share of top 10 Gx companies (2016-21, USD)



- Rapid rise of competition, has eroded share from top 10
- The Gx sector is increasingly fragmented

Notes: Generic companies with sales over \$10mn used to calculate crowding; Developed countries defined as US, EU4 + UK and Japan. Excluded TAs = hospital solutions, Kanpo and Chinese, imaging agents, Diagnostics, vaccines, non-therapeutic agents

Source: IQVIA EMEA Thought Leadership; IQVIA MIDAS MAT Q4 2021; Rx only; Innovation insights; IQVIA Institute General US Medicines Spending Outlook 2018-2023

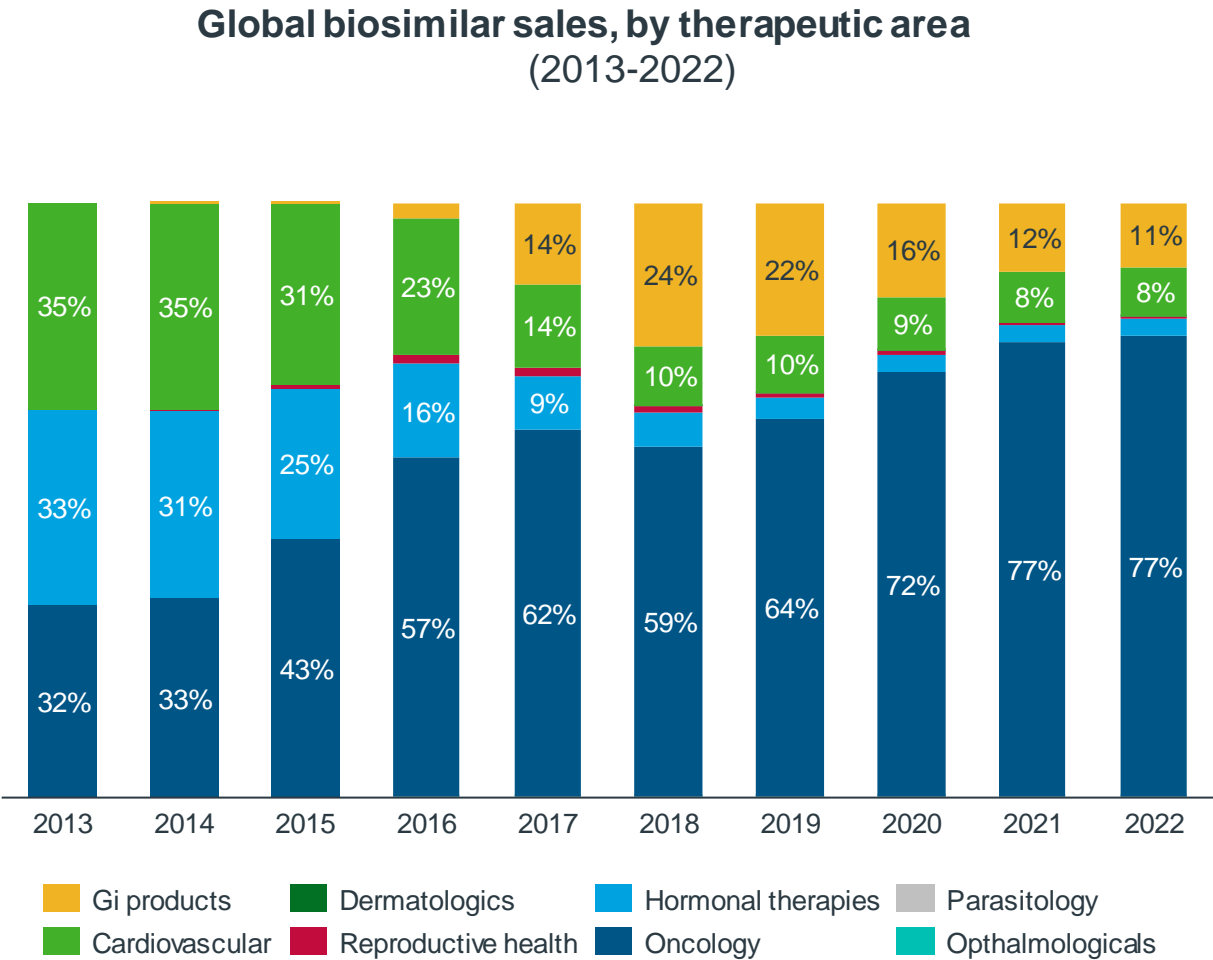
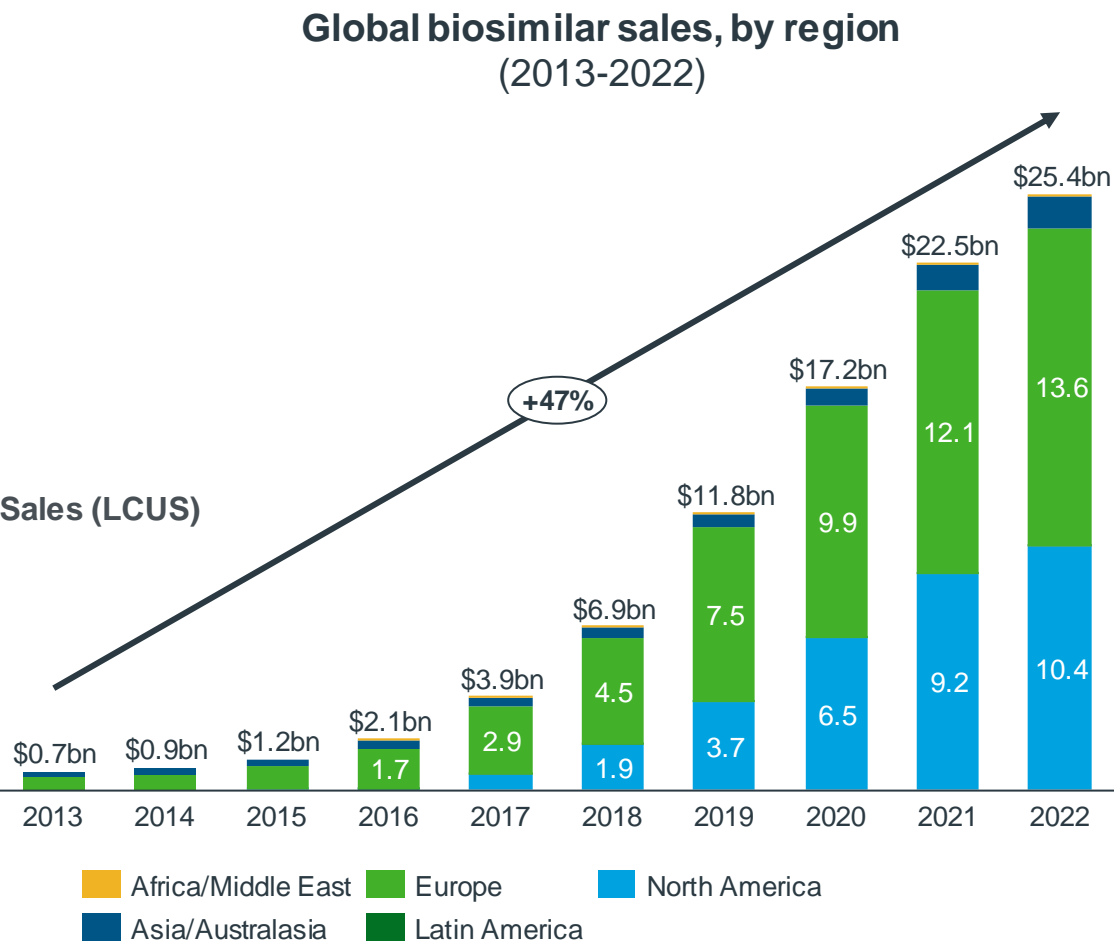


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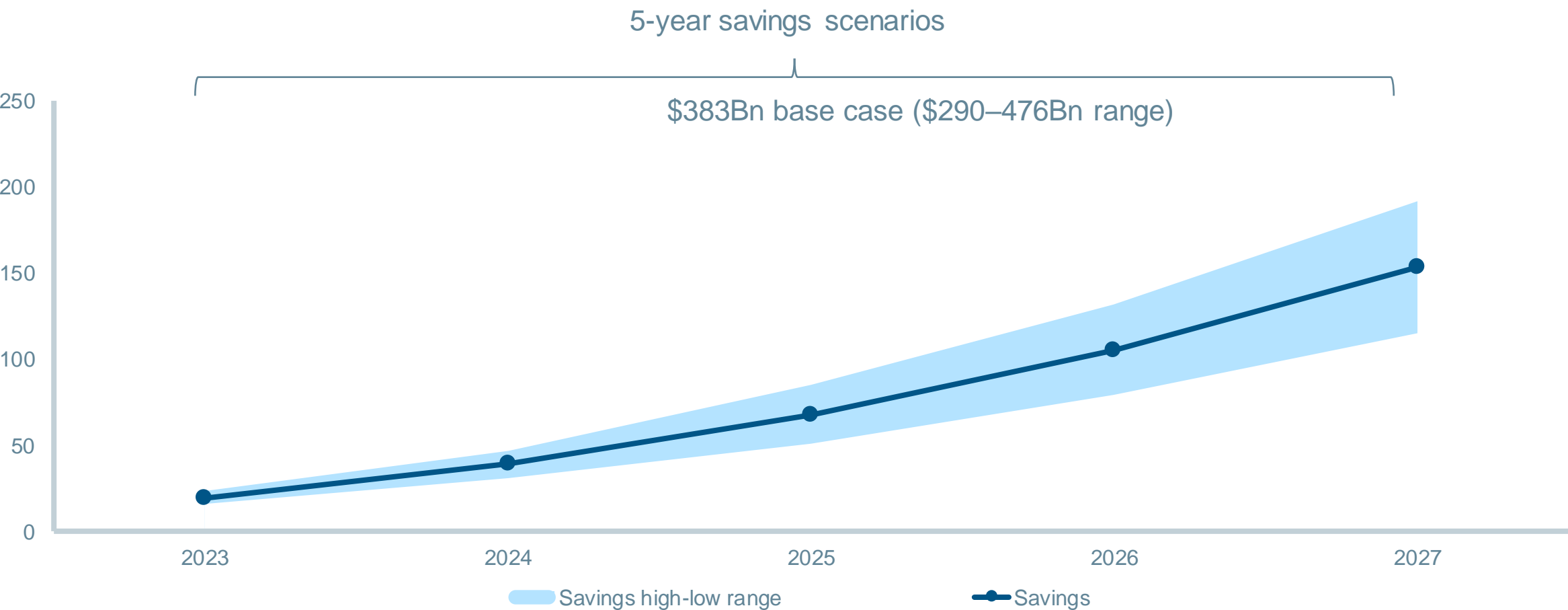
The global biosimilar market grew at a CAGR of 47% between 2013 and 2022

Almost 80% of all sales came from oncology products in 2022



Global savings from biosimilars will have a significant impact on country medicine spending through 2027

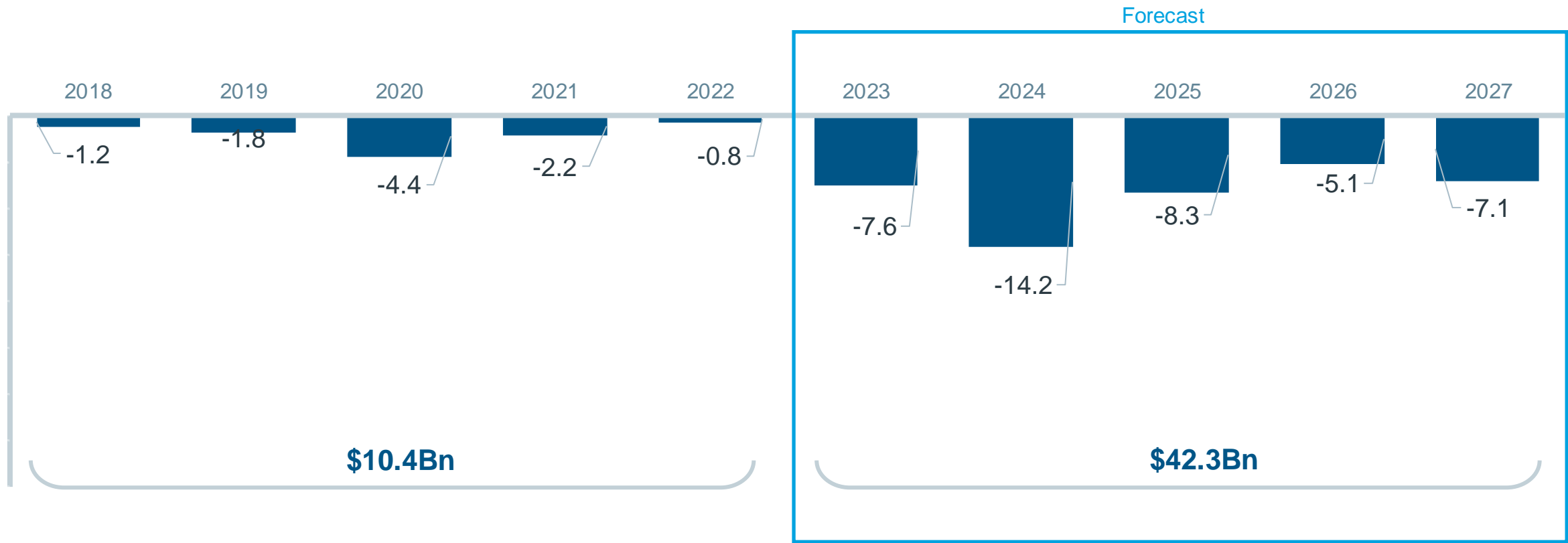
Global savings from biosimilars 2023-2027



Source: IQVIA Market Prognosis, Sep 2022; IQVIA Institute, Nov 2022.
The Global Use of Medicines 2023: Outlook to 2027. Report by the IQVIA Institute for Human Data Science.

In the US, the impact of exclusivity losses for biologics will increase to \$42.3bn over 5 years

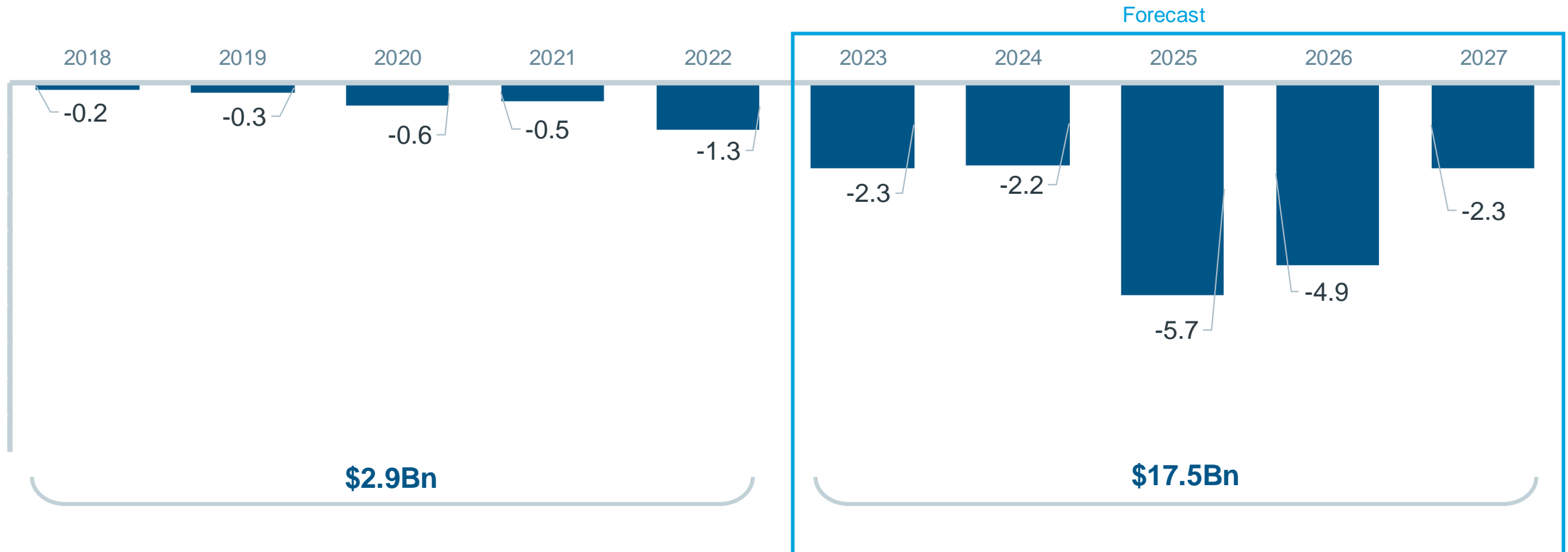
U.S. impact of brand losses of exclusivity 2018–2027, US\$Bn



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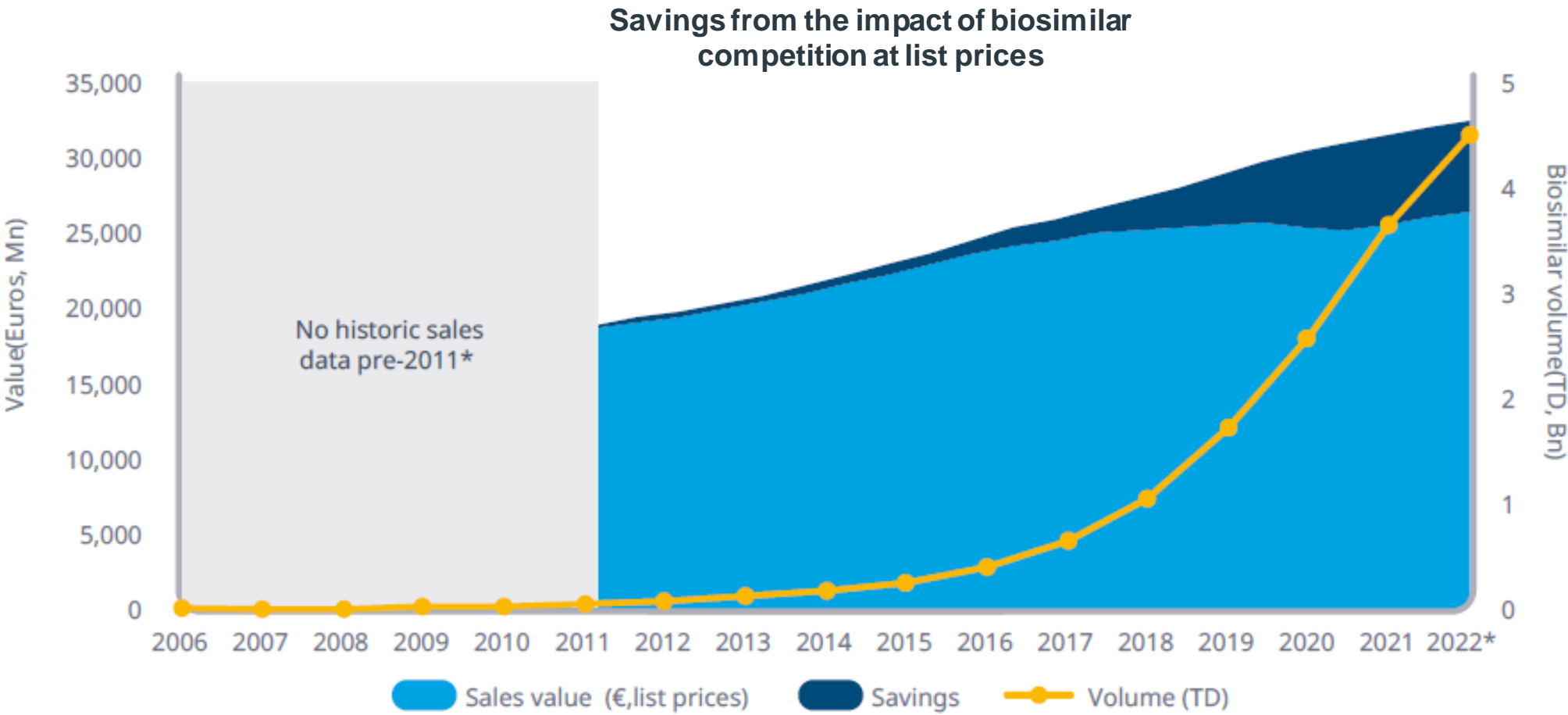
In Europe, the impact of exclusivity losses for biologics will reach \$13.5Bn over 5 years

EU4+UK impact of brand losses of exclusivity 2018–2027, US\$Bn



EU savings from the impact of competition have reached >€30Bn

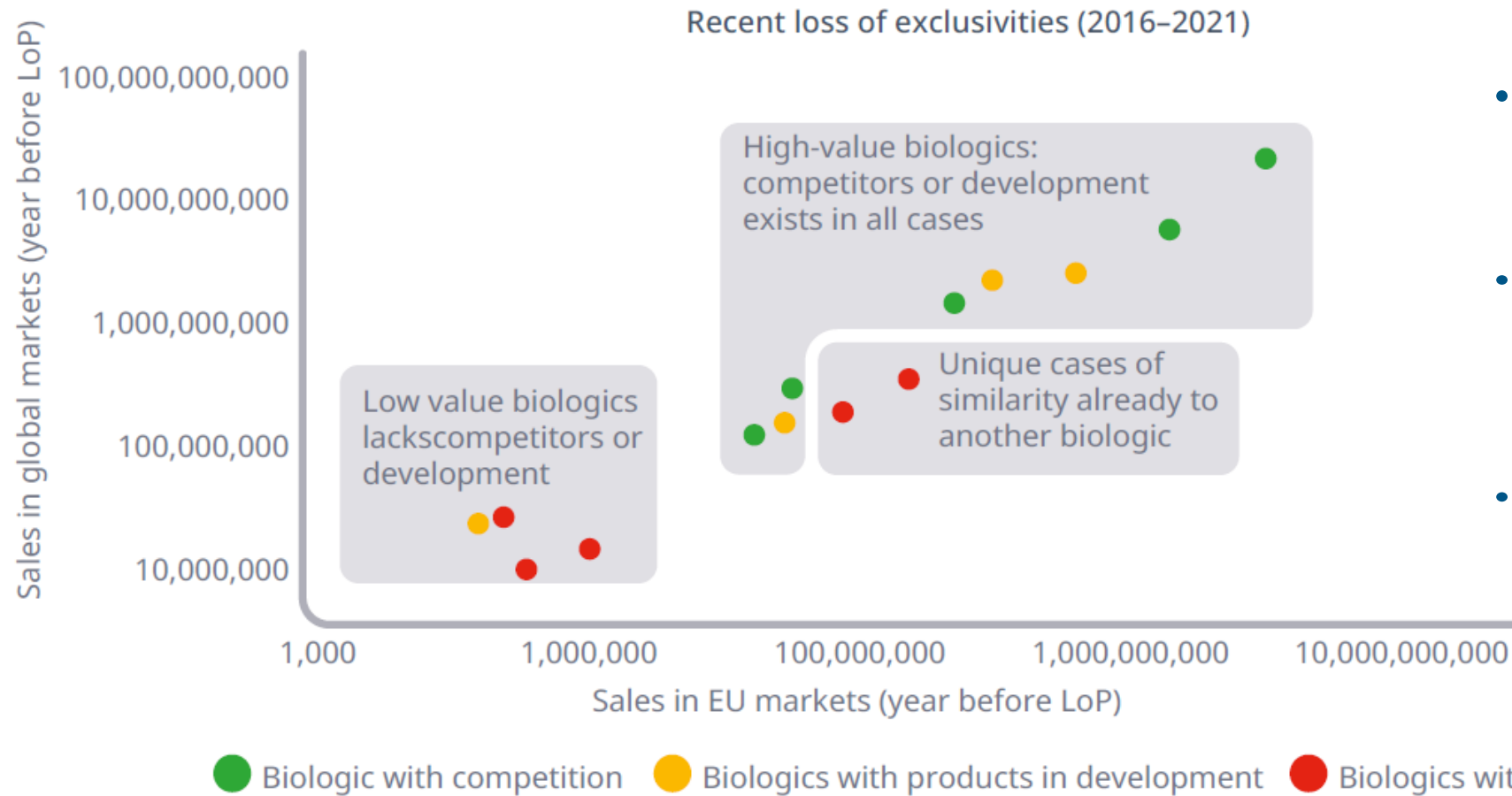
Cost has fallen for multiple years in a row while total volume has increased



Caveats: This figure is not equivalent to all savings. And is therefore an under-estimate. The data does not include the impact of rebates or discounts, which may have been present prior to the introduction of biosimilars in small quantities, and are highly significant post-biosimilar entry as it is based on publicly available list prices.. Source: IQVIA MIDAS™ data from 2006 – 2022, using Euros at constant exchange rates; value includes all originator products with approved biosimilars from 2006 – 2022, covering the full European Economic Area (33 CTYs), calculated volume is in treatment days determined by WHO-DDD, and where values are unavailable via Oncology Dynamics Physician Survey (2017) DDD estimates. Volume is solely biosimilar treatment days

Not all molecules are attractive for competitors to enter

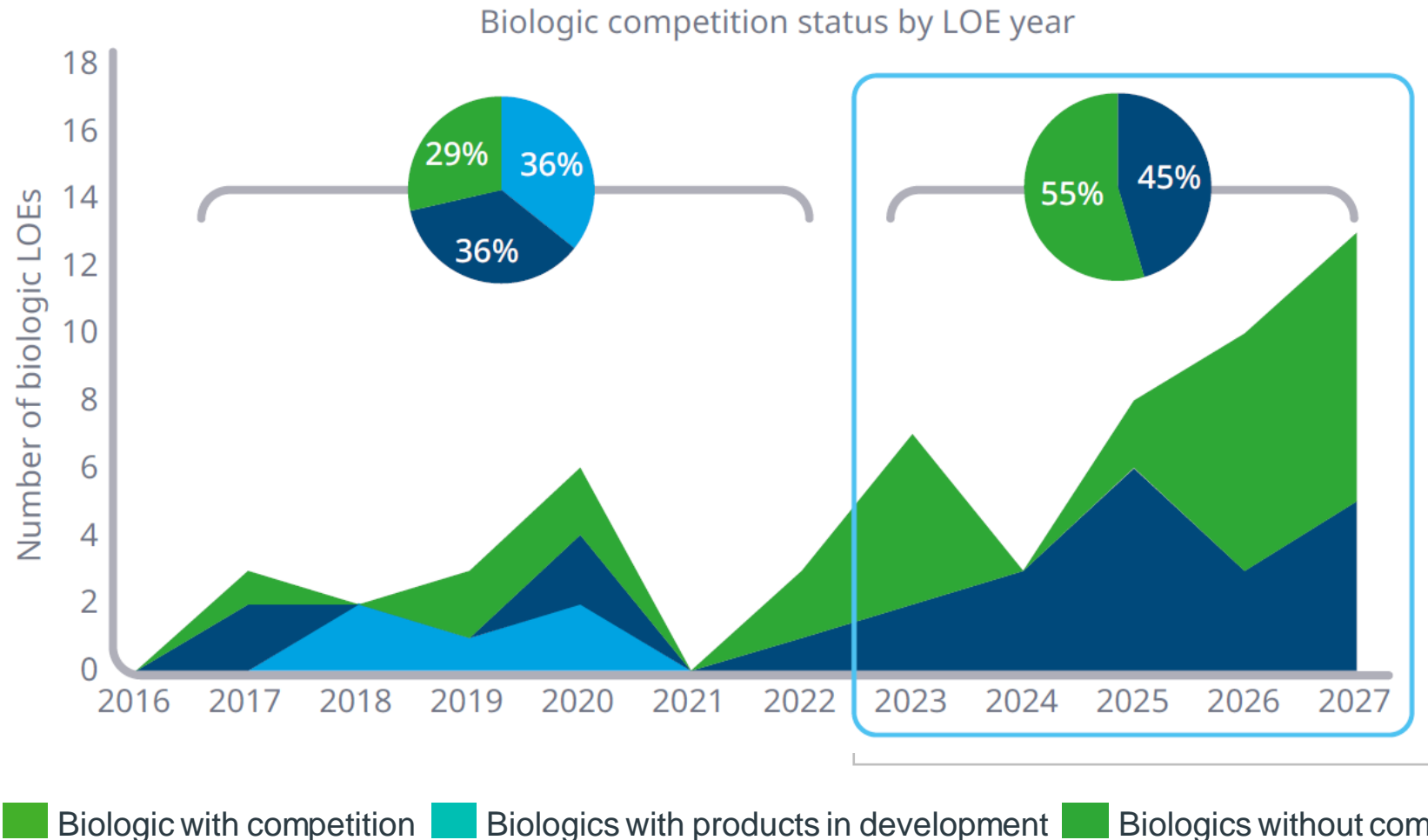
Biologic molecules do not necessarily support a biosimilar in the current system



- Molecules (especially OMPs) may not support multiple competitors at significantly reduced prices
- Products with low sales values are unattractive to biosimilar manufacturers due to the cost of comparators, and development
- Some biologics in this analysis are defined as 'very similar' or 'very slightly different' by the EMA to other biologics and are therefore unlikely to require their own unique biosimilar

Biologic LOEs are increasing, and research has already started

The number of molecules is higher, while average value is lower



- 2/3 of historic LOEs received biosimilar competition, due to molecule size and type
- More biologics will be losing protection that historically (+30)
- More biologics molecules have a competitor in development than before (+14)
- Not all future biologics will have competition, historically this has been ~1/3 of all molecules
- Multiple high value biologics losing exclusivity which explains the uptick in 2025
- Biologics with competitors development are already for products losing exclusivity in 2027





























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Top 10 generics corporations by dollar value and volume











The Gx market remains highly fragmented in 2022 with a large geographical spread

<div>    </div>			<div>    </div>		
Corporation	Sales (Bn, LCUS)	Global market share	Corporation	Volume (Bn, Units)	Global market share
 TEVA	12.7	4.3%	 SANDOZ	3.1	3.2%
 SANDOZ	11.5	3.9%	 CIPLA	2.7	2.9%
 VIATRIS	9.2	3.1%	 SUN PHARMA	2.4	2.5%
 SUN PHARMA	5.5	1.9%	 SANOFI	2.2	2.3%
 NC FARMA	4.4	1.5%	 TEVA	2.1	2.2%
 SANOFI	4.2	1.4%	 MANKIND PHARMA	2	2.1%
 STADA	3.9	1.3%	 ABBOTT	1.5	1.5%
 INTAS	3.4	1.1%	 INTAS	1.5	1.5%
 AUROBINDO	3.2	1.1%	 ALKEM	1.5	1.5%
 LUPIN	3.2	1.1%	 GSK	1.4	1.4%
Top 10	\$65.3	25.3%	Top 10	21.6	22.5%











Top 10 biosimilars corporations by dollar value and volume

US companies control 55% of the global Bx market by dollar value and 40% of the volume



Corporation	Sales (Bn, LCUS)	Global market share
 PFIZER	4.9	19.4%
 SANDOZ	4.1	16.1%
 AMGEN	3.5	14.0%
 LILLY	2	8.2%
 BIOGEN	1.7	6.7%
 CELLTRION	1.4	5.5%
 VIATRIS	1	4.2%
 TEVA	0.7	3.1%
 ORGANON	0.6	2.4%
 COHERUS	0.3	1.4%

Top 10 \$20.7 81.4%

Corporation	Volume (Mn, Units)	Global market share
 SANDOZ	388	17.9%
 AMGEN	337	15.6%
 TECHDOW PHARMA	318	14.7%
 LILLY	162	7.5%
 ROVI	137	6.3%
 PFIZER	132	6.1%
 CELLTRION	90	4.1%
 ORGANON	82	3.8%
 VIATRIS	66	3.0%
 SANOFI	65	3.0%

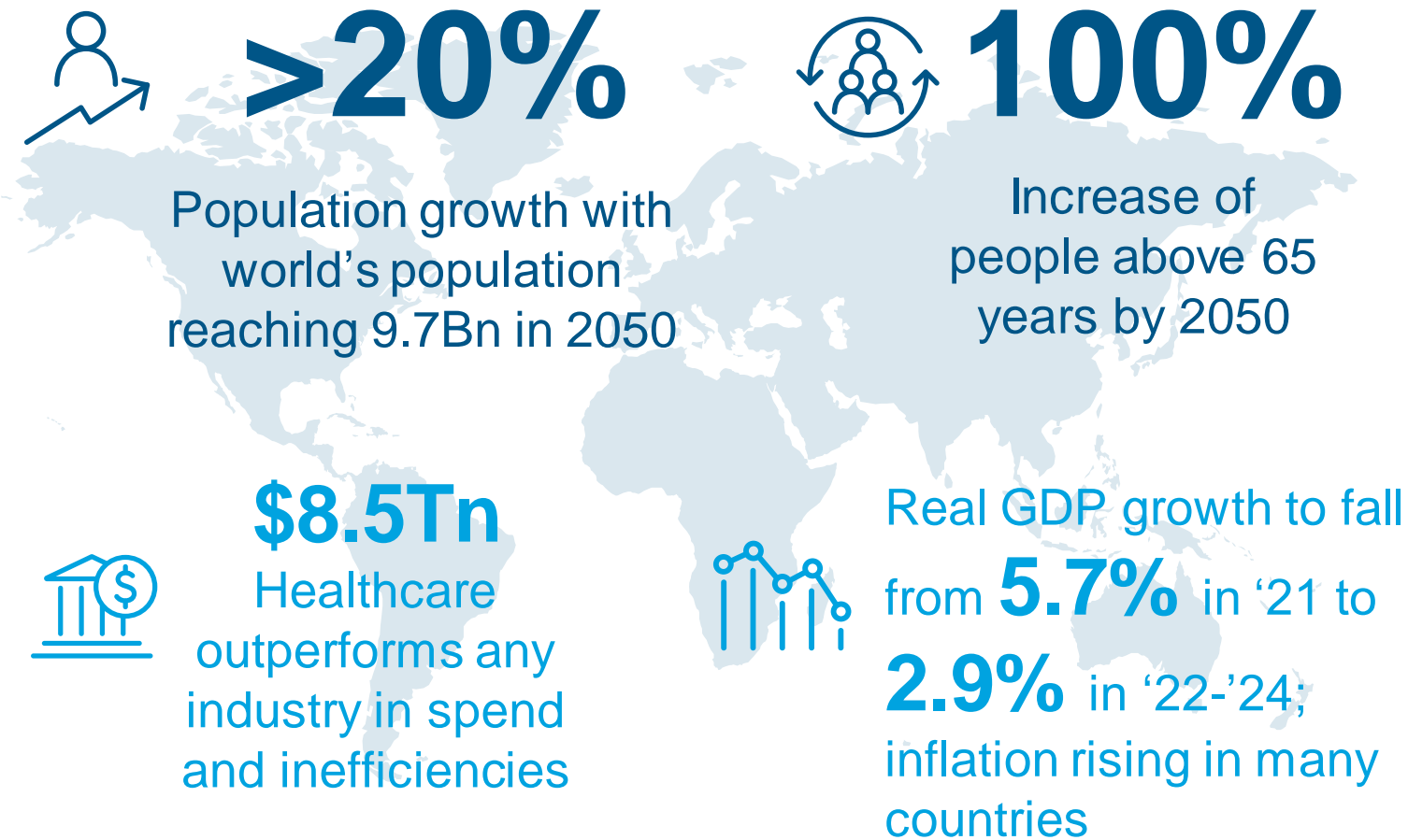
Top 10 178.2 82.3%



Contents

- + Section I: Pharmaceutical market outlook
- + Section II: Global generics market
- + Section III: Global biosimilar market
- + Section IV: Top 10 corporations by unit and dollar value
- + **Section V: Implications for the future**

Healthcare facing significant challenges with imperative to increase value



 **~20%** patients diagnosed with long-COVID creating 104.5Mn conditions

 **Patient backlog**
Has not been resolved

 **Disease burden,**
For key population diseases continues to grow

 **1 in 3 physicians**
Expected to leave their profession by 2024

 **Higher demand,**
Constrained supply with competing budgets

Uneven recovery and stressed healthcare systems mark the post-pandemic pharma environment

Uneven recovery



 Global COVID response inconsistency


 **Backlogs** remain a challenge

 Geopolitical instability


 Rapid **inflation** in major countries

Increased competition



 Emergence of Asian manufacturers

 **Consolidation** among top players

 Faster price erosion in larger markets

Focus on innovation



 Carbon neutrality and tender shaping

 **Reformulations** and better delivery systems

 Entry into emerging geographies

Pharma's Energy Challenge

Near-term pain

Navigating inflationary pressure

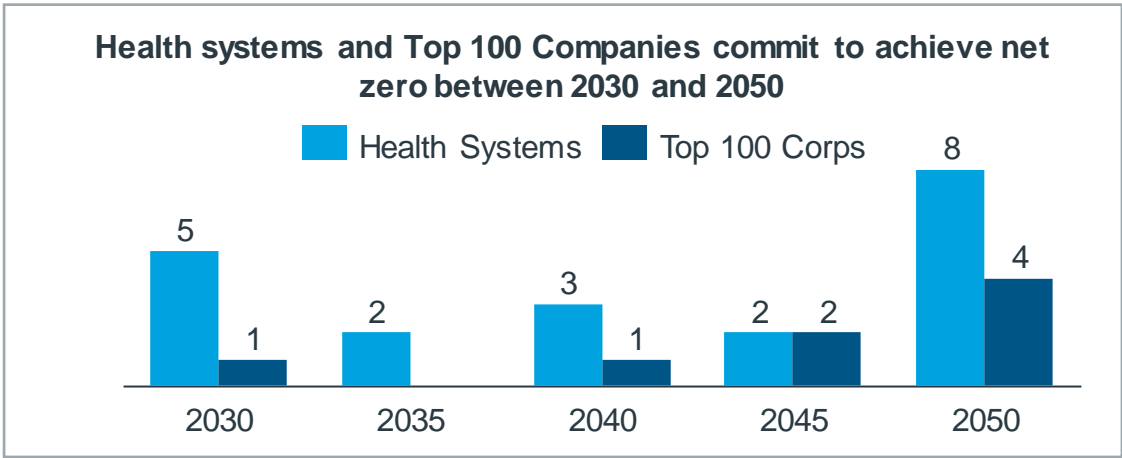
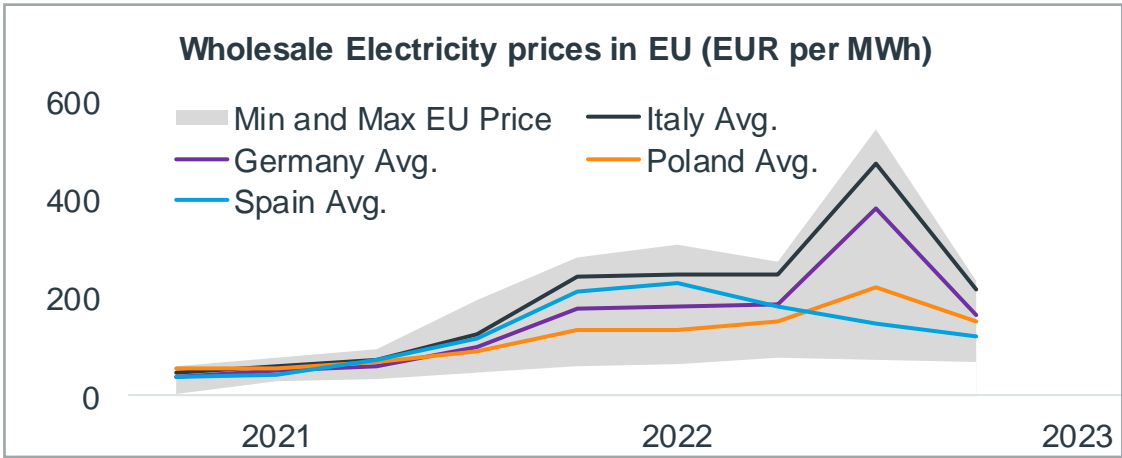
- Persistent inflation continues to impact supply chain
- EU manufacturers of generics and will suffer most.
 - Medicines for Europe states that **Transportation costs** increased up to 500%, **Manufacturing inputs** up by 50-160%, Inflation exacerbating **skills shortage**
- Indian and Chinese suppliers can provide alternatives but a reduced supply will drive prices upwards and risk **shortages**



Long-term green

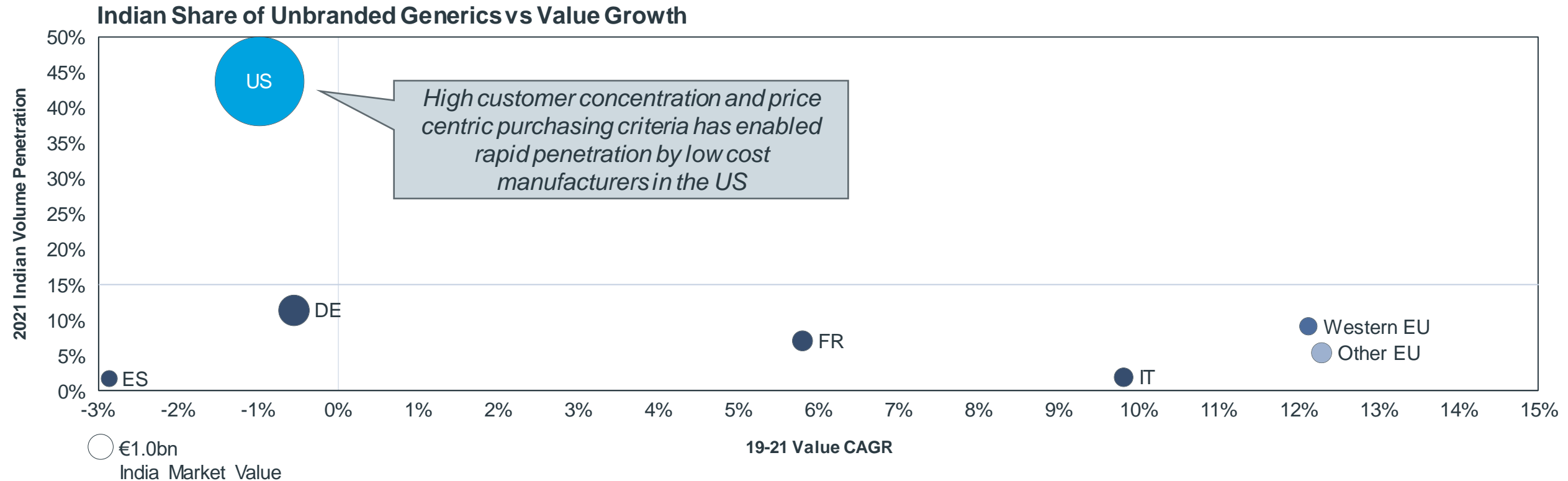
Reforming energy use

- Both Health systems and companies increasingly committing to **eliminating greenhouse gas emissions in the long-term**
- Reporting has improved but still a long way to go to fully understand the impact to the pharma industry
- Companies looking to reduce emissions by adopting **remote and digital tech**, reducing patient and employee travel and reducing single-use items



Source: IQVIA EMEA Thought Leadership; WHO ATACH Dec 2022; Company ESG reports; Medicines for Europe Open Letter to EPSCO; <https://ember-climate.org/data/data-tools/europe-power-prices/>
IQVIA EMEA Thought Leadership: Nine for 2023

Asian manufacturers are seen with high penetration in the US, but not in Europe



- **Indian manufacturer share of generics is substantially lower in Europe vs the US**, contributing to greater pricing stability
- Lower penetration in EU is **driven by fewer opportunities for pricing advantage through economies of scale** related to market fragmentation, procurement behaviour and national discounting rules
- An **increase in raw material prices and shipping costs during COVID** resulted in a **contraction of Indian share** in some markets

Downward pricing pressures and increasing competition are here to stay

Key trends for 2023 and beyond



Greater use of generics

Steady growth trends likely to continue through to 2027 driven by medicine spending growth, concerns on rising drug prices and soaring public deficit



Low biosimilar competition

Global savings from biosimilars are set to reach \$150bn, but **not all biologic molecules will face competition** due to high development costs



Rise of special delivery systems

Most Gx volume still in oral solid, but going forward value growth will be increasingly dependent on **special delivery systems**, particularly injectables



Cost pressures

Pressures on margins are expected to continue as a result of persistent inflation, supply chain bottlenecks and energy constraints in most major markets



Increasing price erosion

Increasing competition will continue to **drive price erosion across major markets** as more Asian manufacturers continue to emerge



Thank you!

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His fundamental task is to help secure data for all existing and new databases supported by IQVIA, manage supplier, manufacturer & association relationships, and develop information for data partners. As direct consequence of his involvement in these areas, Doug has considerable experience with, and a unique perspective on, the changing U.S. and global healthcare marketplace and pharmaceutical distribution.

Doug is a frequent industry speaker and the recipient of many awards from trade groups. Before joining IQVIA Doug held positions at Nielsen Market Research for 16 years in various sales and marketing capacities. A native of Illinois, Doug received a BA from DePauw University and holds an MBA in management from Fairleigh Dickinson University.

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