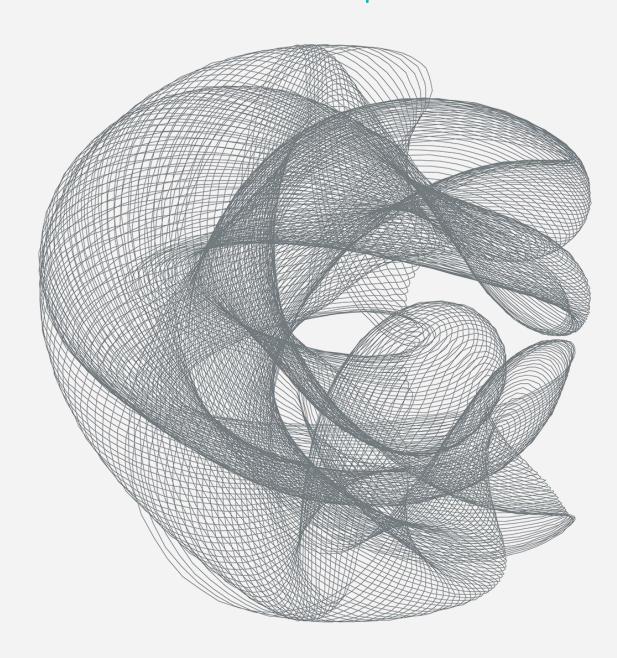
ENSTITUTE FOR HUMAN DATA SCIENCE

The Global Use of Medicines 2022

OUTLOOK TO 2026

JANUARY 2022



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Agenda

Welcome and introductions

Murray Aitken, Executive Director, IQVIA Institute for Human Data Science

Global outlook and drivers

Michael Kleinrock, Research Director, IQVIA Institute for Human Data Science

Regional Highlights

- U.S.
- Europe
- China
- Japan
- Latin America
- Audience questions and moderated discussion Murray Aitken
- Closing



Today's panelists



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Global outlook and drivers

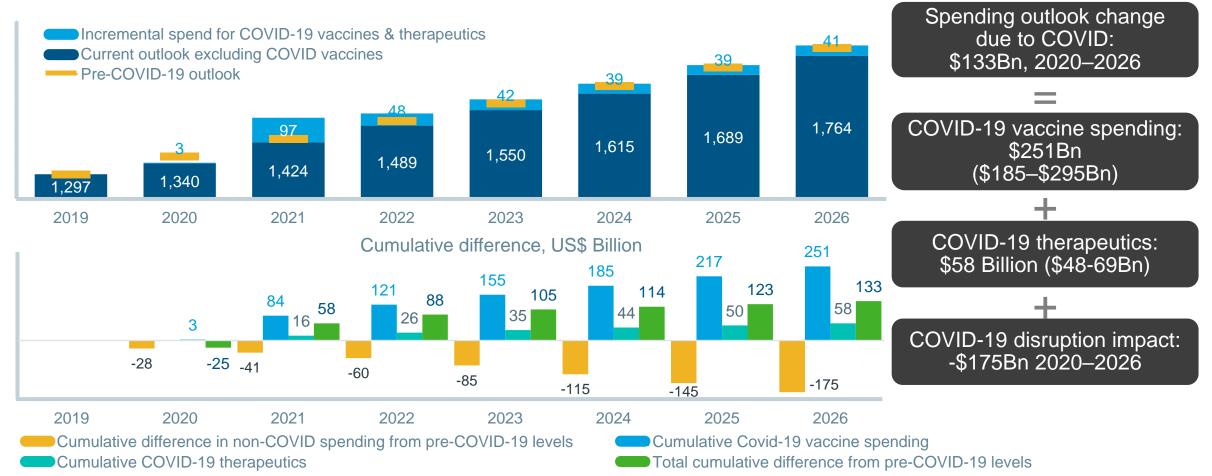
Key Points

- 1. Global spending on COVID-19 vaccines is modeled to be \$250Bn through 2026, though cost and volume estimates vary, and overall medicine spending is expected to exceed the pre-pandemic outlook by \$133Bn to 2026 and grow 3-6% CAGR through 2026, reaching about \$1.8 trillion in total market size.
- 2. Overall volume is projected to grow 1.5% in days of therapy through 2026, driven by pharmerging growth of 2.0% CAGR, while low-income countries are expected to grow at just 0.6% CAGR.
- 3. Slowing growth across key geographies is expected as health systems absorb pandemic costs and manage spending from the continuing historically high numbers of new medicines.
- 4. The two leading global therapy areas oncology and immunology are forecast to grow 9–12% and 6– 9% CAGR, respectively, through 2026.
- 5. Treatments for autoimmune disorders are forecast to reach \$178 billion globally by 2026, driven by steadily increasing numbers of treated patients and new products, and offset after 2023 due to biosimilars.
- 6. New therapies contribute to rapid acceleration of neurology markets, including novel migraine therapies, potential treatments for rare diseases, and the potential for therapies for Alzheimer's and Parkinson's.
- 7. The outlook for next-generation biotherapeutics includes significantly uncertain clinical and commercial prospects for cell, gene and RNA therapies, which will grow to \$20 billion in spending by 2026.



Global spending, including COVID-19 vaccines and therapeutics, to exceed pre-pandemic outlook by \$133Bn to 2026

Changes in the historical and projected global medicine pending model due to COVID-19, 2019–2026, US\$Bn



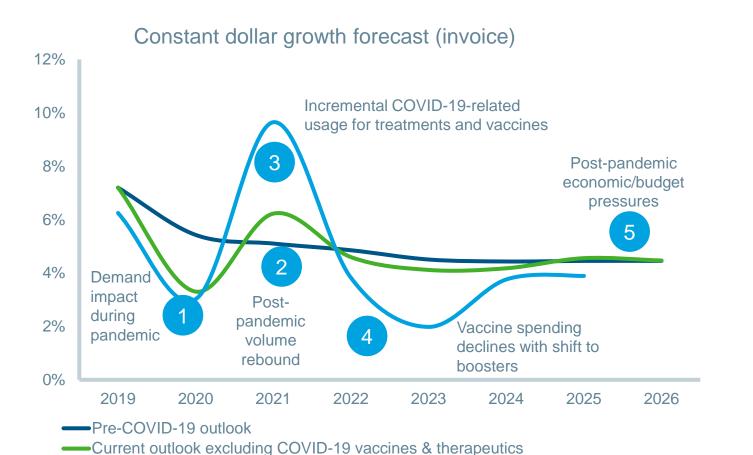
Source: IQVIA Market Prognosis, Sep 2021; IQVIA Institute, Nov 2021

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Global market growth will return to pre-pandemic projections by 2025 despite year-to-year fluctuations

Comparison of current outlook to pre-COVID outlook



Key events in the outlook

- 1 2020: -2.1% (~\$27Bn)
- 2 2021: +1.1% above pre-Covid-19 growth; +2.9% above 2020 growth excluding vaccine and therapeutics
- 3 2021: +8% higher growth including vaccines and therapeutics compared to spending without them
- 4 2022: Significant decline in required spending for COVID-19 vaccines as much of the world is inoculated to some degree
- 5 Expected budget pressures will emerge from longer-term pressures of sustained pandemic

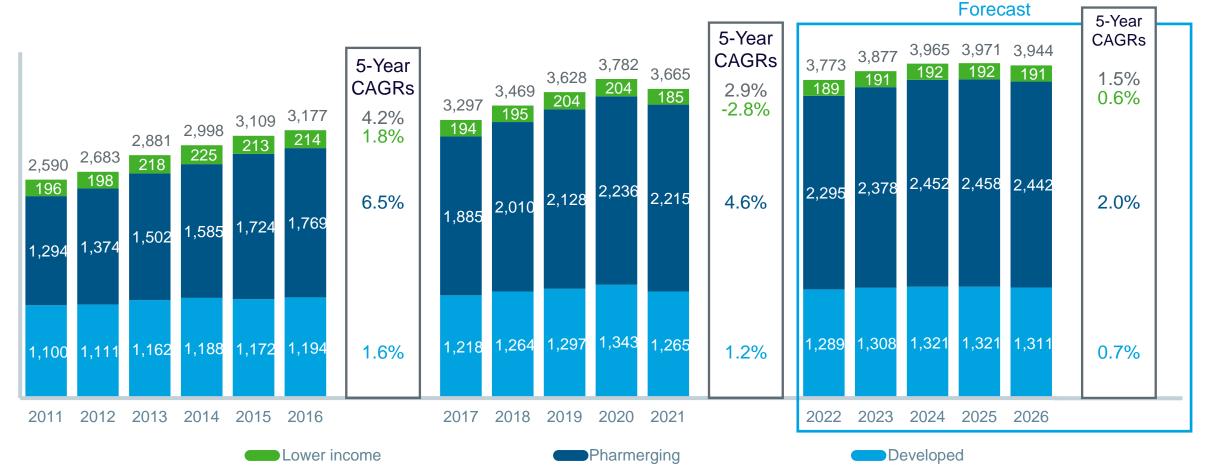


Source: IQVIA Market Prognosis, Sep 2021; IQVIA Institute, Nov 2021 The Global Use of Medicines 2022: Outlook to 2026. Report by the IQVIA Institute for Human Data Science.

—Current outlook including incremental spend on COVID-19 vaccines & therapeutics

The use of medicines particularly in pharmerging markets grew in 2020 despite the pandemic but will normalize beginning in 2021

Historical and projected use of medicine by segment, 2011–2026, Defined Daily Doses (DDD) in Billions



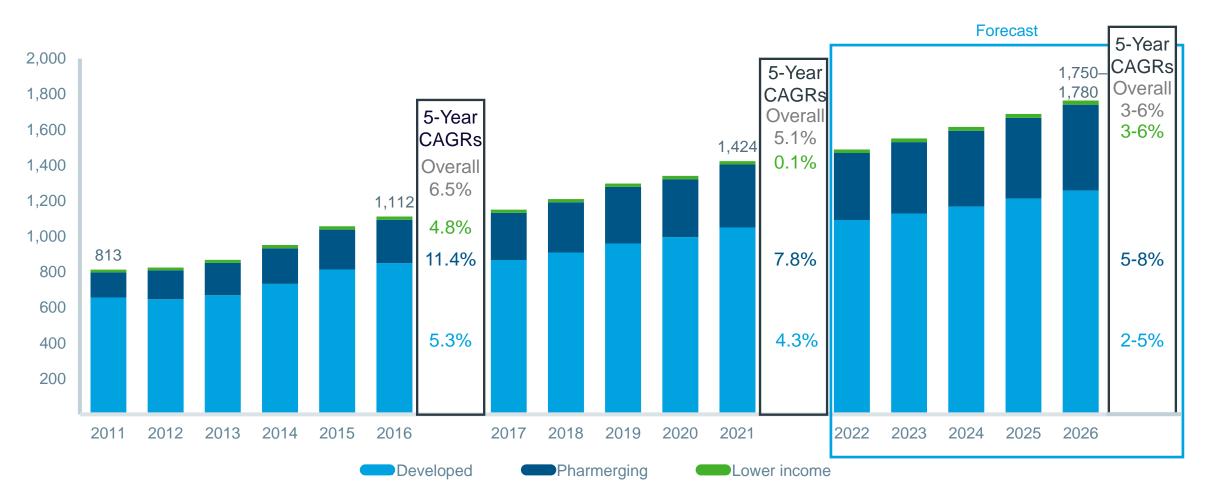
Source: IQVIA Market Prognosis, Sep 2021; IQVIA Institute, Nov 2021

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The global medicine market — using invoice price levels — is expected to grow at 3–6% CAGR through 2026 to about \$1.8Tn

Global medicine market size and growth 2011–2026, const US\$Bn





Strong growth in pharmerging markets and new brands in developed markets will lift global spending through 2026

Spending and growth drivers 2016–2026 const US\$Bn



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New brand spending in developed markets projected to be similar to the last 5 years but a smaller share of spending

Ten developed countries new brand spending



New brand spending

-New brands share of brand spending

Source: IQVIA Market Prognosis, Sep 2021; IQVIA Institute, Nov 2021

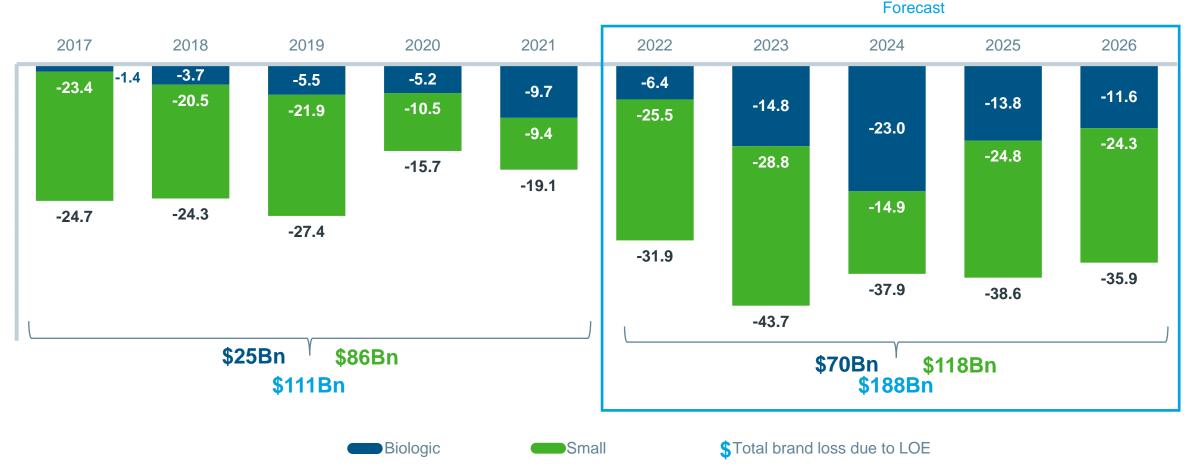
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The impact of exclusivity losses will increase to \$188Bn over the next 5 with a large increase in the impact of biosimilars

Developed markets impact of brand losses of exclusivity 2017–2026, US\$Bn



Source: IQVIA Market Prognosis, Sep 2021; IQVIA Institute, Nov 2021 The Global Use of Medicines 2022: Outlook to 2026. Report by the IQVIA Institute for Human Data Science



Global savings from biosimilars will have a significant impact on country medicine spending through 2026

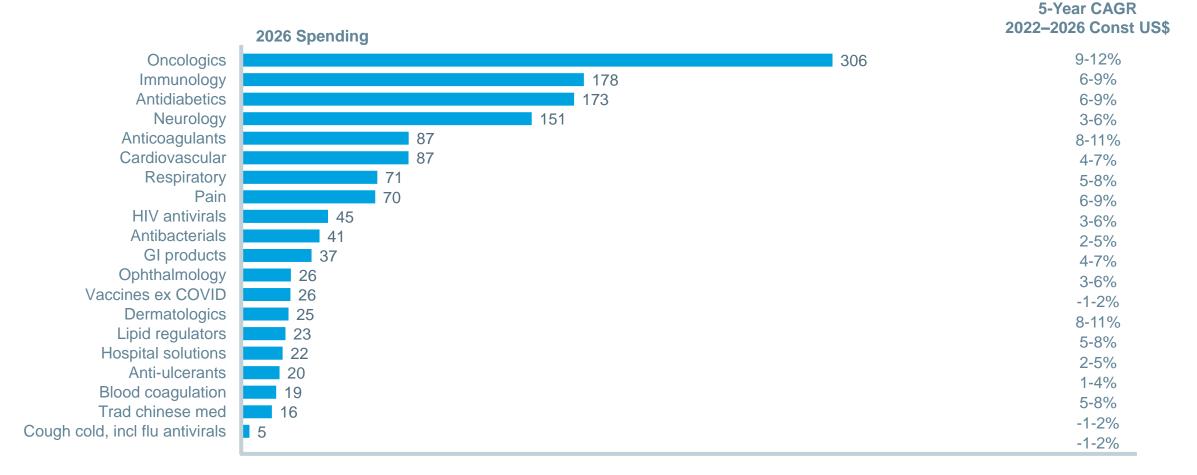
Global savings from biosimilars 2021-2026





Oncology and neurology lead growth while immunology slows due to biosimilars

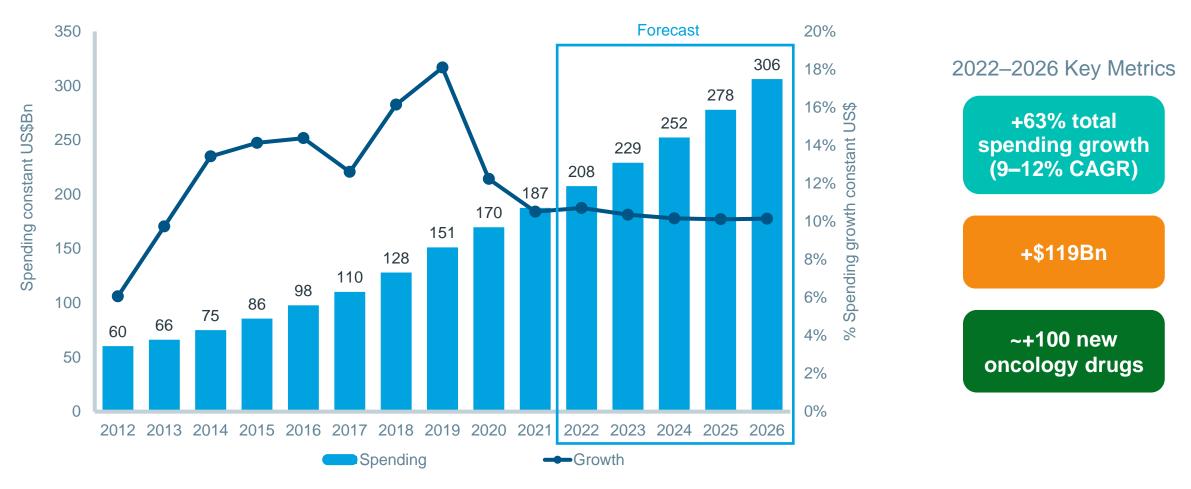
Top 20 therapy areas in 2026 in terms of global spending with forecast 5-year CAGRs, const \$US





Global oncology spending to exceed \$300 billion by 2026, with growth slowing to 10% from biosimilar savings

Global oncology spending and growth

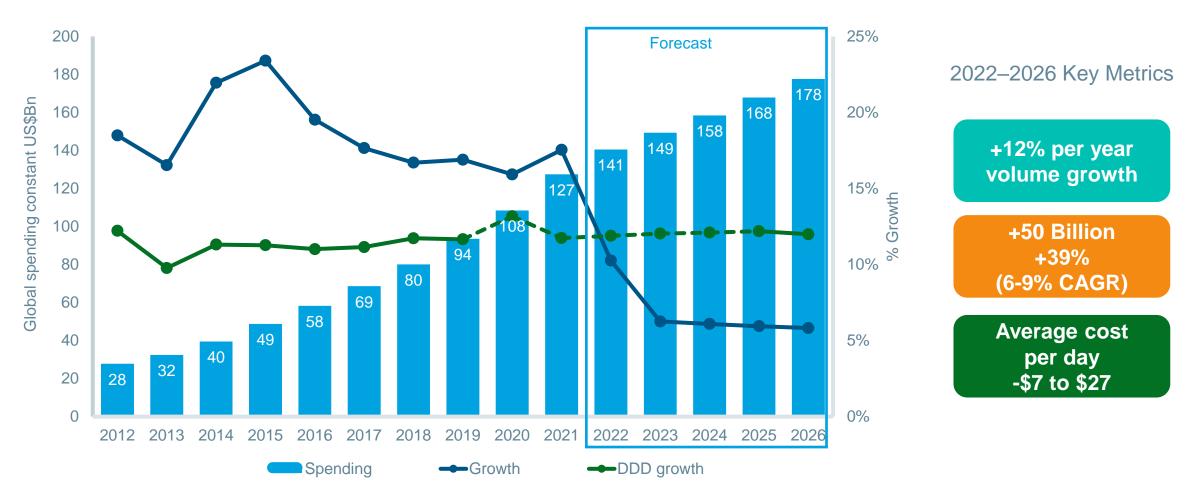


Source: IQVIA Institute, Nov 2021 The Global Use of Medicines 2022: Outlook to 2026. Report by the IQVIA Institute for Human Data Science



Immunology spending growth to slow to 6-9% through 2026 from biosimilar impact as volume growth continues at 12% annually

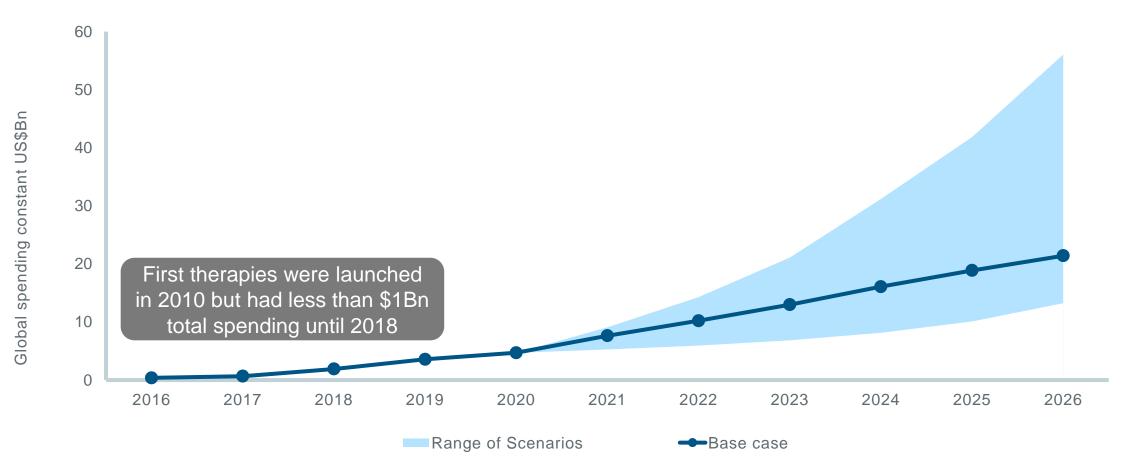
Global immunology Spending and Growth





The outlook for next-generation biotherapeutics includes significantly uncertain clinical and commercial successes

Cell, gene and RNA therapeutics



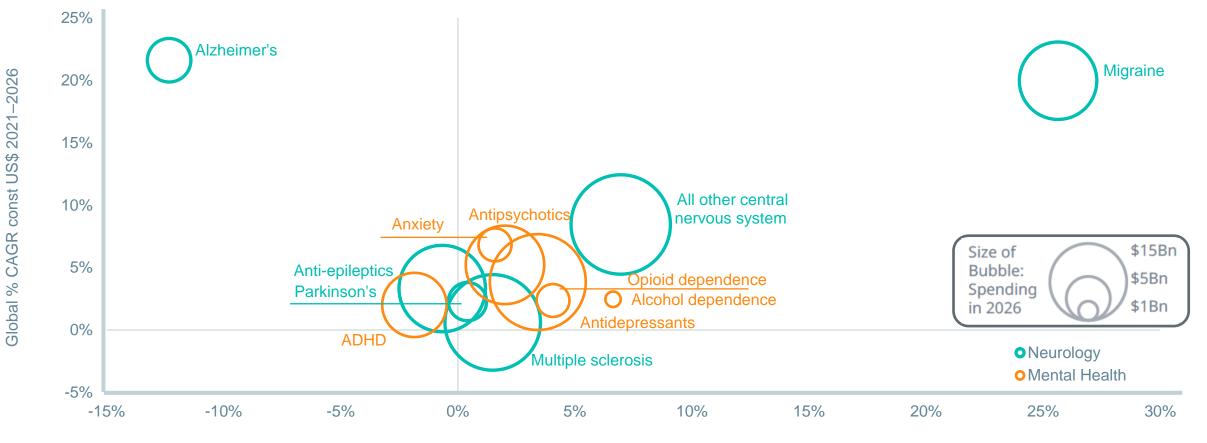
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New therapies in rare neurological disorders, Alzheimer's, and migraine are expected to drive spending growth in neurology

Leading CNS disorders global market growth dynamics



Global % CAGR const US\$ 2016–2021

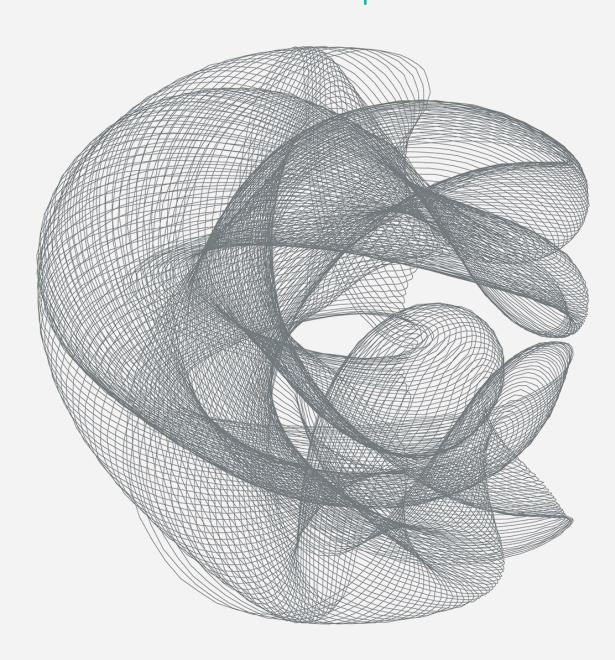


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U.S. MARKET OVERVIEW

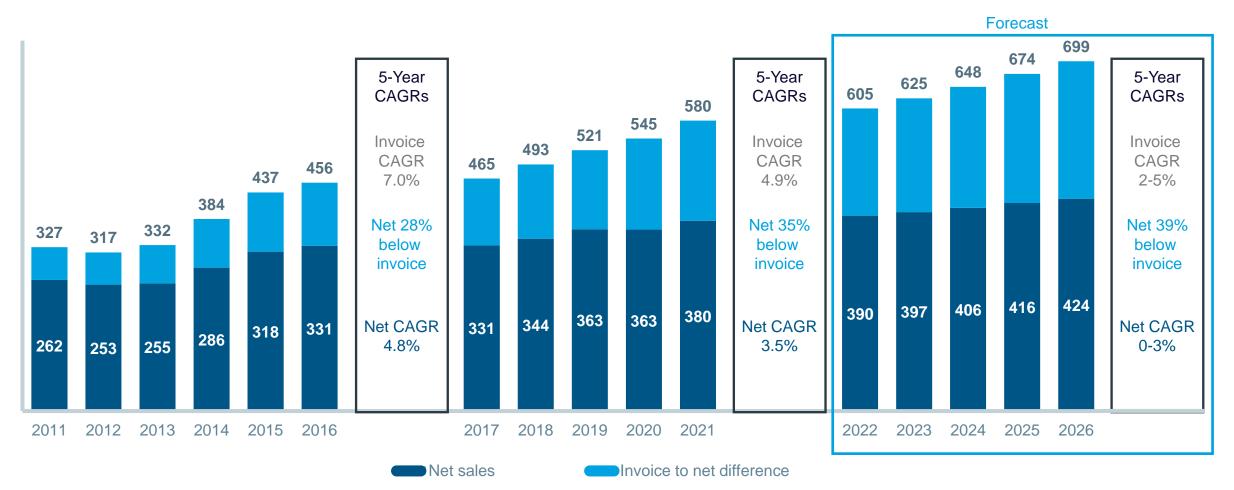
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The U.S. market, on a net price basis, is forecast to grow 0–3% CAGR over the next 5 years, down from 3.5% CAGR for the past 5 years

U.S. Medicine Spending and Growth at invoice-level and estimated net 2011–2026



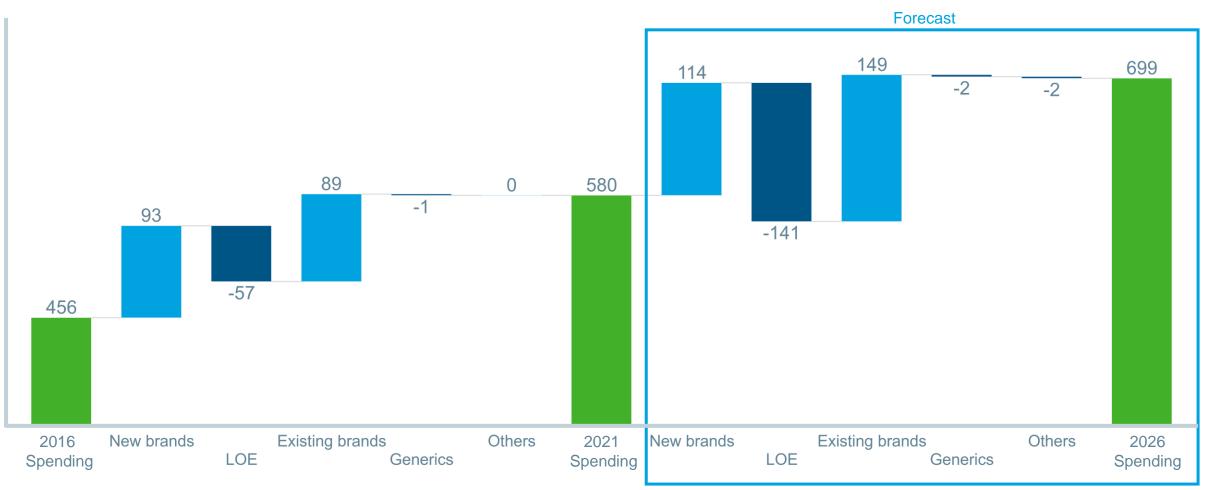
Source: IQVIA Institute, Nov 2021

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Spending in the U.S. is expected to increase by \$119Bn through 2026 driven by new and existing brands

Spending and growth drivers in US 2016–2026 Const US\$Bn

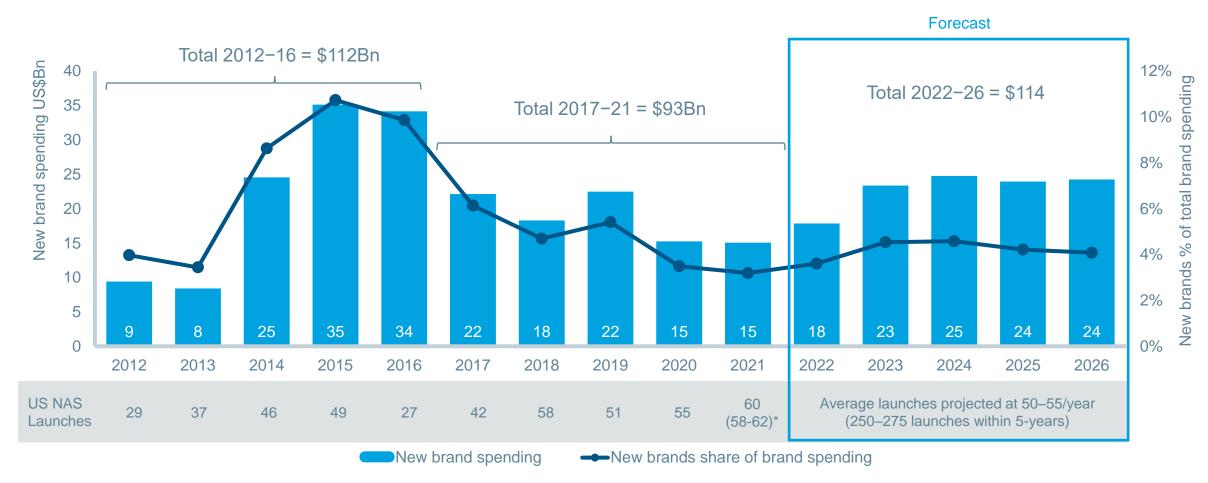


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New brand spending in the U.S. is projected to be higher than the last five years but a smaller share of spending

U.S. New brand spending





The U.S. is an increasingly complex environment

Market dynamics to watch

Perpetual uncertainty of healthcare reform



- Healthcare reform + Part D redesign
- ✓ Growth and controversy in 340B

Payer control in commercial



- ✓ Expanding payer control
- ✓ Formulary exclusions
- Net price pressure in immunology and other specialty
- ✓ New evidence requirements

-3 ,

COVID accelerates new models of care



- New sites, new models pick up impact of loss care
- Rising awareness and evidence of disparity in access
- New opportunity across value chain
- Patient engagement in high demand

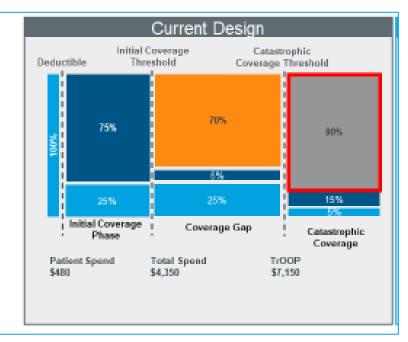


Access and costs under pressure as payers and manufacturers prepare for potential policy changes and new competition

Proposed Part D changes

Reform potential a constant

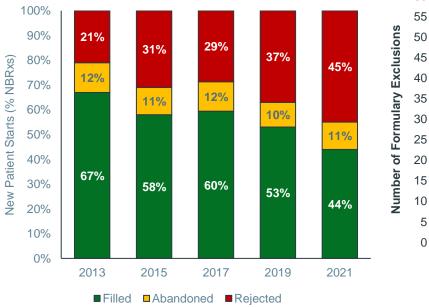
- ✓ Removes coverage gap¹
- Adds manufacturer liability in initial and catastrophic phases¹



Increase in access restrictions

Competitive dynamics matter

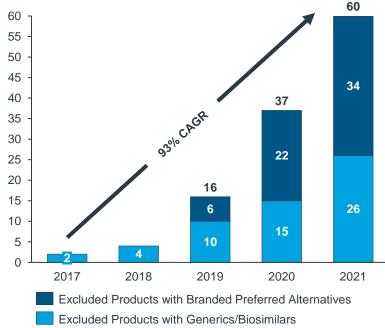
- ✓ Rising number of blocked products in 2021²
- ✓ Specialty patients 20% more likely not to fill a prescription vs 2013³
- ✓ 25% abandonment in specialty for Part D patients⁴



Formulary exclusions

Oncology no longer protected

 Payers address market competition, open the door for more patient alternatives



/∃IQVIA

COVID-19 disrupted care, and the status quo, making room for new players, and new models, to serve and empower patients

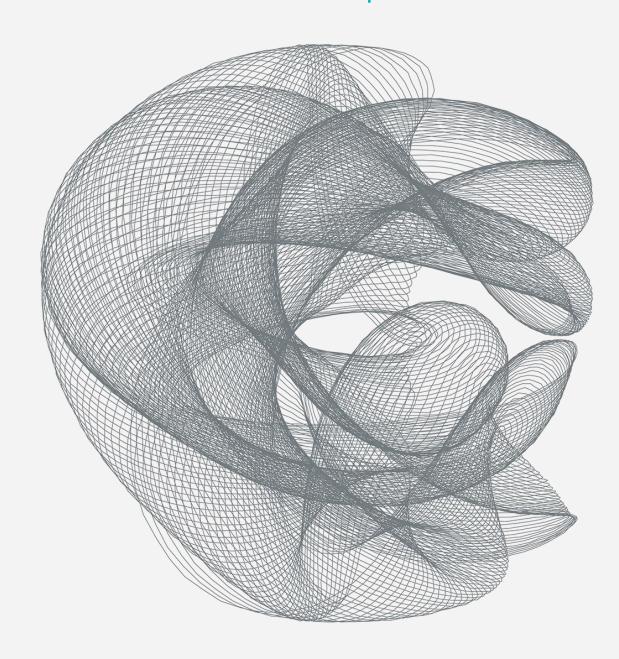
DISR	UPTION				INNOVATION		
<u>/</u> }	8.5M	missed preventive health visits, unevenly distributed ¹	\$15B	Raised in 1H2021 for telemed platforms ⁵	38 Sta	38 States expand telehealth coverage ⁷	
4	269M	missed diagnosis visits in 1H2021 ²	7.9%	CAGR through '27 in home healthcare market ⁶	\$29B	Digital Health Funding in '21 (2x 2020) ⁸	
<u>/</u>	-8%	compound annual growth rate of oncology diagnosis visits from 2019 to 2021 ³	Hospital	Dital-centric		tail Home & Virtual	
<u>/</u>	2,901%	 Growth in telehealth claims compared to 2021 vs 2019⁴ 		the medical CVS Heαlth CVSHeαlth CVSHeαlth	SQLIS O Lund Manualy of the alth		

Sources: ¹Health Equity in the Time of COVID-19, IQVIA; ^{2, 3, 4}IQVIA Claims Data, 2021; ⁵https://mercomcapital.com/product/1h-q2-2021-digital-health-healthcare-it-funding-mareport/; ⁶Advancing Health Outcomes Through Home Healthcare, IQVIA; ⁷; ⁸https://rockhealth.com/insights/2021-year-end-digital-health-funding-seismic-shifts-beneath-the-surfa ENSTITUTE FOR HUMAN DATA SCIENCE

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EUROPE OVERVIEW

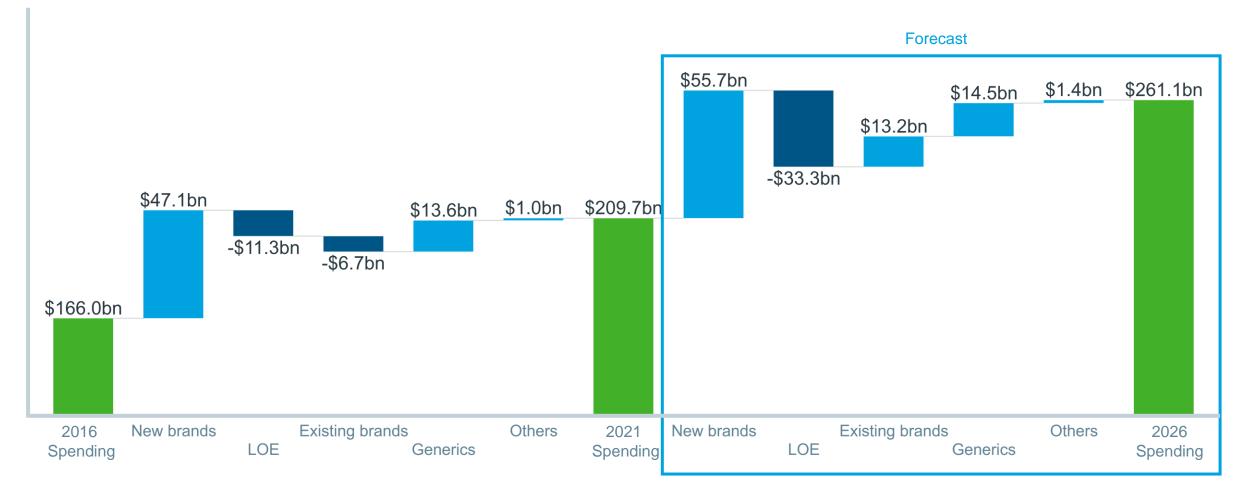
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Spending in top 5 Europe is expected to increase by \$51Bn through 2026 driven by new brands

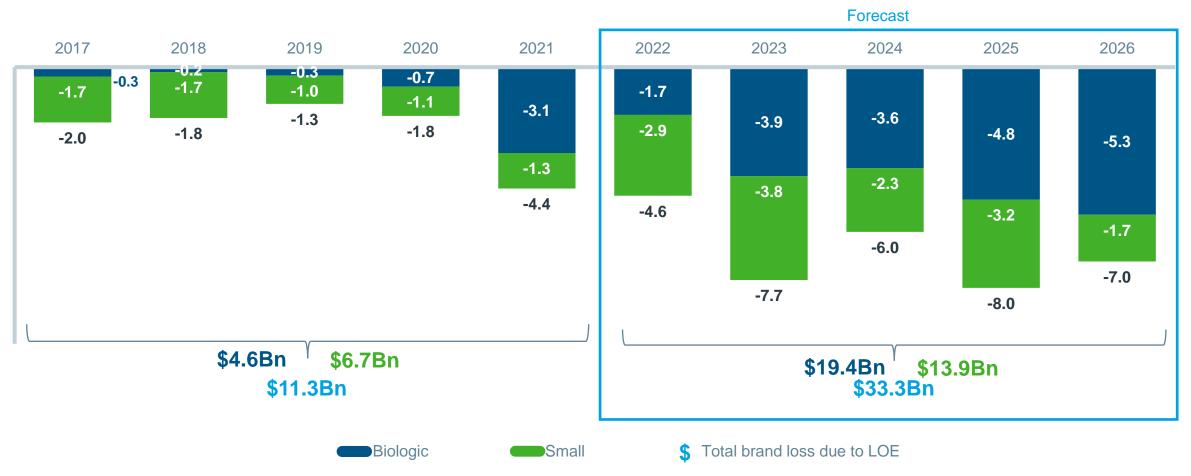
Spending and growth drivers in France, Germany, Italy, Spain, and UK 2016–2026 const US\$Bn





The impact of exclusivity losses will reach \$33 billion over 5 years, with more than half due to the availability of biosimilars

EU4+UK Impact of brand losses of exclusivity 2017–2026, US\$Bn



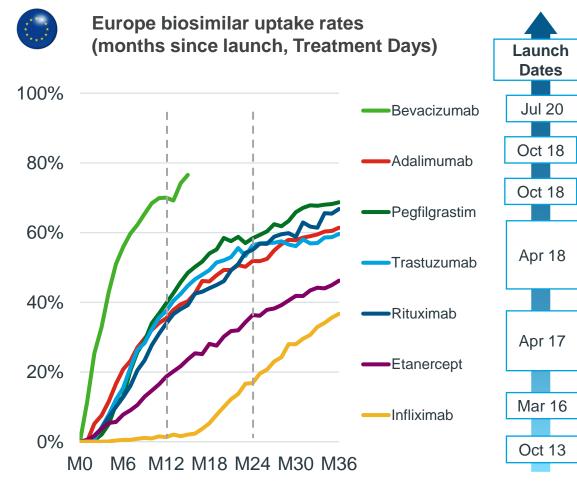
Source: IQVIA Market Prognosis, Sep 2021; IQVIA Institute, Nov 2021

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Rate of uptake of biosimilars has accelerated as stakeholders become increasingly comfortable and competition grows

Biosimilar market averaging 40% after 12 months and likely 60% after 24





Biosimilar market dynamics

- Payers extract steep discounts in EU, eg >80% for Humira in Nordics...
- ...but savings have not translated into consistent volume expansion of biologics



• Originators are also evolving their offer... -Re-formulation (eg sub-Q; improved excipient) can slow erosion, but only for a while -Aggressive price competition to win back tenders

Competitor • strategies

Biosimilar manuf. are **innovating**... –Celltrion launched infliximab sub-Q formulation in EU – while original Remicade only available as IV



- Even greater budget pressures will drive payers to aggressively seek savings
- **9** Catalyst for changing biosims. dynamics?



Market access environment in EU4+UK remains challenging and some countries aim for reforms

Healthcare cost containments as a focus together with improving HTA processes

- Faster, more agile NICE assessments to increase access to innovation
- Population Health Agreement
- Favourable Biosimilar Launch country

France

- Improve Patient Access (LFSS)
- Ensure Drug Supply Security
- Increase Gx and Bx Usage

Spain

- Streamline HTA system
- Approval of Hospital-developed Cell Therapy
- Promote wider Gx and Bx Usage



Germany

- New Coalition focus on Cost Containment (AMNOG)
- Call for end of "Orphan Privilege"
- Discussion Substitution for 26 Biosimilar Candidates

Italy

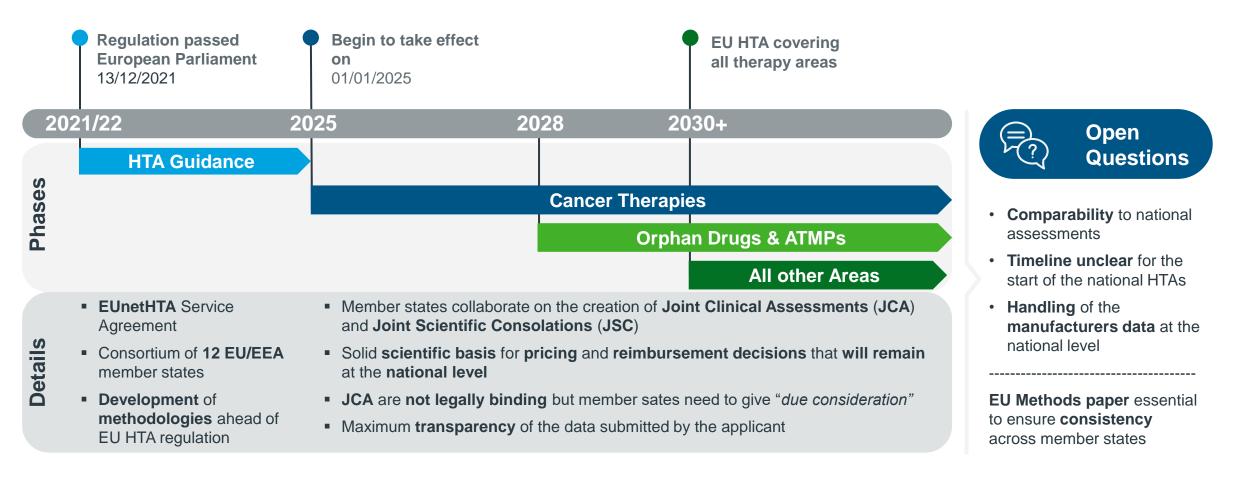
- 30% Increase in Funds for Innovative Medicine
- AIFA reorganisation
- Faster Access to Orphan Drugs

Pan-European HTA by 2025: "a key deliverable of the European Pharmaceutical Strategy and an important building block for a European Health Union" – Health Commissioner Stella Kyriakides



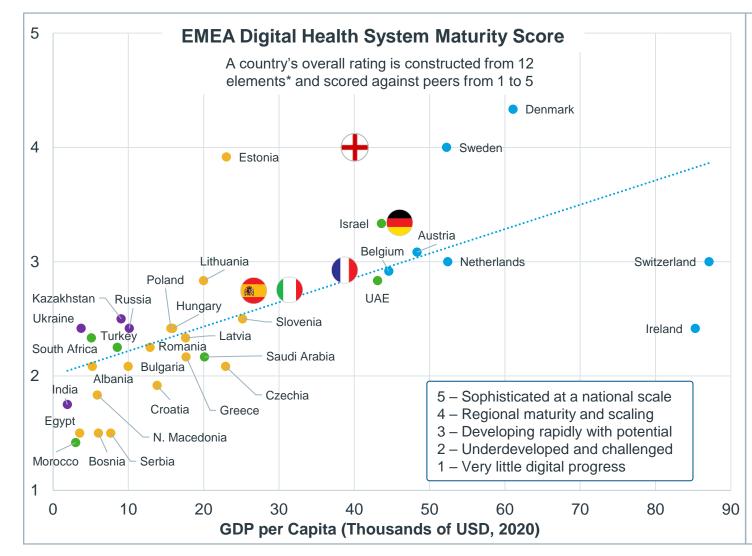
EU proposes harmonised regulation on HTA in a phased approach, starting with cancer therapies in 2025

Aim to improve medicine availability, ensure efficient resource usage and strengthen HTA quality



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Healthcare system digital maturity accelerates, but not all countries develop at the same pace



Impact on Medicines Innovation and use

- Innovation and insight: Mature countries have well developed patient data collection, including EHR, Genomic data and consistent data standards which can drive RWD collection, speed clinical development; telemedicine infrastructure speeds remote trial implementation
- Evaluating medicines use and impact: digitally mature countries have the infrastructure and governance to collect and use nation wide data on medicines use and outcomes, and to act on that – enabling, for example, the possibility of evidence based medicines use and population health agreements
- Rationalising medicines use to drive cost savings: Europe has had the lengthiest history of biosimilar approval and uptake, but uptake is still variable and cost saving impact could be driven faster with better use of data to track progress

Notes: *These 12 elements belong to three groupings. Initiatives: policy, funding, data governance, institutions. Infrastructure: Electronic health records, data standards, omics, interoperability. Implementation: telehealth, AI, information use, virtual studies Source: IQVIA European Thought Leadership; GDP per capita data obtained from World Bank Open Data; Framework scores are based on interviews and surveys with internal IQVIA experts

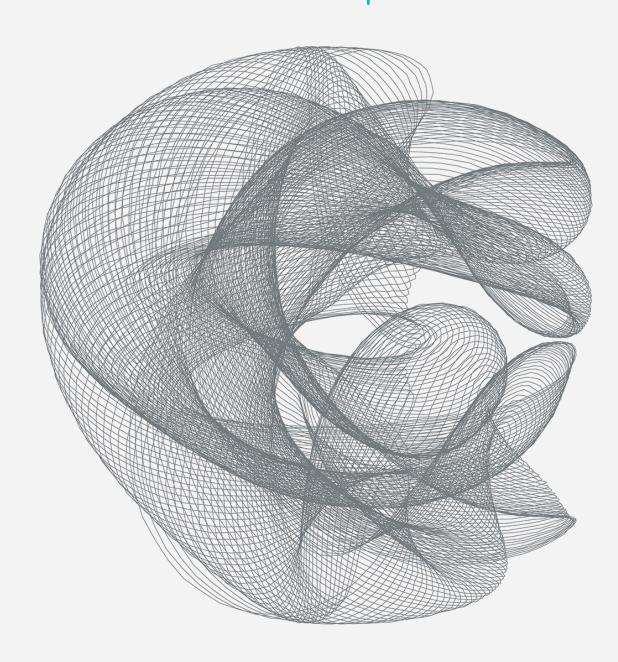


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The Global Use of Medicines 2022

CHINA OVERVIEW

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China's healthcare reform is shifting the market towards a value-based innovation focused market

Market Access in China						
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Regulatory Registration	Manufacturing & Supply	Tendering & Distribution	Hospital Listing	Prescription	Reimbursement	
Expedited Approval	Localization of Manufacturing	Volume-Based Procurement (VBP)	Tiered Care System	Digital Healthcare Revolution	NRDL Adjustment	
Encouraged innovation	Deglobalization	Mechanism normalization and price cut of drugs	Diagnosis and Rx outflow to improve efficiency	Digitalization in the entire industry ecology	Healthcare expenditure control thanks to negotiations	
NMPA (Regulator)	NMPA (Regulator)	NHSA (Payer)	Hospital (Provider); NHC (Regulator)	Hospital (Provider); NHC (Regulator)	NHSA (Payer)	
٢	٢	$\overline{\mathbf{i}}$			$\overline{\mathbf{c}}$	
	Regulatory Registration Expedited Approval Encouraged innovation	Regulatory RegistrationManufacturing & SupplyExpedited ApprovalLocalization of ManufacturingEncouraged innovationDeglobalization	Regulatory RegistrationManufacturing & SupplyTendering & DistributionExpedited ApprovalLocalization of ManufacturingVolume-Based Procurement (VBP)Encouraged innovationDeglobalizationMechanism normalization and price cut of drugs	Regulatory RegistrationManufacturing & SupplyTendering & DistributionHospital ListingExpedited ApprovalLocalization of ManufacturingVolume-Based Procurement (VBP)Tiered Care SystemEncouraged innovationDeglobalizationMechanism normalization and price cut of drugsDiagnosis and Rx outflow to improve efficiencyNMPA (Regulator)NMPA (Regulator)NHSA (Payer)Hospital (Provider);	Regulatory RegistrationManufacturing & SupplyTendering & DistributionHospital ListingPrescriptionExpedited ApprovalLocalization of ManufacturingVolume-Based Procurement (VBP)Tiered Care SystemDigital Healthcare RevolutionEncouraged innovationDeglobalizationMechanism normalization and price cut of drugsDiagnosis and Rx outflow to improve efficiencyDigitalization in the entire industry ecologyNMPA (Begulator)NMPA (Begulator)NHSA (Payer)Hospital (Provider); Hospital (Provider);Hospital (Provider); Hospital (Provider);	



Spending growth in China is expected to accelerate post-COVID, driven almost entirely by new original medicines

China medicine spending by product type 2011–2026

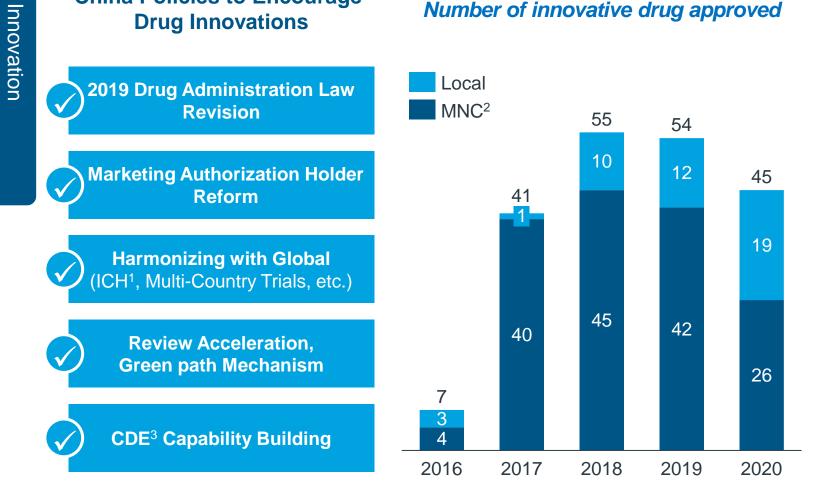


Source: IQVIA Market Prognosis, Sep 2021; IQVIA Institute Nov 2021

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Fueled by favorable policies since 2017, new launches of innovative medicines have rapidly increased



Launch lag between China and Global



Source: IQVIA database, IQVIA analysis, desk research

1. ICH: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

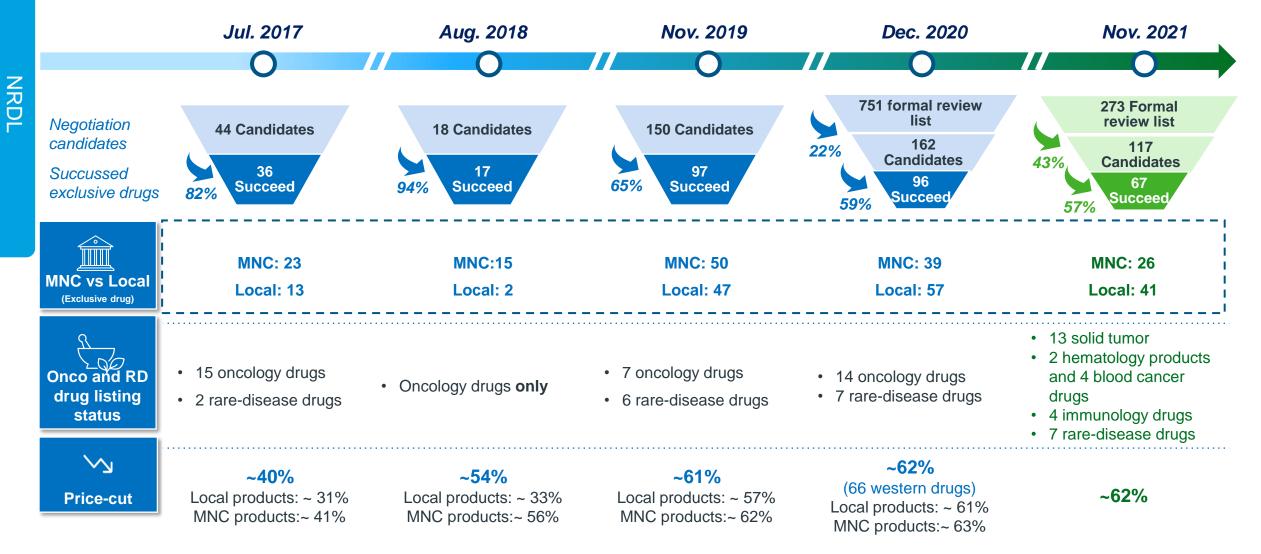
2. MNC: Multi-National Company; 3. CDE: Center for Drug Evaluation

China Policies to Encourage



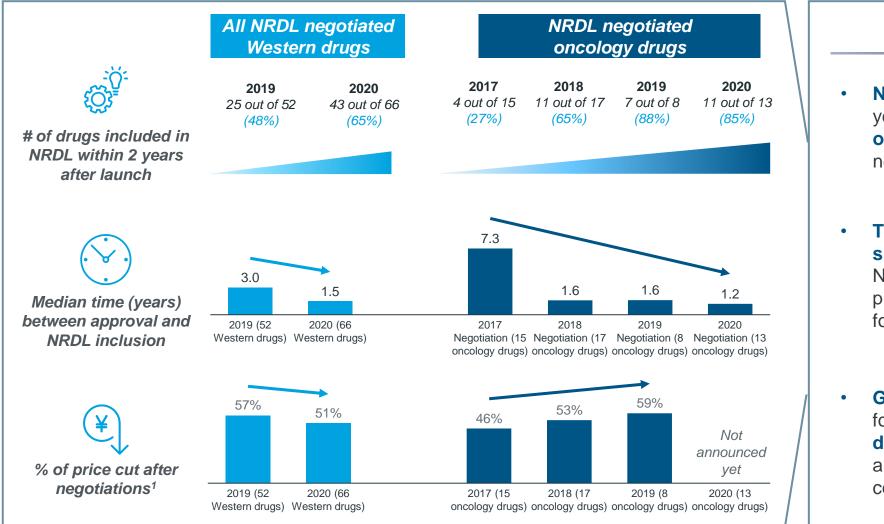
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Innovative drugs are increasingly gaining NRDL access, however, pressures on price-cuts to enter is continuing to increase





Timeframe from approval to NRDL listing have shortened significantly with increased pressure for price reductions



Key takeaways

- Newly-launched drugs in recent years have more reimbursement opportunities to be included by negotiation
- **Time interval is sharply shortened** between launch and NRDL listing than ever, indicating products must **prepare in advance** for entering market
- Greater price cut is observed for newly listed innovative drugs, especially oncology drugs, and the trend is expected to continue

Note: 1. Price cut was calculated by comparing the reimbursement price negotiated against the lowest provincial bid price before negotiation Source: External Interview; IQVIA analysis

NRDL



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Volume-Based Procurement (VBP) is the national tendering for off-patent drugs in China



- Volume Based Procurement (VBP) was first introduced in 2018, which kicked off national tendering on off-patent drug in China. 5 rounds national-wide by far, while this mechanism would become normalized and institutionalized
- Led by NHSA, VBP bid winners will have sales guarantee for the committed volume (~70% of total hospital market) at the negotiated price with a 2-year contract; while the remaining non-committed market (~30% of total hospital market) is still free-selection based

Healthcare Security Administration

Off-patent drugs with ≥ 2 generics 1) approved in China, 2) passed Generics Quality Equivalence Test (GQCE), are exposed to VBP risk

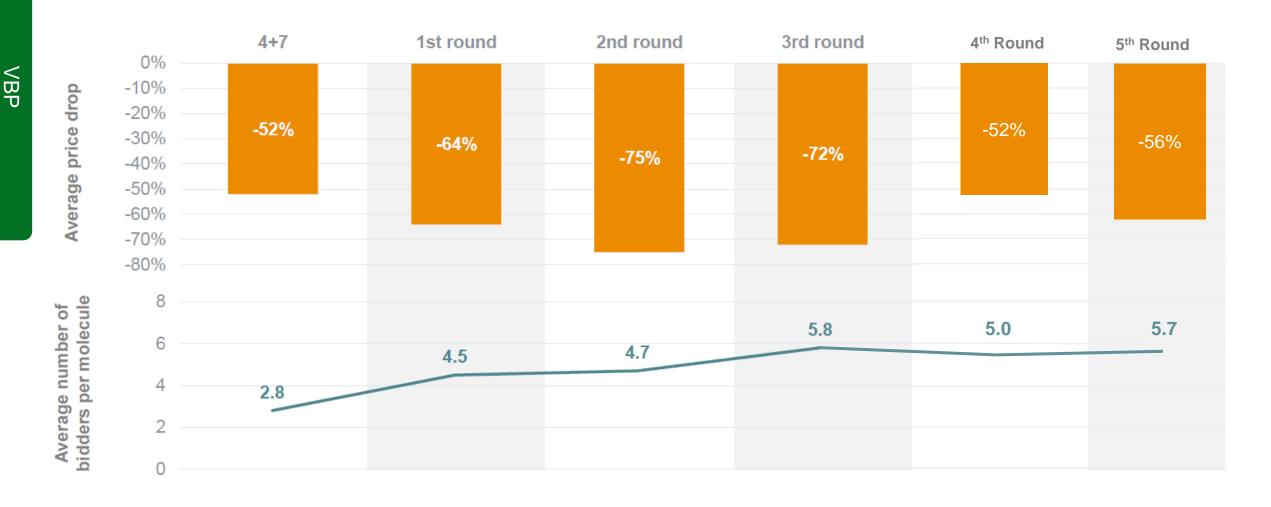
Key Facts on VBP	VBP Mechanisms
 Six rounds of national-wide VBP organized by NHSA with direct impact on off-patent originators since 2019 Average price cut level >50%, with highest at 99% 	 • Originator and GQCE Gx in same competition group • Lowest tender price will be set as <i>bid ceiling price</i> • <i>Lowest price</i> to win the bid
- Over 200 molecules involved contributing beyond	Multiple winners to ensure national supply and share the 70%
 20% of total China market VBP price cut levels varies across molecules because of 	Impact on winners committed market volume by splitting provinces
competitiveness and COGS (Cost of Goods Sold).	
 Chemical drugs face with strong price cut, while competition is milder in biologics, i.e., all insulins won the bidding with average price cut at 41% 	 The remaining 30% non-committed market is still free-selection ~30% price cut enforced on originators after VBP becomes effective

Key findings:

VBP is regarded as China version of patent cliff, as originator will still experience enforced price cut (~30%) even lose-bid. Early planning on patent and launch strategy in China is crucial to prolong product lifecycle



The price drop required vs the lowest pre-VBP price to be stabilizing around $\sim 60\%$, and the average # bidders per molecule continues to increase



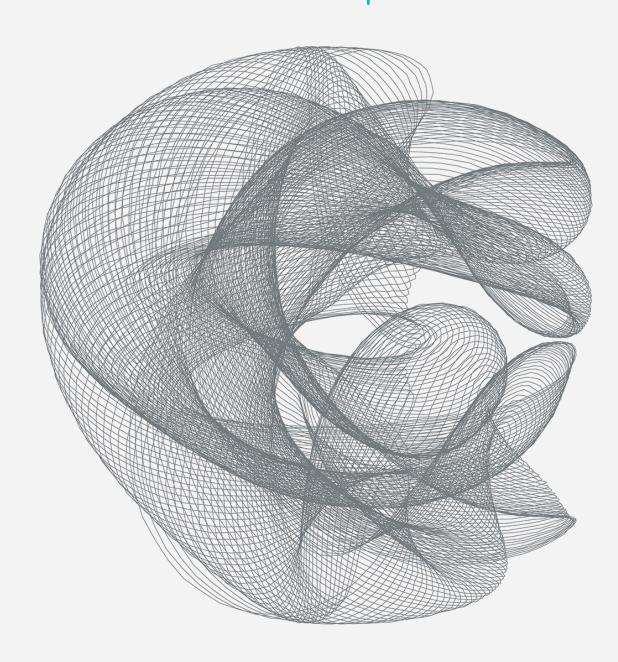


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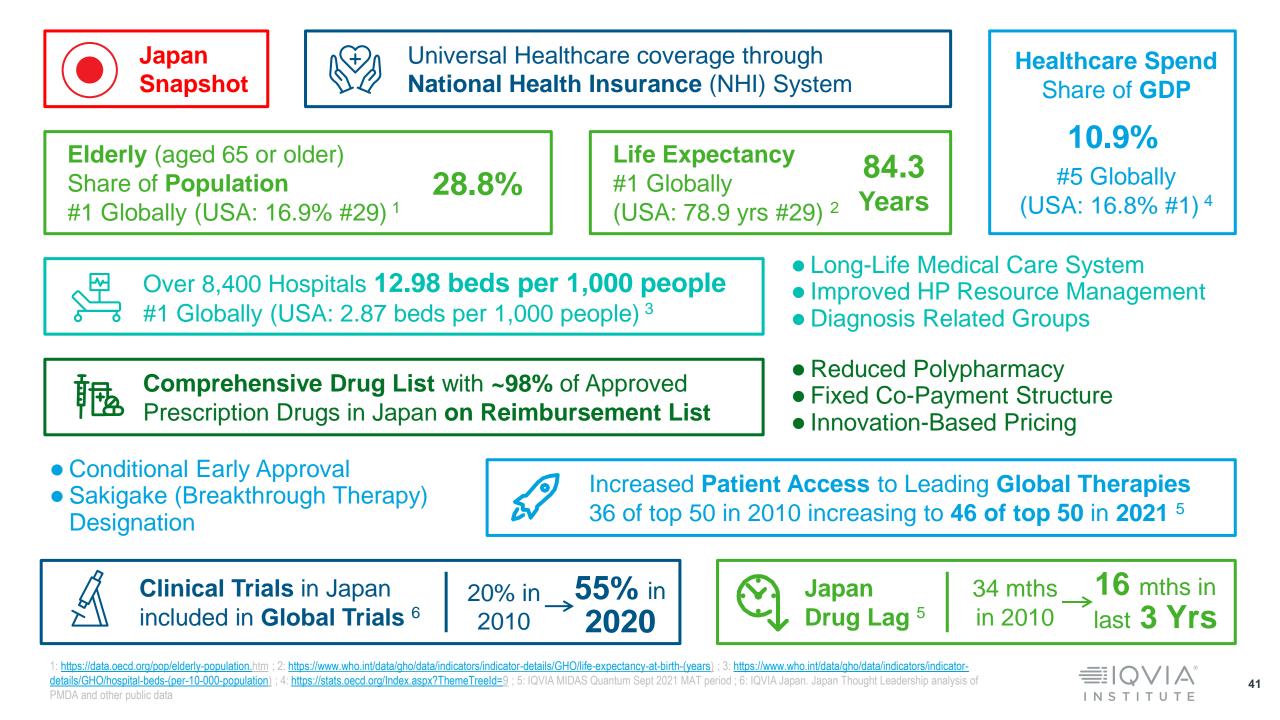
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JAPAN OVERVIEW

JANUARY 2022

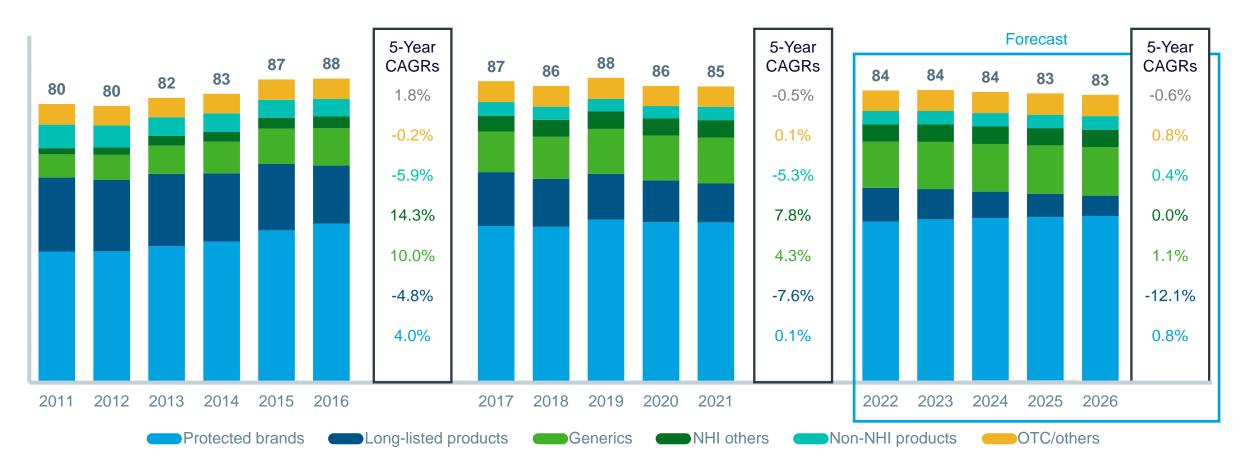


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Japan medicine spending is forecast to decline slightly through 2026 as stronger innovation is offset by shift to annual price cuts

Japan medicine spending by product type 2011–2026, constant US\$ Billions

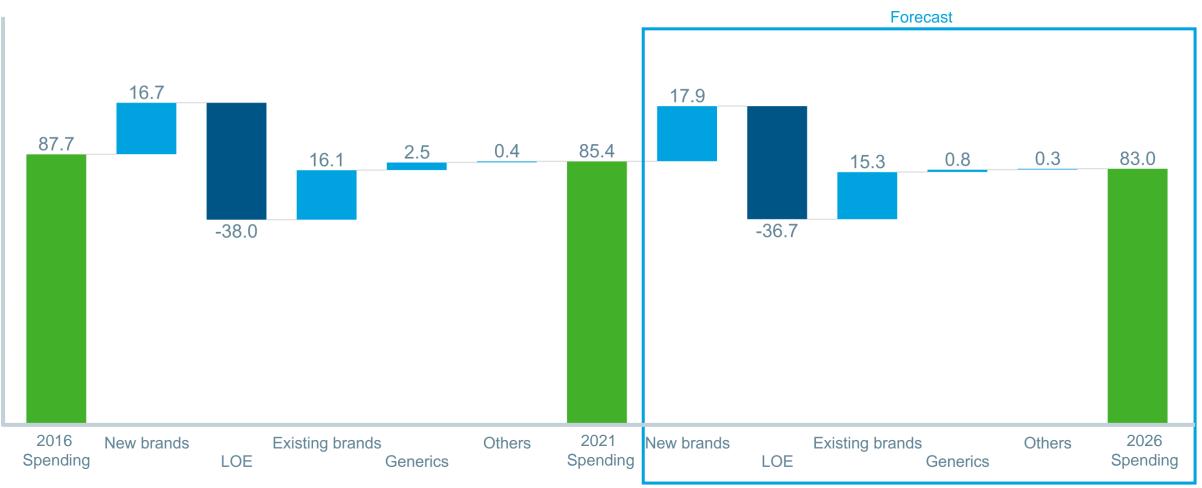


Source: IQVIA Market Prognosis, Sep 2021; IQVIA Japan, Sep 2021; IQVIA Institute, Nov 2021 The Global Use of Medicines 2022: Outlook to 2026. Report by the IQVIA Institute for Human Data Science



While top-line spend remains flat, continued growth expected in Japan from existing brands and contribution from new brands

Spending and growth drivers in Japan 2016–2026 Const US\$Bn



Source: IQVIA Market Prognosis, Sep 2021; IQVIA Institute, Nov 2021

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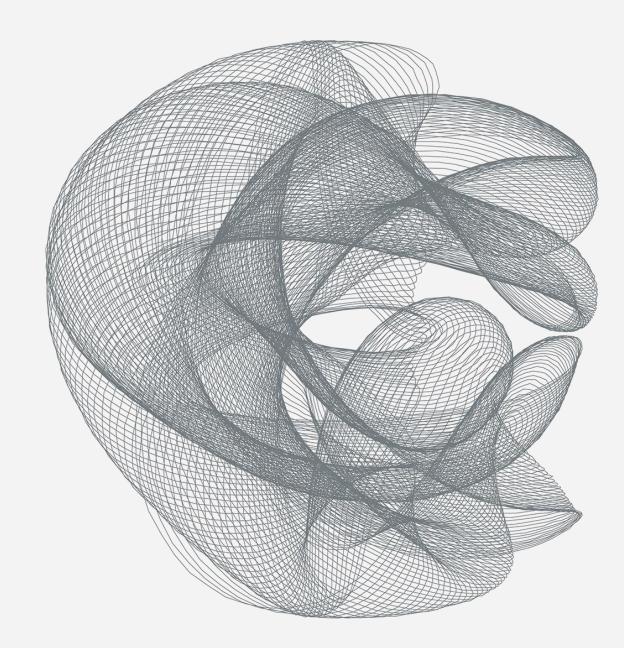


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LATIN AMERICA OVERVIEW

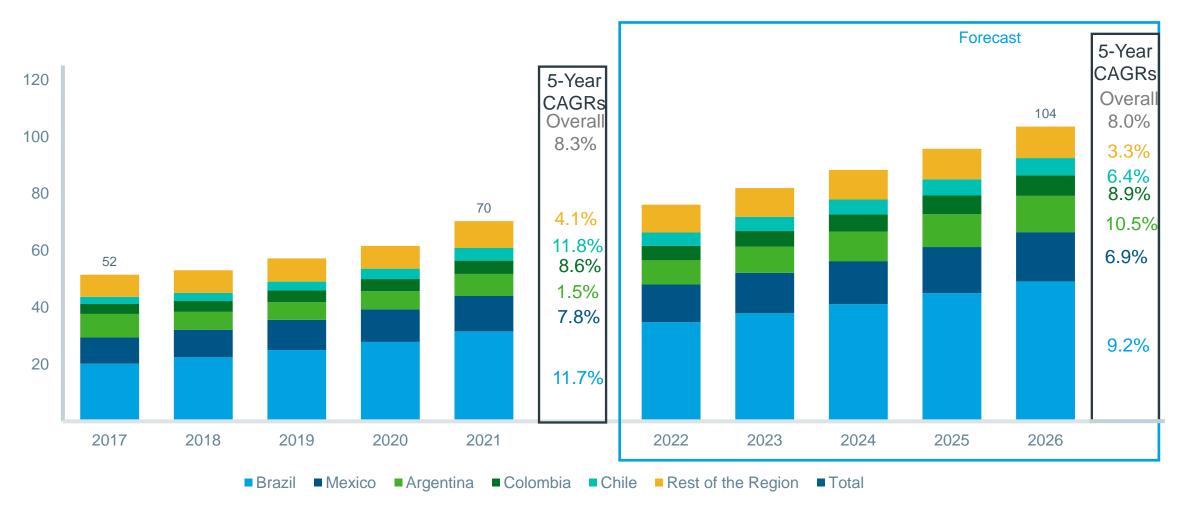
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Medicine spending — using list price levels — is expected to grow at 7-10% CAGR through 2026 to over \$100bn

Latin America medicine market size and growth 2017–2026, const US\$Bn



Source: IQVIA Market Prognosis, Sep 2021; IQVIA Institute, Nov 2021 The Global Use of Medicines 2022: Outlook to 2026. Report by the IQVIA Institute for Human Data Science.

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Spend growth drivers drug type / channel in LatAm

Spend, funding and growth dynamics by drug type / channel in Latin America

	Pharmacy Retail Channel OTC / Consumer Health	Pharmacy Retail Channel Prescription Drugs	Non Retail Channel Prescription Drugs
% of total drug spend	~20% of total spend	~55% of total spend	~25% of total spend
Drug funding model	Mostly Out of Pocket (limited payer funding)	Mostly Out of Pocket (limited payer funding)	Mostly Payer Funded (public and private payers)
Top 5 Therapy Areas / Categories	 Dermatology VMS Analgesics Cough & Cold Anti-acids 	 Cardiovascular Central Nervous System Diabetes Women's Health Antibiotics / fungals 	 Oncology Antibiotics / fungals Immunology Central Nervous System Vaccines
Key Growth drivers	 Post pandemic market accomodation Economic recovery Prevention Ageing population 	 Ageing population Lifestyle habits Mental health Innovation 	 Innovation Post pandemic market accomodation Payer dynamics

Source: Source: IQVIA MIDAS and IQVIA LOCAL COUNTRY AUDITS The Global Use of Medicines 2022: Outlook to 2026. Report by the IQVIA Institute for Human Data Science

Dr

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Several initiatives aimed at broadening access while reducing cost

- Slow implementation of Insabi
- Move to centralize purchases under UNOPS
- **Delays in sanitary registration** given frequent changes in the commissioner
- Reduction in times at Cofepris for new molecules thanks to process optimization and equivalence agreements with other agencies
- National drug formulary changed to the consolidated "Compendio Nacional"
- For **new medicines**, request of forms for "Anexo 5" to gain **access to the National formulary**
- Consolidation of SERCOP process for purchases in the public sector
- Slow progress in legislating the Organic Health Code bill
- Increased adoption of DRG in hospital setting
- Increased central procurement through CENABAST
- "Ley de Fármacos II" which approved INN* prescription and labeling changes; price control mechanism still under discussion
- **Increased demand** driven by Ley Ricarte Soto oncology, HIV, vaccines), "Cancer Law" and funding of high cost drugs

Source: IQVIA Analysis *International Nonproprietary Name

- Increased HC spending expected from new left-wing government
- **Slow progress** in approving Rare Disease and Cancer legislations, as well as SIS rollout
 - Increasing number of therapy areas and molecules under direct control
 - Potential changes in the INVIMA and IETS roles for approval, value-based pricing and funding of medicines
 - **Presidential elections May 2022** healthcare likely to be a key point in candidate programs
 - Tax reform may increase tax rates for medicines
 - **IP protection** remains strong despite recent legislation (Article 40 and vaccines IP protection)
 - Continued development and **growth of private sector**, with potential expanded coverage (e.g., oncology, vaccines)
 - Digitalization of public sector through ConnectSUS
 - · Increase use of tenders in public sector
 - Creation of "free" medicines list for PAMI patients
 - Widening price differentials between **PAMI prices** and list prices
 - Lack of new innovative medicines included in PAMI
 - Delay in AGNET (HTA) implementation; high degree of rejection (75%) from CONETEC



Concluding thoughts

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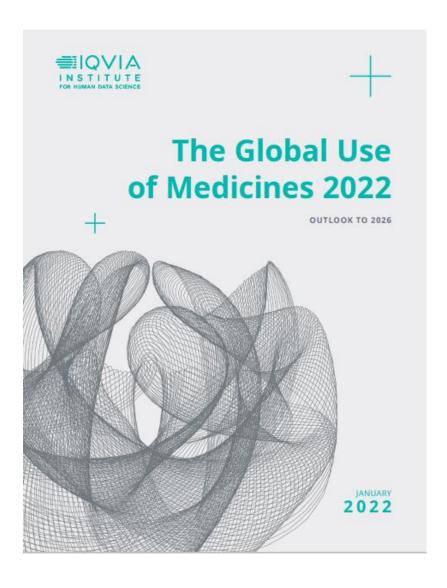
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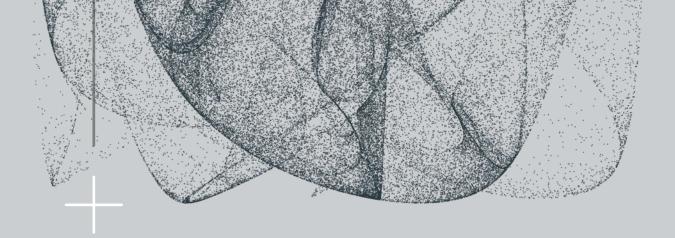
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