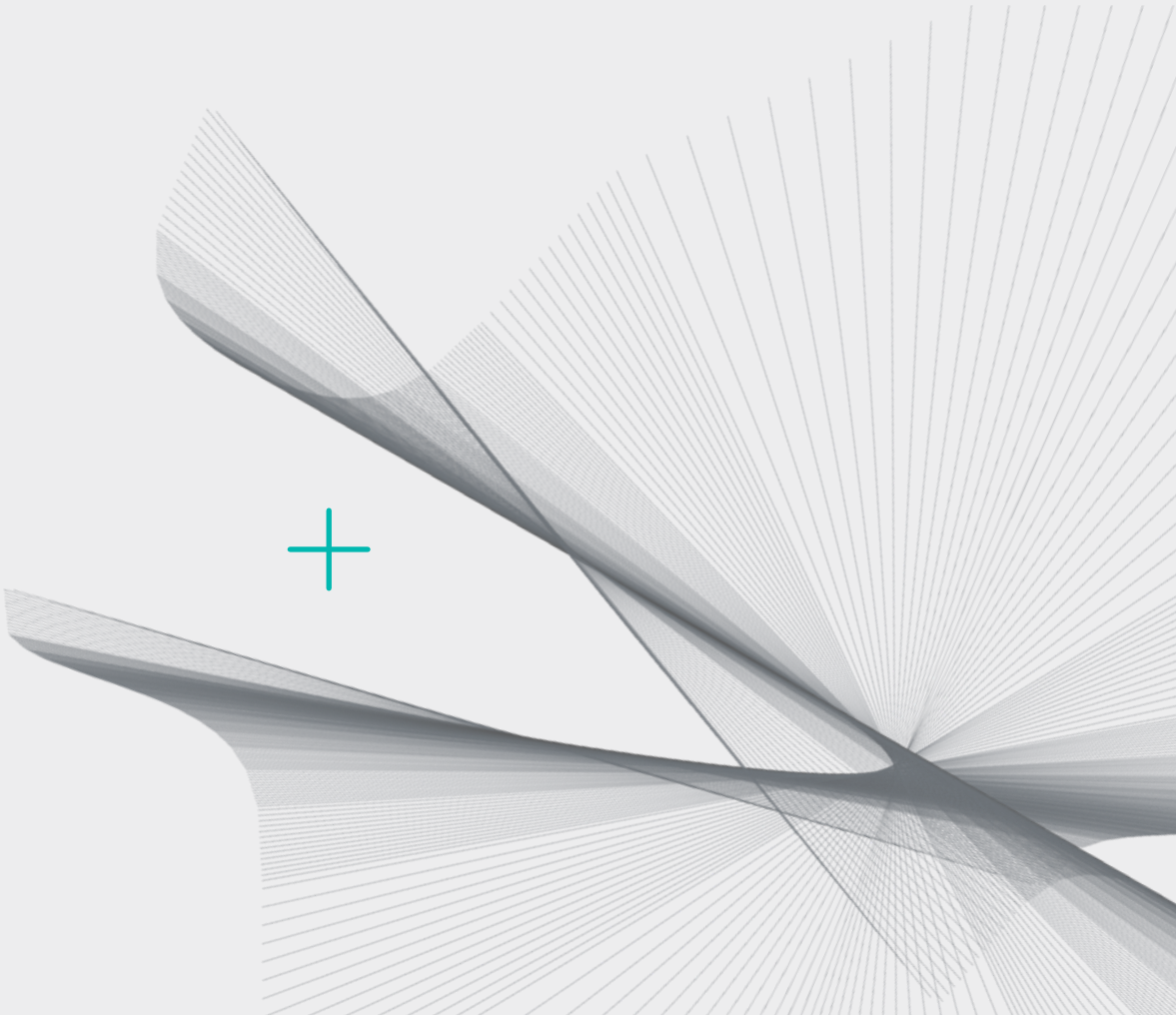
IQVIA INSTITUTE FOR HUMAN DATA SCIENCE

U.S.–India Medicine Partnership

INDIA'S CONTRIBUTION TO THE U.S. HEALTHCARE SYSTEM



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2024

Introduction

The supply of affordable medicines is crucial for the overall health of U.S. residents and managing chronic health conditions. Indian pharmaceutical companies play a critical role in supplying affordable medicines that enhance patient access, improve management of health conditions, and bring savings and sustainability to the overall health system. Concerns around the geographic consolidation of manufacturing of key starting materials and active pharmaceutical ingredients supply chain provide further opportunity for Indian companies to partner with the U.S in de-risking the supply chain.

This report summarizes data on the importance of generic medicines and their role in treating chronic health conditions and providing savings to the U.S. healthcare system. The contributions of Indian companies to the U.S. drug supply are detailed in terms of prescriptions, patient access, and savings.

We also characterize the state of the supply chain of generic medicines, including the supply of key starting materials and active pharmaceutical ingredients used in manufacturing processes. The current state of the supply chain presents challenges and opportunities that could be potentially addressed through further partnership with Indian pharmaceutical companies.

The study was produced independently by the IQVIA Institute for Human Data Science, drawing on proprietary IQVIA data. Funding for this report was provided by the Indian Pharmaceutical Alliance.
The contributions to this report of Sebastian van der Ree are gratefully acknowledged.

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MURRAY AITKEN
Executive Director
IQVIA Institute for Human Data Science

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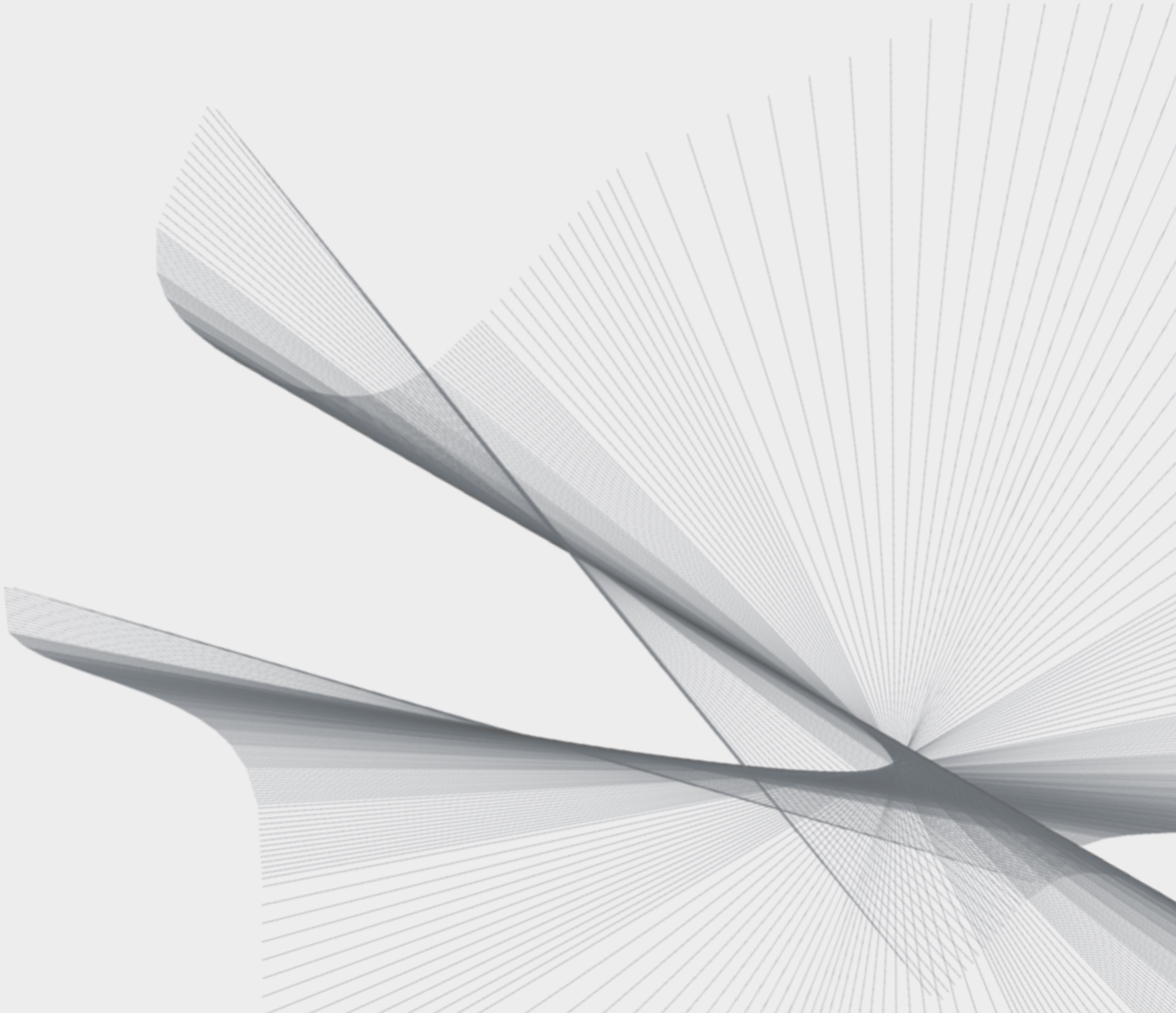
Table of Contents



BACKGROUND ON GENERICS

In the U.S., chronic diseases are prevalent among adults and account for 90% of national health expenditures. Prescription medicines, particularly affordable generic drugs, are essential for managing these conditions. In 2022, Americans filled 6.7 billion prescriptions, and more than 90% of these were for generics. Generic medicines also contribute significantly to the sustainability of the U.S. health system by generating savings. In 2022, generic drugs saved the U.S. health system $408Bn, and nearly $2.9Tn over the last decade. These savings relieve the financial burden on stakeholders and pave the way for financing more expensive innovative drugs.

INDIA'S CONTRIBUTION: PRESCRIPTIONS AND PATIENT ACCESS

In terms of prescriptions, Indian pharmaceutical companies supply a substantial proportion of drugs to U.S. residents, with four out of ten of all prescriptions filled in the U.S. in 2022 being supplied by Indian companies. In particular, Indian companies supplied 47% of all generic prescriptions filed in the U.S. and 15% of the volume of biosimilars. Indian companies provide nearly half of generic medicines paid for through Medicare and commercial insurance, providing affordability to employers and federal programs. The supply of affordable drugs by Indian companies can help enhance the reach of crucial drugs for patients. A case study of Rosuvastatin showcases that entry generics, mostly from Indian companies, led to 28 million additional patients (54 million total estimated patients with generic entry vs. 26 million projected patients without generic entry between 2016 and 2022) receiving the drug compared to the trend that was observed prior to generic entry.

Out of the top 10 therapy areas by prescription volume, Indian companies supplied more than half of the prescriptions for five: hypertension, mental health, lipid regulators, nervous system disorders, and anti-ulcerants. The important role of Indian companies can be highlighted by assessing these therapy areas in more detail. For example, nearly half of all adults suffer from hypertension in the U.S. with greater prevalence among males and non-Hispanic adults. High blood pressure can lead to substantial costs for the health system, estimated at $131Bn per year for the direct and indirect medical costs. In 2022, 23 Indian companies supplied 60% of all hypertension drug prescriptions in the U.S. and brought $25.3Bn in savings due to their affordability. Similar trends are observed in the case of mental health drugs as well.

Overall, medicines from Indian companies provided $219Bn in savings to the U.S. healthcare system in 2022 and a total of $1.3Tn between 2013 and 2022.

INDIA'S CONTRIBUTION: SUSTAINABILITY AND SAVINGS

Drugs from Indian companies also support the sustainability of the overall U.S. health system through regular supply and savings due to lower prices. Generic medicines where Indian companies market products are more competitive than those with no Indian company involvement. The market share concentration among competitors is an indicator of competitiveness and the potential resilience to events that may result in

shortages. Overall, medicines from Indian companies provided $219Bn in savings to the U.S. healthcare system in 2022 and a total of $1.3Tn between 2013 and 2022.

Indian companies are expected to continue to play a significant role in providing savings to the U.S. healthcare system over the next five years, contributing $1.3Tn in savings through the supply of generic medicines.

UNDIVERSIFIED SUPPLY CHAIN FOR GENERIC DRUG MANUFACTURING

Ensuring uninterrupted access to these affordable medicines is a vital concern for health and security in the U.S. The COVID-19 pandemic led to notable drug shortages across many countries, including the U.S., highlighting vulnerabilities in the current global pharmaceutical supply chain. In particular, concerns around the concentration and lack of diversification of the overall generic medicine supply chain have been raised in many countries.

The U.S. supply of generic drugs depends on the global supply chain for sources of generic Active Pharmaceutical Ingredients (APIs), with 87% of FDA-registered plants that manufacture APIs used in generics located outside the U.S. Overall, global API production is highly concentrated with China alone generating more than 2 million tons of APIs annually, fulfilling around 40% of global needs.

The U.S. is impacted by the concentration of Key Starting Materials (KSMs) and API production indirectly as well. For example, while India is the main source of affordable generic drugs for the US., it itself depends on China for nearly 70% of its APIs. Likewise, countries in Europe and beyond also experience similar dependencies.

DIVERSIFYING SUPPLY CHAINS: OPPORTUNITIES FOR U.S.–INDIA PARTNERSHIP

For the U.S. health system as a whole, India serves as an important ally, not only for the supply of affordable high-quality drugs, but also through its comparative cost advantages in skilled human resources and through opportunities for collaborations with Indian and U.S. companies. India brings value and quality through its human resources, which are skilled in STEM related subjects. These resources can aid in the global competitiveness of pharmaceutical companies in the U.S. Additionally, there are numerous examples of collaborations between U.S. and Indian pharmaceutical companies in terms of contract manufacturing, research and development, and market penetration. India's history of supplying high-quality affordable medicines and collaborating with U.S. companies positions India well for future engagements with the U.S. health system as a key partner in the uninterrupted supply of these drugs. U.S. has strategic partnerships with India as well as other countries in several important sectors such as energy, minerals, and semi-conductors. Such bilateral and multilateral trade initiatives and partnerships can bolster economic growth, national security, supply chain resilience, and technological innovation, and provide frameworks that can be used for future partnerships.

The U.S. and India governments, through joint statements, have both acknowledged that supply chains for APIs and KSMs are insufficiently diversified, and that there is scope to collaborate to de-risk and diversify. Several policies and other interventions can be considered to develop this partnership, such as bilateral trade agreements, providing incentives to build a reliable supply chain, considering joint manufacturing and other collaborations across Indian and U.S. companies, generating scientific collaborations, and technological upgrades.

Importance of affordable generic drugs in the U.S. healthcare landscape

+ **In the U.S., chronic diseases are prevalent among adults and account for 90% of national health expenditures.**

+ **Prescription medicines, particularly affordable generic drugs, are essential for managing these conditions.**

+ **In 2022, Americans filled 6.7 billion prescriptions, and more than 90% of these were for generics.**

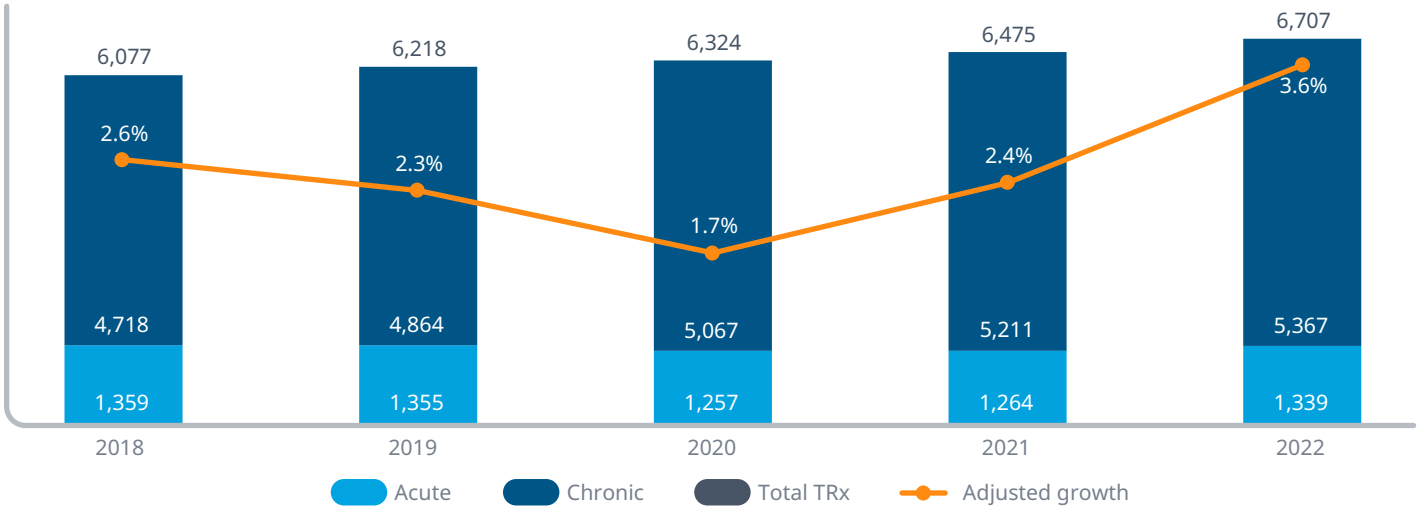
+ **Generic medicines also contribute significantly to the sustainability of the U.S. health system by generating savings; in 2022, generic drugs saved the U.S. health system $408Bn and nearly $2.9Tn over the last decade.**

PATIENTS

Affordable generic drugs contribute to ensuring the management of health conditions for patients in the U.S., which in turn provides benefits to the economy as a whole

In the United States, six out of every ten adults suffer from at least one chronic disease, while four out of ten adults grapple with two or more chronic conditions, including hypertension, heart disease, cancer, and diabetes. Chronic diseases are the primary cause of death and disability in the United States, with individuals afflicted with these diseases accounting for 90% of the nation's health expenditures.[1,2] Prescription medicines play a crucial role in managing these chronic conditions, as well as treating acute conditions that may arise, such as bacterial infections. Notably, affordable generic drugs significantly contribute to this health management; they not only enhance the health of U.S. residents but also bring savings that can help alleviate the financial strain of healthcare spending.

Exhibit 1: Adjusted dispensed prescriptions (Mn) and growth, 2018–2022



Source: The Use of Medicines in the U.S. 2023: Usage and Spending Trends and Outlook to 2027. Report by the IQVIA Institute for Human Data Science.
Notes: Adjusted prescription counts are adjusted for length of prescription and re-aggregated (see methodology). Includes prescriptions dispensed in retail, mail, and long-term care settings. Excludes COVID-19 vaccines and therapeutics. Chronic is determined as whether the medicine is generally intended to be prescribed for more than 180-days, and acute are all other medicines. Chronic and Acute are not specific patent or prescription attributes and do not reflect the potential for some medicines to be used on a long-term basis against recommendations.

PRESCRIPTIONS

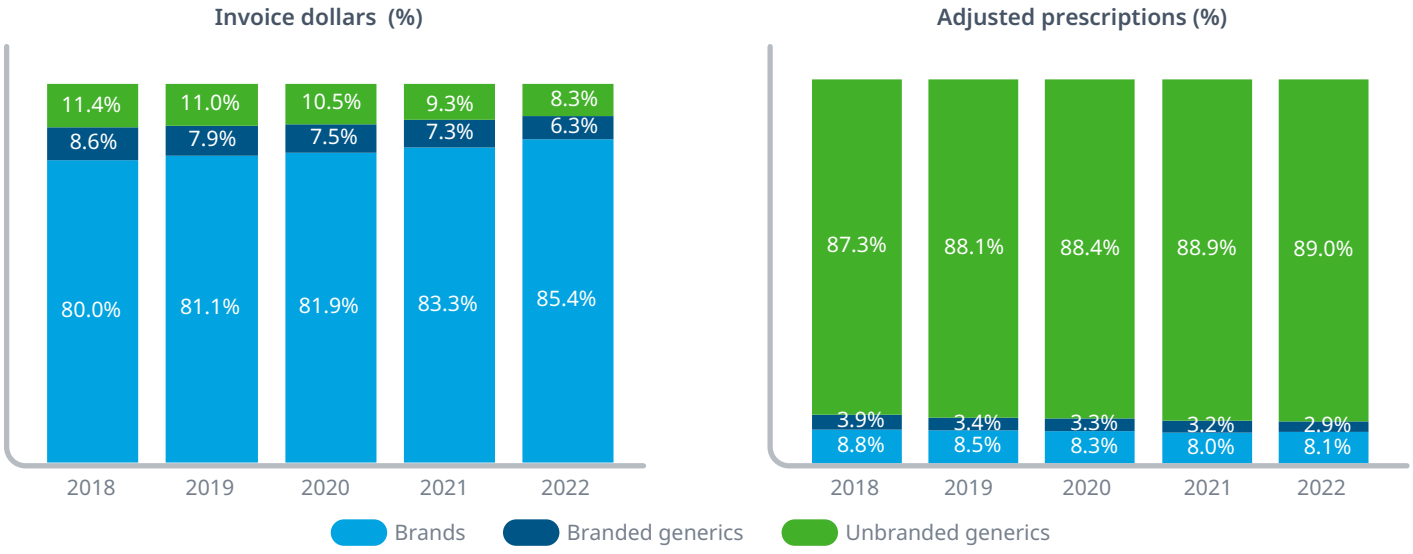
Affordable generic drugs constitute over 90% of the prescriptions filed in the U.S. and are crucial for treating chronic and acute health conditions for patients

In 2022, the number of prescriptions filled by Americans rose to 6.7 billion, marking a 3.6% increase from 2021. This growth continues the upward trend observed from 2018 to 2022, during which prescription volume experienced an average annual rise of 2.5% (Exhibit 1). Of the 6.7 billion prescriptions dispensed, 80% were for chronic therapies. Over the last five years, chronic prescriptions have seen an average annual growth rate of 3.4%, reflecting the rising number of individuals receiving treatment for chronic conditions such as diabetes, anxiety and depression, and cancer.[3] Prescriptions for acute conditions have declined slightly on average -0.7% annually over the last five years, driven primarily by disruptions during the pandemic on the respiratory illness season.[4]

The availability and affordability of generic drugs are vital to addressing both chronic and acute health conditions in the United States. More than 90% of prescriptions filled by U.S. residents are dispensed as generic drugs (Exhibit 2). These medications are relatively inexpensive, accounting for just 15% of the total invoice spending on all medicines in 2022.

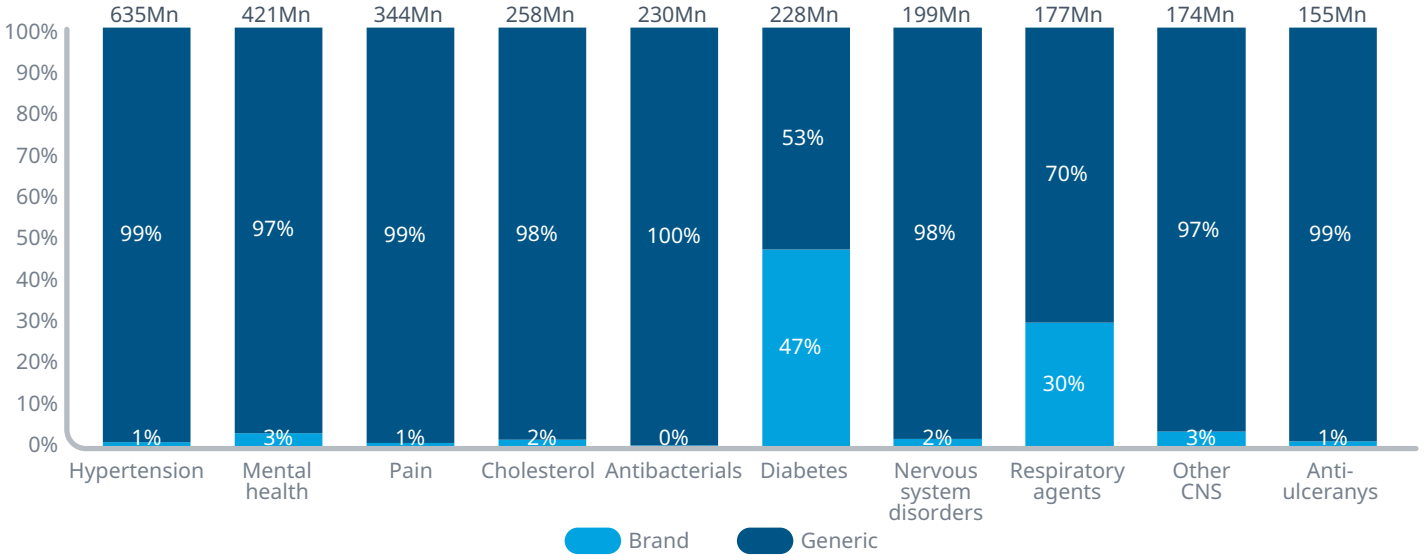
The use of generic drugs is prevalent across the top 10 therapy areas by prescription volume (Exhibit 3). When it comes to the treatment of highly common chronic conditions such as hypertension and mental health disorders, generic drugs make up nearly all prescriptions filled by U.S. residents. However, they constitute a smaller percentage of prescriptions for conditions such as diabetes and respiratory disorders, which have recently begun to lean more towards complex biologic medicines. Antibacterials, which are the most commonly prescribed drugs for acute conditions, are primarily dispensed as generic drugs since most of these medicines have been on the market for decades and are no longer protected by patents.

Exhibit 2: Share of spending and prescriptions by product type, 2018–2022



Source: The Use of Medicines in the U.S. 2023: Usage and Spending Trends and Outlook to 2027. Report by the IQVIA Institute for Human Data Science.
Notes: Prescription counts are adjusted for length of prescription and re-aggregated (see methodology). Excludes COVID-19 vaccines and therapeutics.

Exhibit 3: Share of prescriptions by product type across top 10 therapy areas, 2022



Source: IQVIA National Prescription Audit, Dec 2022; IQVIA Institute, Jan 2024.
Notes: Prescription counts are unadjusted for length of prescription. Includes brand and generic medicines.

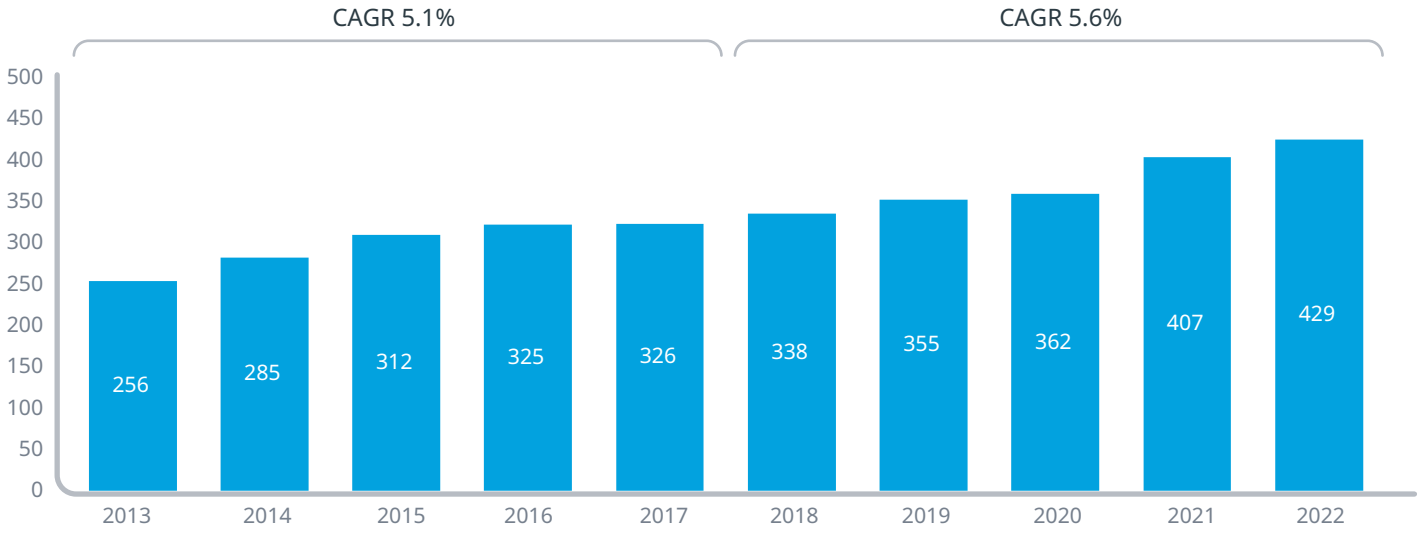
SUSTAINABILITY AND SAVINGS

Affordable generic medicines play a critical role in the sustainability of the overall health system by generating savings across stakeholders

Affordable generic medications not only ensure access to critical health treatments but also enable employers to provide comprehensive healthcare benefits, foster the financial stability of families, and enhance the effectiveness of federal healthcare programs.

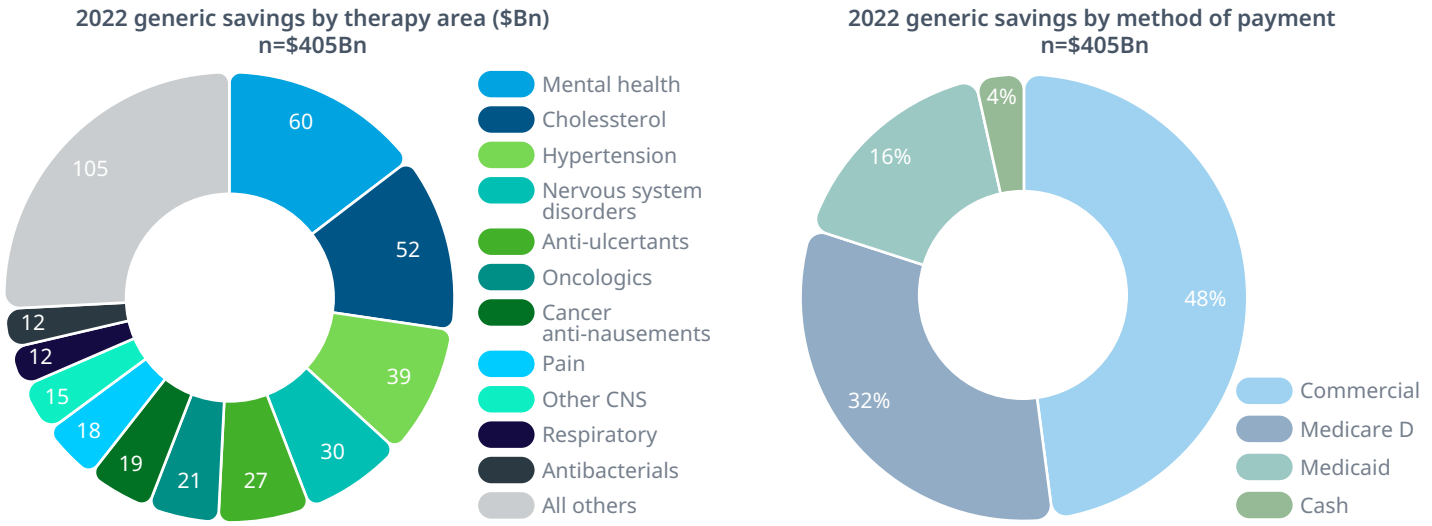
The market for medicines — at manufacturer net sales level — grew 5% in 2022, reaching $429Bn (Exhibit 4).

Exhibit 4: U.S. medicine spending at estimated net manufacturer prices, 2013–2022, US$Bn



Source: The Use of Medicines in the U.S. 2023: Usage and Spending Trends and Outlook to 2027. Report by the IQVIA Institute for Human Data Science.
Notes: Measures total value of spending on medicines, including generics, branded products, biologics, small molecules, and retail and non-retail channels. Net spending reflects company recognized revenue after off-invoice discounts, rebates, and price concessions are applied. Estimates of COVID-19 vaccine and therapeutic spending are based on company financials. Company financials report net revenues recognized by the companies in the U.S. but not necessarily consumed by U.S. patients and it is understood a substantial value of the vaccines were donated to other countries.

Exhibit 5: 2022 generic savings by therapy area and method of payment (n=$405Bn)



Source: IQVIA National Sales Perspective, PayerTrak, Dec 2022.
Notes: Savings is calculated by comparing actual spending to projected spending if total brand and generic volume were at brand pre-expiry prices.

Net spending increased $103Bn in the last five years with a 5.6% CAGR and accounting for 60% of the $174Bn in growth over the past decade. Spending growth between 2017 and 2022 was driven by increased spending on new brands and branded medicine volume growth, particularly in immunology, oncology, and diabetes, as well as COVID-19 vaccines and therapeutics.[4] Increased spending on new and protected brands is offset by the savings generated from the introduction and use of lower-priced generic medicines.

Overall, generic drugs saved the U.S. health system $408Bn in 2022 and nearly $2.9Tn over the last 10 years.[5] Over one-third of generic savings in 2022 was from medicines treating mental health, hyperlipidemia, and hypertension (Exhibit 5). The majority of prescriptions are dispensed to commercially insured patients[3] and, therefore, commercial plans had the highest amount of generic savings in 2022, accounting for $194Bn (48%). Medicare and Medicaid programs saved $130Bn and $67Bn, respectively,[6] in 2022 from the use of generics. These savings provide significant benefits to the federal government as Medicare and Medicaid spending reached $944.3Bn and $805.7Bn, respectively, in 2022 but would have been much higher without the savings from generic medicines. Generic drugs cost patients on average $7.12 per prescription compared to $24.06 for branded drugs,[2] highlighting the significant savings generic medicines provide for patients.

These savings help relieve the financial burden on families, employers, the federal government, and insurers. These savings also pave the way for the financing of more expensive innovative drugs often used to treat more complex chronic diseases and rare diseases. Ensuring uninterrupted supply of affordable generic drugs is critical for management of health conditions and the sustainability of the overall health system as they provide access to high-quality medicines to U.S. residents at affordable costs.

Contribution of Indian pharmaceutical companies

+ **Indian pharmaceutical companies supply a substantial proportion of drugs to U.S. residents, with four out of ten of all prescriptions filled in the U.S. in 2022 being supplied by Indian companies; in particular, Indian companies supplied 47% of all generic prescriptions filled in the U.S. and 15% of the biosimilar volume.**

+ **A case study of rosuvastatin highlights that the introduction of lower cost generics, mostly from Indian companies, led to 28 million additional patients (54 million total estimated patients with generic entry vs. 26 million projected patients without generic entry between 2016 and 2022) receiving the drug compared to the trend that was observed prior to generic entry.**

+ **Out of the top 10 therapy areas by prescription volume, Indian companies supplied more than half of the prescriptions for five: hypertension, mental health, lipid regulators, nervous system disorders, and anti-ulcerants.**

+ **Indian companies provide nearly half of generic medicines paid for through Medicare and commercial insurance, providing affordability to employers and federal programs.**

+ **Overall, medicines from Indian companies provided $219Bn in savings to the U.S. healthcare system in 2022 and a total of $1.3Tn between 2013 and 2022, and generics from Indian companies are expected to generate an additional $1.3 trillion in savings over the next five years.**

Indian Pharmaceutical companies play a multifaceted role in bolstering the U.S. health system and economy. Their contributions span various crucial aspects, including capital investments, job creation, and the provision of affordable medicines that enable the sustainable management of health conditions. These companies have proven to be important partners in addressing the health needs of U.S. residents and in promoting the overall sustainability of the health system.

PATIENT AND PRESCRIPTIONS

Indian pharmaceutical companies play a significant role in supplying drugs to U.S. residents; the affordability of drugs supplied by Indian companies can also enhance the reach for patients

Overall prescriptions

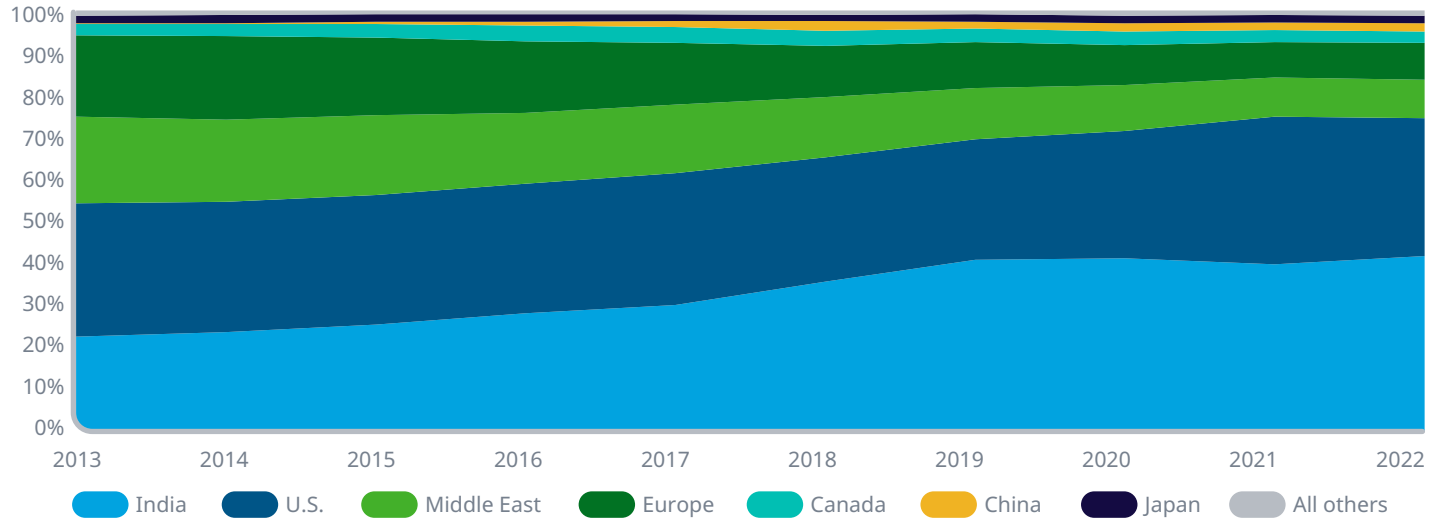
In 2022, 42% of all prescriptions filled by U.S. residents were supplied by Indian companies, a notable increase from the 22% recorded a decade ago (Exhibit 6). Indian companies were responsible for 1.8 billion prescriptions filled by U.S. residents in 2022, a considerable rise from 954 million in 2013. This increase represents an average annual growth of 7% over the past decade.

Indian companies are extremely important for the supply of affordable generic drugs, with 47% of generic prescriptions being supplied by Indian companies (Exhibit 7). Indian companies account for a lower but important share of biosimilar production as well, manufacturing 15% of biosimilar volume used by U.S. patients in 2022. While both Korean and Indian companies account for one-third of biosimilar volume, these companies only manufacture these products, while they are marketed by U.S. companies. This reflects the importance of collaborations and the complexity of marketing biosimilars in the U.S., which have seen varying degrees of uptake across molecules as originators use a variety of techniques to defend their market share.[7]

Contribution to patient access and use

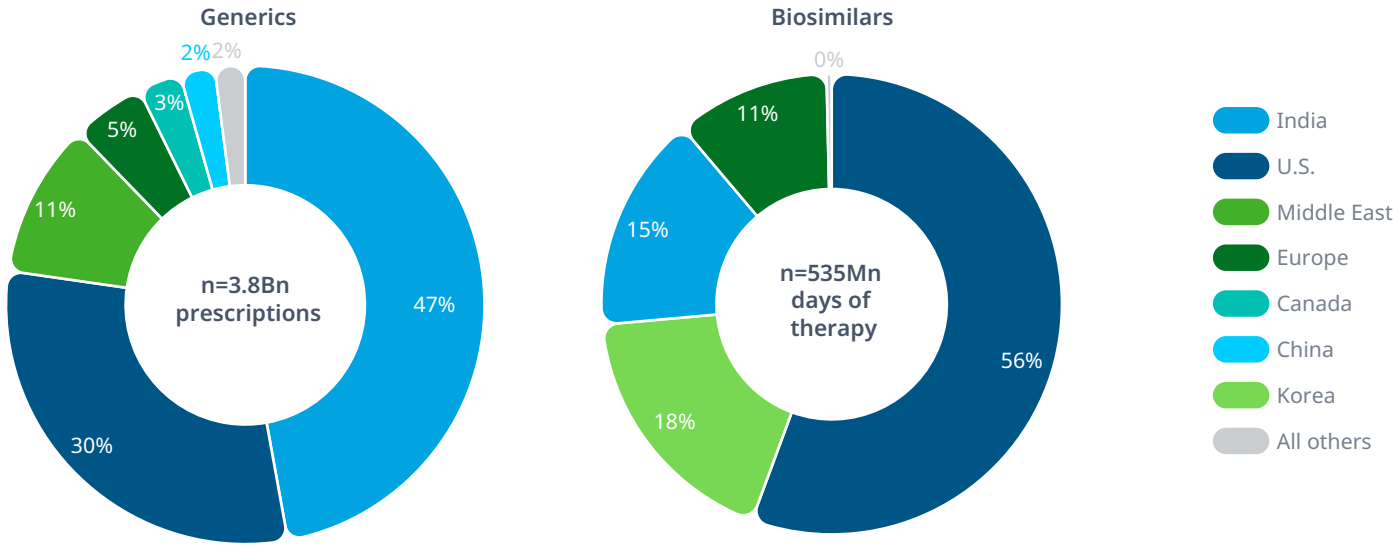
The supply of affordable drugs by Indian companies can help enhance the reach of crucial drugs for patients. Rosuvastatin provides an example to showcase this important role that Indian companies play. This drug saw generic entry in 2016, leading to an increase in competitiveness, as measured by the Herfindahl-Hirschman Index (HHI). Indian companies had between 80–90% of the overall market share from 2019 to 2022. The increased affordability after generic entry in 2016 is associated with 28.2 million additional patients (54 million total patients with generic entry vs. 26 million projected patients without generic entry between 2016 and 2022) receiving this drug compared to the trend that was observed prior to generic entry. This patient count is an average estimate based on days of therapy. Actual patient counts may vary based on potential differences in dosage, duration of therapy, or patient adherence.

Exhibit 6: Share of total prescriptions (brand and generic) by company headquarters, 2013–2022



Source: IQVIA National Prescription Audit, Dec 2022; IQVIA Institute, Feb 2024.
Notes: Prescription counts are unadjusted for length of prescription. Company headquarters is determined by parent company location for subsidiaries.

Exhibit 7: Generic and biosimilar volume share by company headquarters, 2022



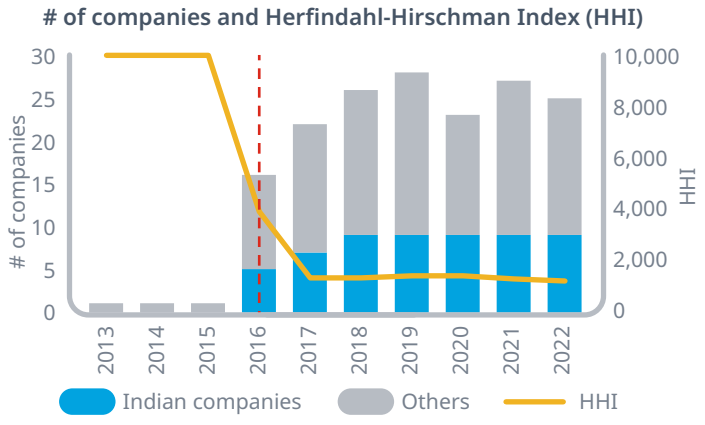
Source: IQVIA National Prescription Audit, IQVIA National Sales Perspective, Dec 2022; IQVIA Institute, Feb 2024.
Notes: Prescription counts are unadjusted for length of prescription. Company headquarters is determined by parent company location for subsidiaries. Generic volume share based on prescriptions and marketing company headquarters location. Biosimilar volume share based on defined daily doses (DDDs) and manufacturing company headquarters location.

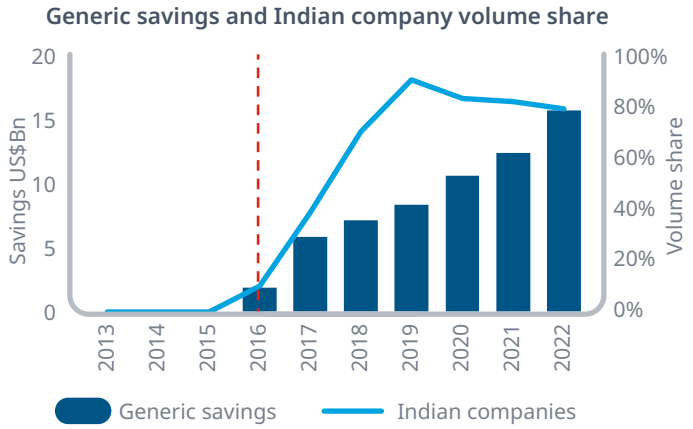
The rosuvastatin example reiterates the important role that Indian companies play in reducing medicine costs which can enhance patient access (Exhibit 8).

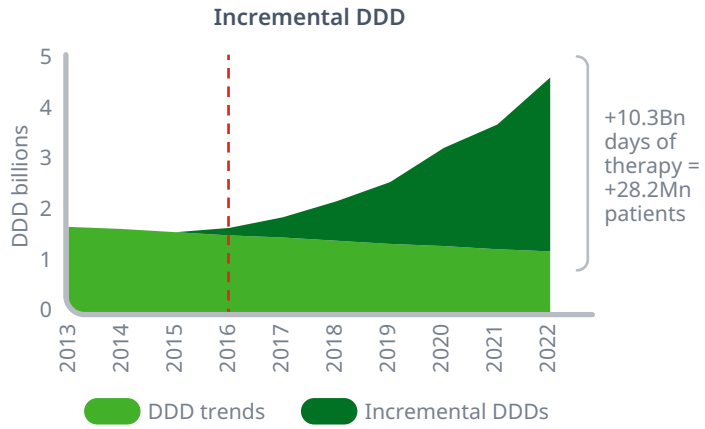
Contribution across top ten therapy areas

Out of the top 10 therapy areas by prescription volume, Indian companies supplied more than half of the prescriptions for five: hypertension, mental health, lipid regulators, nervous system disorders, and anti-ulcerants (Exhibit 9). Indian companies have the lowest representation in diabetes medicines, which also have a lower share of generic medicines compared to the other top therapy areas. Indian companies do not supply insulins and newer generation diabetes medicines, such as DPP-4 inhibitors, SGLT2 inhibitors, and GLP-1 agonists, which are largely still patent protected and represent a growing share of the diabetes market. However, Indian companies supply 43% of traditional diabetes medicines, such as metformin and sulphonylureas, which are less complex small molecules and almost entirely dispensed as generics.

Exhibit 8: Rosuvastatin: Number of companies, savings and incremental defined daily dose (DDD)

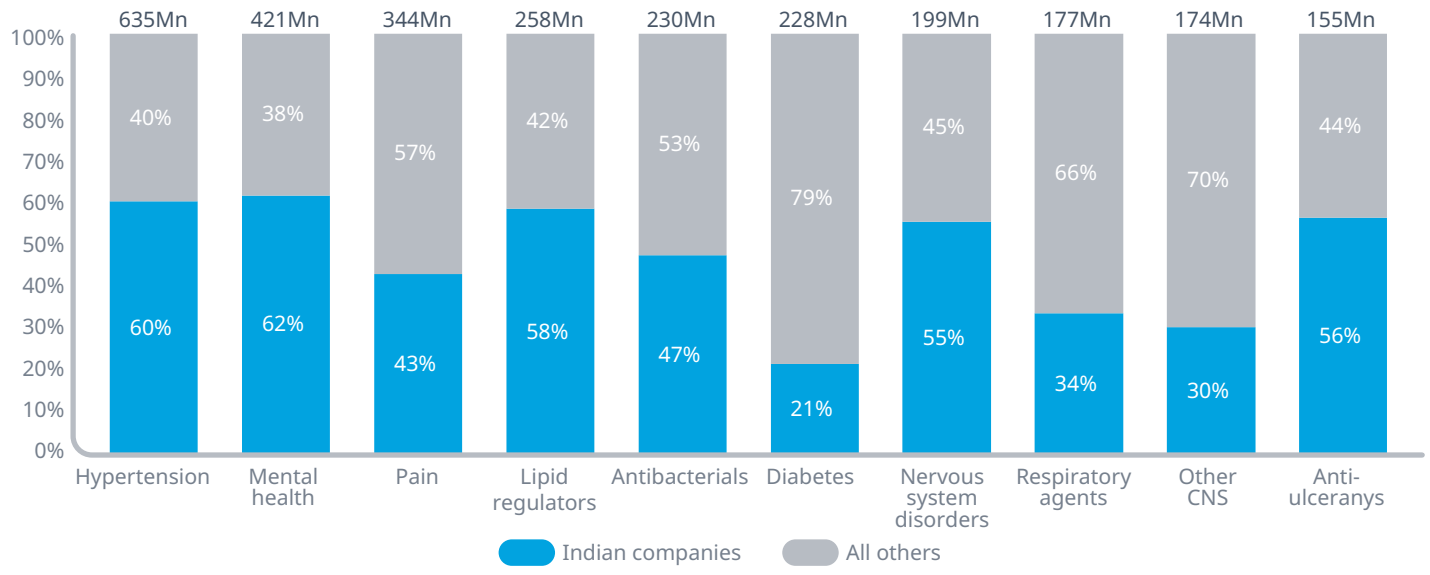






Source: IQVIA National Sales Perspective, Dec 2022; IQVIA Institute, Apr 2024.
Notes: The number of patients was calculated by dividing the days of therapy by 365. The patient number is an hypothetical average estimate based on the days of therapy. It may not be equivalent to actual patient count as it does not account for potential differences in dosage, duration of therapy, or patient adherence.

Exhibit 9: Share of prescriptions by company headquarters across top 10 therapy areas, 2022



Source: IQVIA National Prescription Audit, Dec 2022; IQVIA Institute, Jan 2024.
Notes: Prescription counts are unadjusted for length of prescription. Company headquarters is determined by parent company location for subsidiaries.

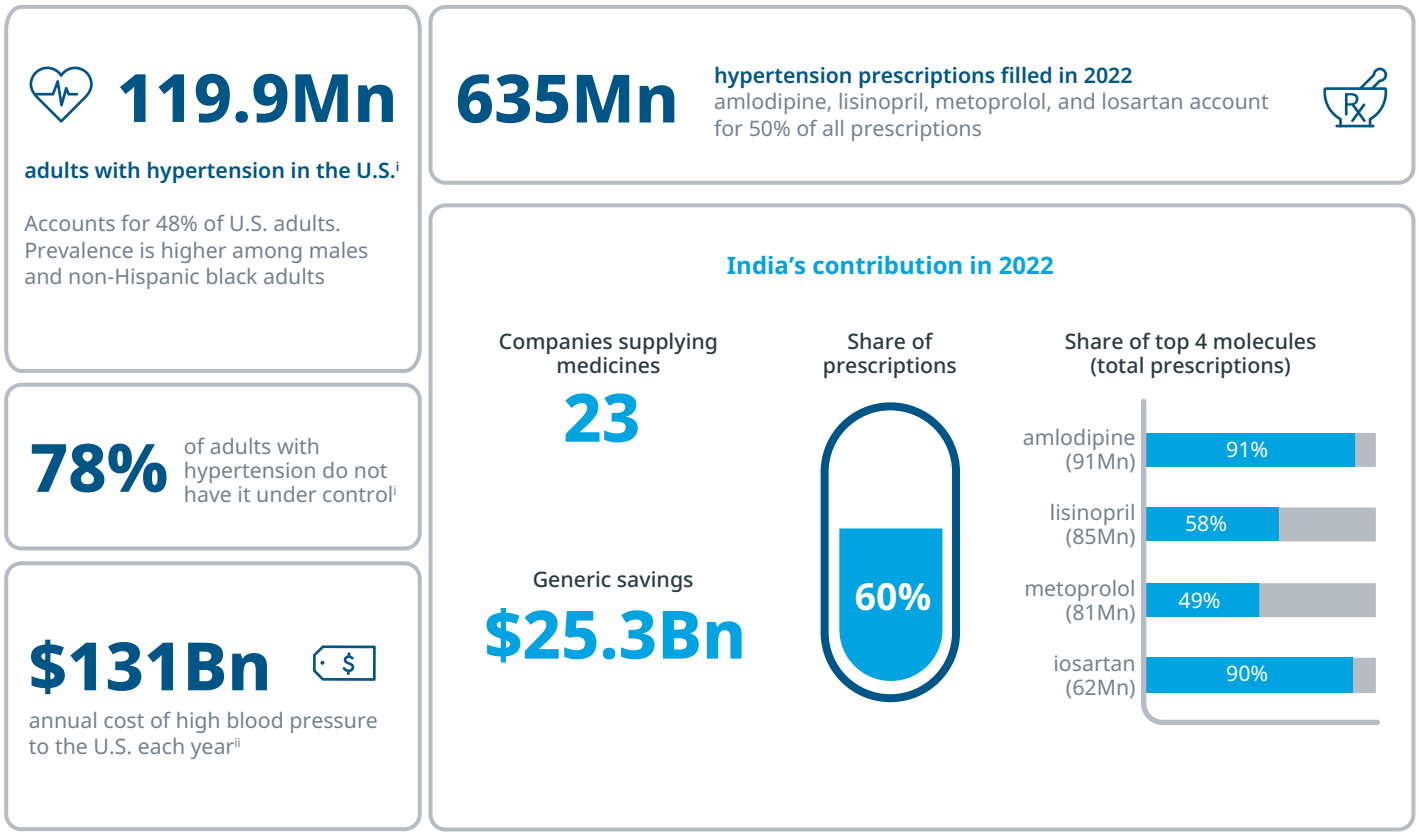
CASE STUDY: HYPERTENSION

Nearly half of all adults suffer from hypertension in the U.S. with greater prevalence among males and non-Hispanic black adults. Over three quarters of these adults do not have their hypertension under control. High blood pressure can lead to substantial costs for the health system, estimated at $131Bn per year for the direct and indirect medical costs.

Generic hypertension drugs are crucial for the management of this condition and Indian companies play an extremely important role in supplying these drugs. In 2022, 23 Indian companies supplied 60% of all hypertension prescriptions in the U.S. Indian companies supply of hypertension medicines varies across molecules, supplying 90% of amlodipine and losartan, but roughly half of lisinopril and metoprolol. Indian companies also provide lower costs medicines with generic prices that are half of other generics from non-Indian companies. Overall, in 2022, Indian companies generated $25.3Bn in savings for hypertension treatment.

This case study highlights the vital role that Indian companies play in this highly prevalent and critical therapy area (Exhibit 10).

Exhibit 10: Spotlight on hypertension



Source: IQVIA Institute, Apr 2024.
Notes: i. https://millionhearts.hhs.gov/data-reports/hypertension-prevalence.html; ii. https://pubmed.ncbi.nlm.nih.gov/29848493/

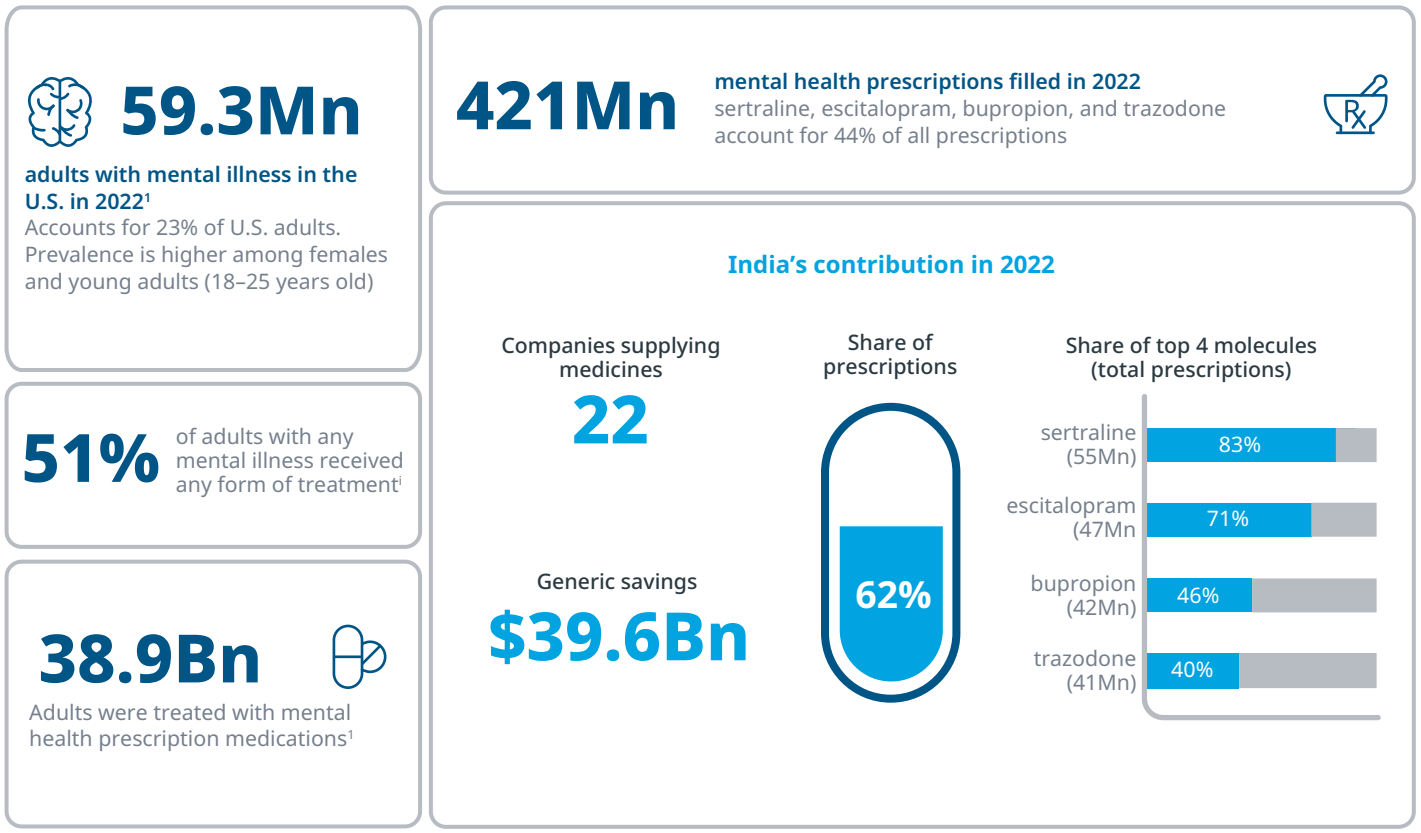
CASE STUDY: MENTAL HEALTH

The supply of drugs for mental health conditions also highlights the pivotal role of Indian companies in the health and well-being of U.S. residents.

With nearly a quarter of adults in the U.S. suffering from mental illness and prevalence being higher in younger populations (18 to 25 years old), affordable supply of drugs for the management of these conditions is crucial. Indian companies play an important role in this therapy area as well with 62% of all prescriptions being supplied by Indian companies in 2022. Sertraline is the most prescribed mental health drug in the U.S. and Indian companies supply 8 out of 10 prescriptions for this drug.

The average cost of mental health drugs by Indian companies is half that of generics by non-Indian companies. Indian companies were associated with nearly $40Bn in savings for mental health drugs in 2022 alone (Exhibit 11).

Exhibit 11: Spotlight on mental health



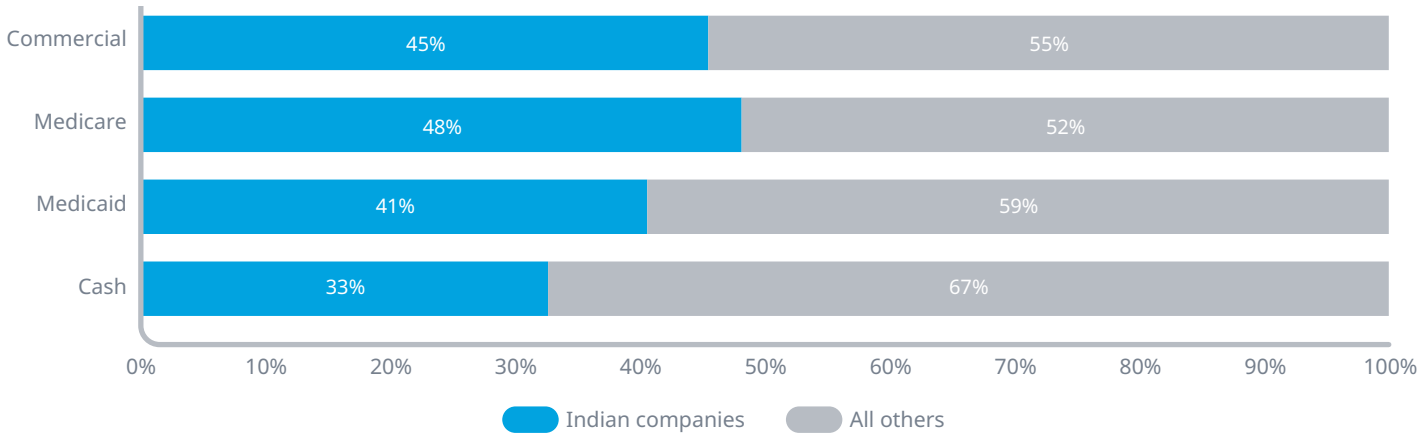
IQVIA Institute, Apr 2024.
Notes: i. https://www.samhsa.gov/data/report/2022-nsduh-detailed-tables

Contribution by patient insurance coverage and age

Half of all generic prescriptions in the U.S. market are filled by commercially insured patients. Medicare accounts for 28% of generic prescriptions, while Medicaid accounts for 18% and only 4% of prescriptions are filled by people paying cash. Indian companies provide nearly half of generic medicines paid for through Medicare and commercial insurance (Exhibit 12), providing lower costs to employers and federal programs. Only one-third of cash generic prescriptions are supplied by Indian companies, which is due to the difference in the makeup of medicines that are paid for with cash versus with insurance.

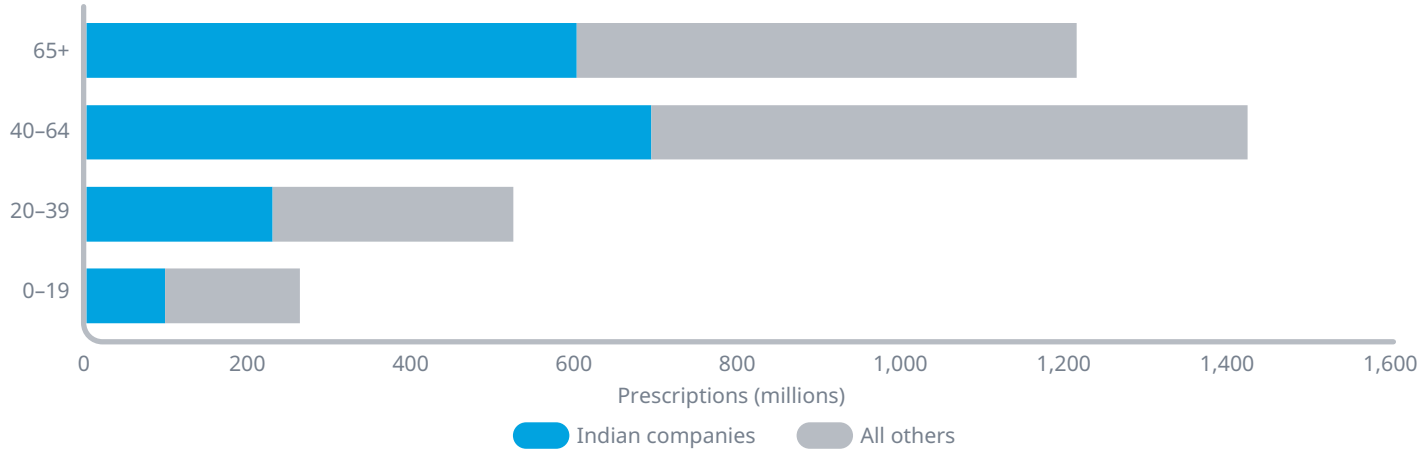
The majority of prescriptions are dispensed for adults over the age of 40; young adult and pediatric patients account for 23% of prescriptions (Exhibit 13). Chronic conditions, for which most generic prescriptions are for, are more common in older adults than young adults.[8] Indian companies share of prescriptions goes up as age does. For pediatric patients, medicines for ADHD and dermatologics, particularly prescription creams to treat acne and rashes, account for over 20% of prescriptions and are not areas of focus for Indian companies who supply less than one-third of these prescriptions for pediatric patients. Medicines in older individuals are predominantly for treating common chronic conditions.

Exhibit 12: Share of generic prescriptions by pay type and company headquarters, 2022



Source: IQVIA National Prescription Audit: Managed Care, Dec 2022; IQVIA Institute, Feb 2024.
Notes: Prescription counts are unadjusted for length of prescription. Company headquarters is determined by parent company location for subsidiaries.

Exhibit 13: Generic prescriptions by age and company headquarters, 2022



Source: IQVIA National Prescription Audit: New to Brand, Dec 2022; IQVIA Institute, Feb 2024.
Notes: Prescription counts are unadjusted for length of prescription. Company headquarters is determined by parent company location for subsidiaries.

Hypertension and hyperlipidemia account for one-third of prescriptions in people over age 65 with over 60% supplied by Indian companies.

Refills and adherence

Patients getting refills are more likely to receive medicines from Indian companies than those with new prescriptions (Exhibit 14). For patients filling prescriptions for the first time, 41% of these prescriptions are supplied by Indian companies; however, Indian companies supply a slightly higher share of prescriptions that are refills. These differences suggest that patients whose prescriptions are supplied by Indian companies have better adherence, which may be correlated with better affordability.

SUSTAINABILITY

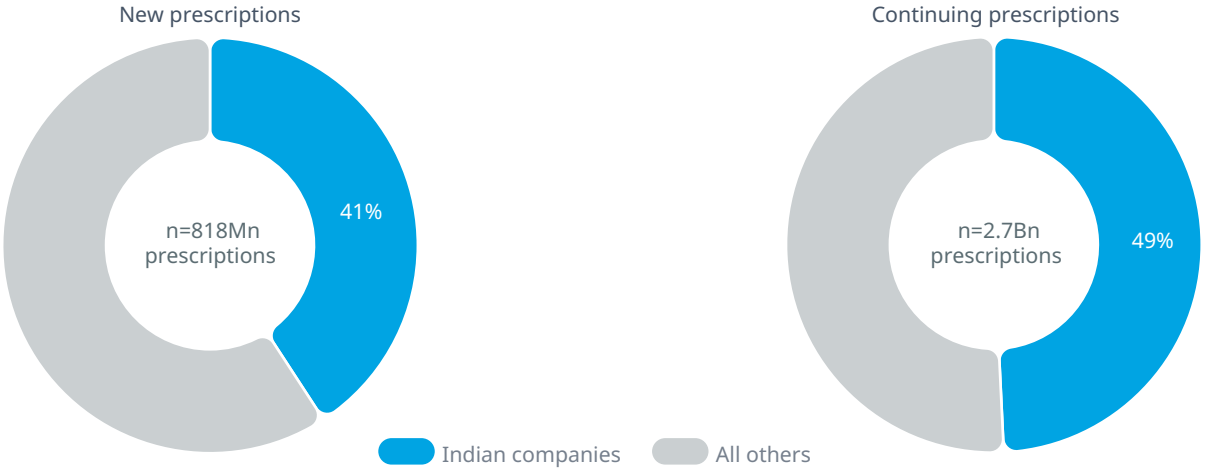
Indian companies add competitiveness to the generics market which can potentially aid with resilience to events that result in shortages

Generic medicines where Indian companies market products are more competitive than those with no Indian involvement. Medicines where generics are available have varying numbers of companies involved in filling prescriptions. There are typically more companies supplying product for medicines where Indian companies supply a portion of prescriptions (Exhibit 15).

The median number of companies supplying medicines when an Indian company is involved is 10, compared to two for those where Indian companies are not involved. This could be due to differences in profitability of specific medicines which may attract more competitors.

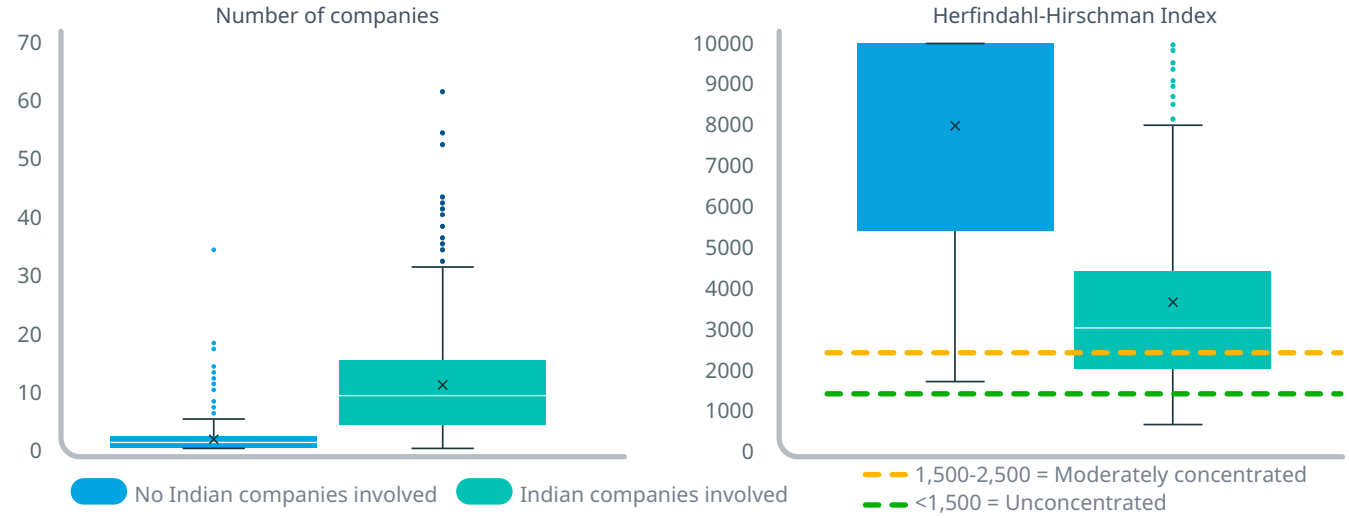
The market share concentration among competitors is an indicator of competitiveness and the potential resilience to events that may result in shortages.[9] Market concentration can be measured with the Herfindahl-Hirschman Index (HHI), with highly concentrated markets above 2,500 on HHI and moderately concentrated markets between 1,500 and 2,500. Highly competitive, unconcentrated markets where market share is divided among many competitors are those with an HHI below 1,500. Few generic medicines are considered unconcentrated. Generic medicines where Indian companies are involved have a lower median HHI (3,041) than those where no Indian companies are involved (9,994). The very high median HHI for medicines where Indian companies are not involved indicates that many of these molecules are predominantly sourced from a single supplier. There are only 22 generic medicines where Indian companies are the sole supplier.

Exhibit 14: Patients getting refills are more likely to receive medicines from Indian companies than those with new prescriptions



Source: IQVIA National Prescription Audit: New to Brand, Dec 2022; IQVIA Institute, Feb 2024.
New prescriptions are those where the patient had no prescription of the medicine in the prior year and includes naïve patients as well as those who switch from another drug or add a new drug to their existing regimens. Continuing prescriptions are those where the patient has filled a prescription of the same medicine in the past year and can include gaps in dispensing.

Exhibit 15: Number of companies and Herfindahl-Hirschman Index for generic molecules with Indian companies marketing products vs. no Indian companies marketing products, 2022



Source: IQVIA National Sales Perspective, Dec 2022; IQVIA Institute, Mar 2024.
Notes: Generic molecules are those where generics or branded generics are available, and brands may still be available. Brand molecules are those where only brands are available. See Definitions for more information about Herfindahl-Hirschman Index (HHI).

SUSTAINABILITY

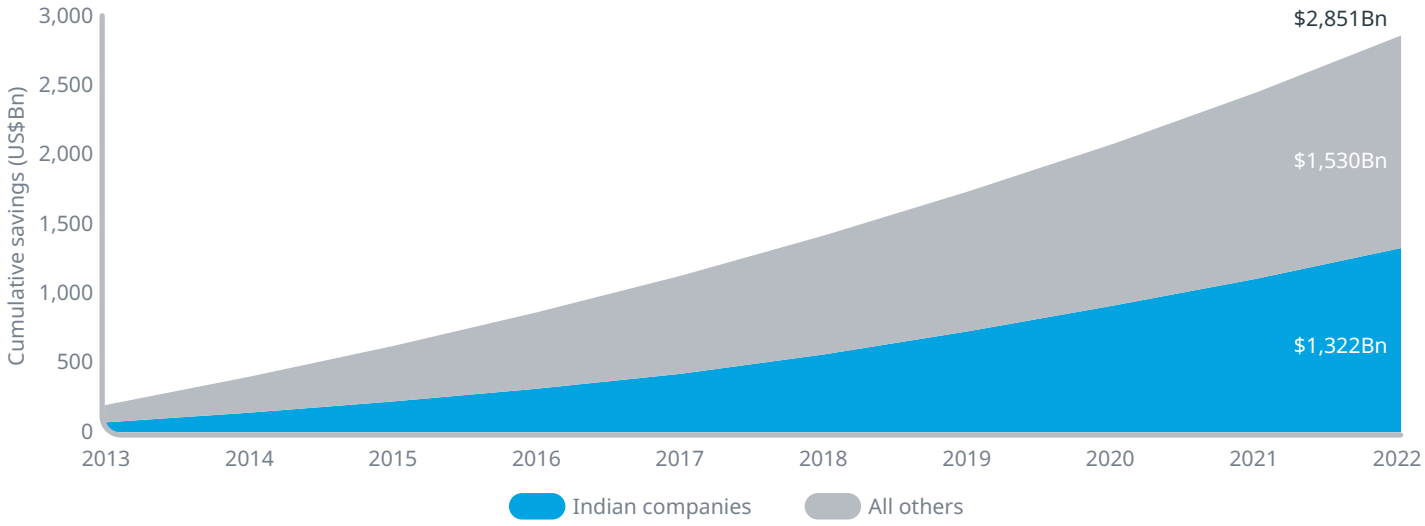
Indian companies provide substantial savings for the health system, thereby enhance its overall sustainability. These companies will continue to be a crucial contributor to savings in the future.

As discussed earlier, generics play a crucial role in the overall sustainability of the health system by providing competition in the market, and lowering costs.

Indian companies play a major role in providing these savings. Medicines from Indian companies provided $219Bn in savings to the U.S. healthcare system in 2022 and a total of $1.3Tn between 2013 and 2022 (Exhibit 16).

Indian companies contributed 46% of the $2.9Tn in generic savings to the U.S. healthcare system over the last decade through supplying generic medicines.

Exhibit 16: Cumulative ten-year savings from generics by company headquarters, US$Bn

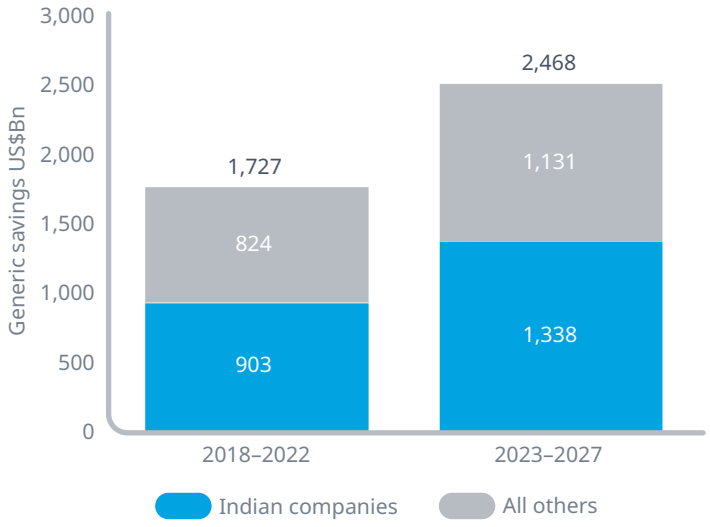


Source: IQVIA National Sales Perspectives, Dec 2022; IQVIA Institute, Jan 2024.
Notes: Savings is calculated by comparing actual spending to projected spending if total brand and generic volume were at brand pre-expiry prices. Company headquarters is determined by parent company location for subsidiaries.

Overall, Indian companies have been key partners in ensuring the stability of the health system through management of chronic and acute conditions of U.S. residents and through savings for stakeholders across the system.

From 2023 to 2027 generics are expected to provide over $2.4Tn in savings, primarily from older generic medicines in mental health, hyperlipidemia, and hypertension. Indian companies are expected to continue to play a significant role in providing savings to the U.S. healthcare system over the next five years, contributing $1.3Tn in savings through the supply of generic medicines (Exhibit 17).

Exhibit 17: Savings from generics 2018-2022 and projected savings 2023-2027, US$Bn



Source: IQVIA National Sales Perspectives, Dec 2022; IQVIA Institute, Apr 2024.

Indian companies are expected to continue to play a significant role in providing savings to the U.S. healthcare system over the next five years, contributing $1.3Tn in savings through the supply of generic medicines

Risks to the active pharmaceutical ingredients and key starting materials supply chain for generics

+ **Ensuring uninterrupted access to these affordable medicines is a vital concern for health and security in the U.S.; in particular, concerns around the concentration and lack of diversification of the overall generic medicine supply chain has been raised in many countries.**

+ **The U.S. supply of generic drugs depends heavily on the global supply chain for sources of generic active pharmaceutical ingredients (APIs), with 87% of FDA-registered plants that manufacture APIs used in generics located outside the U.S.**

+ **Overall, global API production is highly concentrated, with China alone generating over 2 million tons of APIs annually, fulfilling around 40% of global needs.**

+ **The U.S. is impacted by the concentration of key starting material (KSM) and API production indirectly as well; for example, while India is the main source of affordable generic drugs for the U.S., it depends on China for nearly 70% of its APIs.**

+ **The U.S. and India governments, through jointstatements, have both acknowledged that supply chains for APIs and KSMs are insufficiently diversified, and that there is scope to collaborate to de-risk and diversify.**

+ **India has made efforts to incentivize the production of APIs and KSMs through production-linked incentive (PLI) programs**

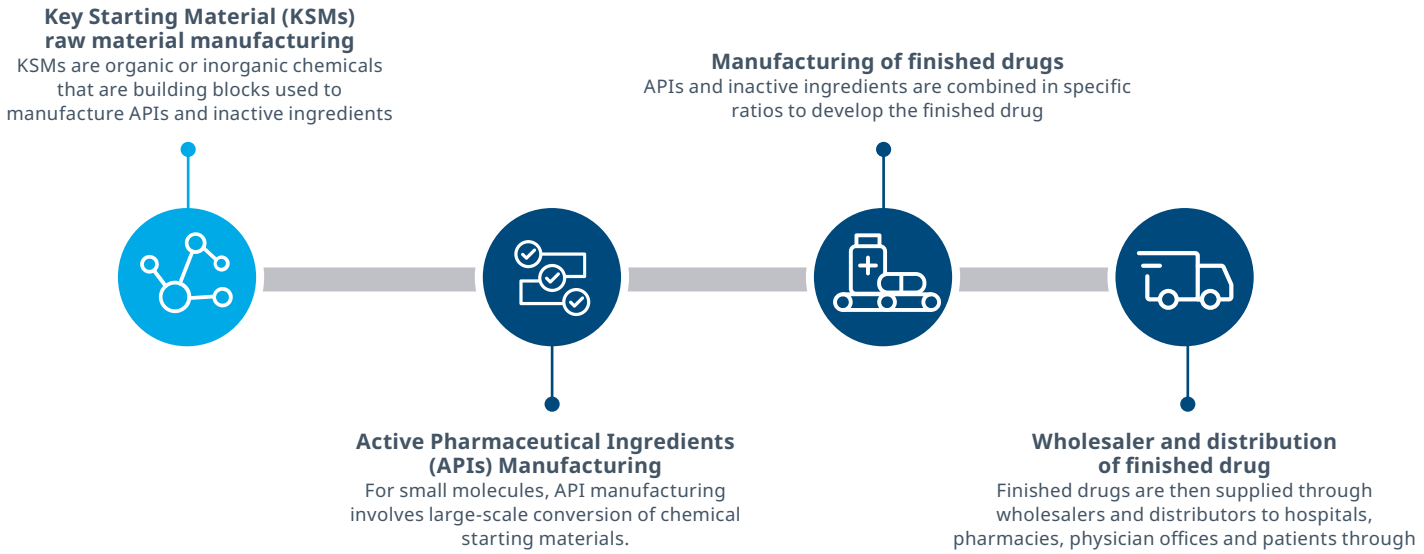
As discussed, affordable medicines are crucial for maintaining a healthy society, with India playing a significant role in the supply of generic drugs to the U.S. Ensuring uninterrupted access to these medicines is a vital concern for U.S. health and security. The COVID-19 pandemic led to notable drug shortages across many countries, including the U.S., highlighting vulnerabilities in the current global pharmaceutical supply chain.[10,11] This situation underscored the urgent necessity to guarantee uninterrupted access to medicines for the U.S. and other countries globally. To fully understand these vulnerabilities and devise strategies to address them, it is essential to have a comprehensive understanding of the entire medicine supply chain, particularly in the context of affordable generic drugs.

Background on the drug supply chain

The supply chain for medicines is complex, involving a multitude of resources, steps, and stakeholders. At a high-level, the supply chain progresses from key starting material (KSM) — or raw material — and active pharmaceutical ingredient (API) suppliers to drug manufacturers, to drug wholesalers and distributors, and finally to hospitals, pharmacies, physician offices and patients (Exhibit 18). Given this, manufacturing of generics starts with KSMs and APIs.[12]

Raw materials or KSMs, both organic and inorganic chemicals, are the building blocks used to manufacture APIs and inactive ingredients that together make up a finished drug product. For small molecules, API manufacturing involves large-scale conversion of chemical starting materials. For large molecules (e.g., biologics or vaccines), APIs are manufactured through various forms of fermentation and bioprocessing. In both instances, API manufacturing involves the conversion of raw materials, solvents, reagents, catalysts, and other materials through multistep chemical syntheses with a range of processing technologies. Following API production, formulation, primary packaging, and secondary packaging are completed before being handed over to drug wholesalers and distributors (Exhibit 18).[12]

Exhibit 18: Simplified medicine supply chain



Source: IQVIA Institute, Apr 2024.

Concentration of supply of APIs and KSMs for generic drugs and the impact on the U.S.

The U.S. supply of generic drugs depends heavily on the global supply chain for sources of generic APIs,[13] with 87% of FDA-registered plants that manufacture APIs used in generics located outside the U.S.[14] Based on a 2020-21 analysis, 565 facilities manufactured 1,379 unique generic APIs in 42 countries.[13] The leading producers were India, China, and Italy, with only 14% of APIs made in the U.S.[13]

In terms of monetary value of imported pharmaceuticals, Ireland stands as the leading pharmaceutical importer to the U.S. APIs from Ireland are primarily utilized in the production of branded products. In 2023, the value of pharmaceutical imports from Ireland exceeded $41Bn, yet only amounting for 19 million kilograms of volume. China, India, and Mexico accounted for 61% of all pharmaceutical imports by weight in 2023, up from 52% in 2019. Mexico has had the largest growth in import volume, more than doubling from 2019 to 2023, while India has grown 29% and China 18%.[15]

In the last decade, China's API production facilities more than doubled, solidifying its leading position in the global API industry. Asia, particularly China and India, is the primary region for total API production, contributing over 60% of global output.[16] China alone generates over 2 million tons of APIs annually, fulfilling around 40% of global needs.[17]

The U.S. is impacted by the concentration of KSM and API production directly through a heavy reliance on limited sources for imports. Additionally, the concentration of the overall global supply chain also has indirect impacts on the U.S. which can cause vulnerabilities. For example, while India is the main source of generic drugs for the US., it itself depends on China for nearly 70% of its APIs.[18]

Additionally, the U.S. leans on other international companies, such as those in the UK, the EU, Canada, and South Korea, to fulfill the demand for medicines. These nations in turn rely significantly on China and India for APIs, KSMs, and intermediates. European direct and indirect dependency on Asia, in terms of both APIs and precursors, is estimated to be around 74% of total market volume (in kg), with China being responsible for almost 70% of this dependency.[19]

Responses to the undiversified supply chain

This lack of diversity presents vulnerabilities to the overall health system, in the U.S. and across the globe. The U.S., India, and Europe have all expressed concerns about lack of diversification of supply of APIs and KSMs used to make generics.[20–22]

EUROPEAN UNION

EU efforts are underway to diversify and secure drug supply chains and address shortages.[23,24] Security of supply was identified as a central objective of the November 2020 Pharmaceutical Strategy for Europe. The Commission announced several actions aimed at improving the availability of medicines, including a structured dialogue on security of medicines supply. This dialogue identified broad categories of products for which the EU is considered dependent on a small number of non-EU suppliers. In 2022, the European Parliament noted that it is "imperative to prevent medicine shortages and to mitigate their effects should they occur."[25] In October 2023, the European Commission adopted a set of actions to better prevent and mitigate critical medicine shortages in the EU, including a plan to establish a network of international partners to address supply chain resilience.[26]

INDIA

Similar to the EU, India has also been taking steps to reduce its dependence on China for the supply of key pharmaceutical components. The Indian government launched a strategy in March 2020 with the goal of increasing local production of these components.[27] One element was a production-linked incentive (PLI) program providing financial incentives to makers of drug ingredients. The initial program, PLI 1.0, offered an incentive to promote domestic manufacturing of KSMs and APIs for 41 eligible drugs for six years and promoted creation of bulk drug parks.[28,29] These consist of fermentation-based bulk drugs with an incentive rate of 20% for the first four years, 15% for the fifth year, and 5% for the sixth year and chemical synthesis-based bulk drugs with an incentive rate of 10% for six years viz, 2022–23 to 2027–28.

Production of 89,545 million tons per annum has been committed under the 48 approved projects. The updated version, PLI 2.0, launched in March 2021, included incentives based on global manufacturing revenue with an aim to enhance India's manufacturing capabilities by diversifying into higher-value drugs such as complex generics, biologicals and biosimilars. The overall goal is to "create global champions out of India who have the potential to grow in size and scale using cutting-edge technology and thereby penetrate the global value chains."[30] The scheme has a financial outlay of ~USD 1.8Bn. An investment of ~USD 2Bn was committed by 55 successful participants under this scheme, against which an actual investment of ~USD 3.3Bn has already been realized as of December 2023.[31,32] These schemes are intended to add resilience to the overall supply chain for generic drugs by reducing the dependence on imports.

The U.S. and India have both acknowledged that supply chains for APIs and KSMs are insufficiently diversified, and that there is scope to collaborate to de-risk and diversify. On January 12, 2024, the United States-India Trade Policy Forum issued a joint statement emphasizing a "mutual interest in furthering public health discussions to ensure safe and effective medical products… The Ministers shared concerns related to the overdependence and lack of diversity in active pharmaceutical ingredients within the global pharmaceutical supply chain and welcomed the opportunity to collaborate to de-risk and diversify with a focus on key starting materials." [33]

The U.S. and India have both acknowledged that supply chains for APIs and KSMs are insufficiently diversified, and that there is scope to collaborate to de-risk and diversify.

Future opportunities for U.S.–India collaboration

+ **For the U.S. health system as a whole, India also serves as an important ally, not only for the supply of affordable high-quality drugs, but also through its comparative cost advantages in skilled human resources and through opportunities for collaborations with Indian and U.S. companies.**

+ **U.S. has strategic partnerships across sectors, such as energy technology, mining, and semiconductors, with India and other countries which can provide a template for further partnership in de-risking the pharmaceutical supply chain.**

+ **Several policies and other interventions can be considered to develop this partnership, such as establishing a joint pharma supply chain working group, providing incentives to build a reliable supply chain, considering joint manufacturing and other collaborations across Indian and U.S. companies, and generating scientific collaborations and technological upgrades along with bilateral trade agreements.**

India and Indian pharmaceutical companies have been important partners in achieving an affordable and high-quality healthcare system in the U.S.
For the U.S. health system as a whole, India serves as an important ally, not only for the supply of affordable high-quality drugs, but also through its comparative cost advantages in skilled human resources and through opportunities for collaborations with Indian and U.S. companies. India brings value and quality through its human resources which are skilled in STEM related subjects.[34] These resources aid in the global competitiveness of pharmaceutical companies in the U.S. Additionally, there are numerous examples of collaborations between U.S. and Indian pharmaceutical companies in terms of contract manufacturing, research and development, and market penetration. India's history of supplying high-quality affordable medicines and collaborating with U.S. companies[35] positions India well for future engagements with the U.S. health system as a key partner in the uninterrupted supply of these drugs.

U.S. has a history of strategically partnering with India and other countries for critical industries which can provide templates for future partnerships to de-risk the pharmaceutical supply chain
U.S. has strategic partnerships in several important sectors with India as well as other countries. Such bilateral and multilateral trade initiatives and partnerships can bolster economic growth, national security, supply chain resilience, and technological innovation. Some examples include:

U.S.–India Energy Partnership[36]
The U.S.-India Strategic Energy Partnership launched in 2018 has facilitated bilateral engagements in oil and gas, power and energy efficiency, renewable energy, and sustainable growth. This initiative includes cooperation on the development and deployment of new technologies and offers a platform for U.S. energy firms to engage in India's transition to cleaner fuels. The aim is to increase energy trade and investment between the two countries, diversify energy sources and contribute to global energy security.

U.S.–India Mineral Collaboration as part of broader Minerals Security Partnership[37]
The collaboration between U.S. and Indian companies in mining and mineral processing. This includes the sharing of resources and technology to explore and extract critical minerals essential for manufacturing electronics and renewable energy technologies. The aim is to reduce the concentration critical minerals supply, thereby enhancing the resilience of their industrial and defense sectors.

Global Semiconductor Partnerships[38]

U.S.–Taiwan: A significant example is the collaboration in semiconductor manufacturing, where U.S. semiconductor firms have deepened ties with Taiwanese counterparts to secure chip supplies. Initiatives such as the construction of new semiconductor fabrication plants in the U.S. by Taiwanese companies underscore this strategic partnership.

These examples provide templates for partnerships that can be explored in the medicine sector to de-risk the supply chain.

De-risking the supply chain: exploring opportunities for partnerships between U.S. and India

As discussed earlier, there is a high degree of concentration of APIs and KSMs. A dependable strategic partner country could be a useful focus for U.S. policy direction as it considers strategies to de-risk and diversify the supply chain. India would be an ideal strategic partner for the U.S. in this endeavor for a variety of reasons:

- India is already an essential part of the existing U.S. and global drug supply chain, consistently utilizing its comparative cost advantage to provide high quality and affordable medicines, including during COVID-19
- India has a history of working collaboratively with the U.S. and its agencies, seeking to address issues when they arise
- Indian companies have a history of investment and job creation in the U.S., which sets them up for future collaborations[39]

Several policies and other interventions can be considered to develop this partnership for de-risking the supply chain via a bilateral arrangement between the U.S. and India, such as:

- **Bilateral trade arrangement:** The two countries could explore a pharmaceutical trade arrangement to enable uninterrupted access to drugs and raw materials during natural disasters or pandemics. This could be achieved by giving India a preferred status and adding it as a designated country under the Trade Agreements Act. Establishing a joint pharma supply chain working group with the goal of coordinating end-to-end pharmaceutical supply chains can be helpful in setting up appropriate partnerships. This high-level group would include representatives of key government departments and regulatory bodies, with input from industry.
- **Providing incentives from the Indian government to build a reliable pharmaceutical supply chain:** India already promotes investment in production of APIs and KSMs by setting up bulk drug parks and PLI schemes. Such policy initiatives can reduce single source dependency for India and other countries. The 26 molecules not currently covered by PLI programs could potentially be covered by future iterations of these programs, along with other high concentration risk products. In return for helping build U.S. supply security, India could potentially gain access to technologies and intellectual property in areas where it faces shortages, such as the critical raw materials needed for vaccines and other biologics.
- **Scientific collaboration:** The U.S. and India have in place a memorandum of understanding on safe drugs, aimed at supporting engagement in regulatory, scientific, technical, and public health arenas. This forum could be used to identify and address supply chain issues.

- **Technology upgrades:** India is already investing in technologies such as continuous manufacturing, which can enable more rapid response to API shortages. A partnership could apply U.S. innovations to Indian manufacturing to further secure supply chains.

The U.S. has a pressing need to address bottlenecks in its API supply chain. Enhanced strategic partnerships with allied countries could offer benefits beyond cost savings, such as vertically integrated production, high quality, and reliability. India can be a strong candidate for such a partnership, as a reliable and significant contributor to the US drug supply chain.

A partnership between the U.S. and India would benefit from scale, technology, and a superior skill base, helping the U.S. to de-risk its pharmaceutical supply chain and mitigate national security risks due to medicine shortages resulting from trade tensions, natural disasters, or global health emergencies. Requiring focused investments in technology and international collaboration, such a partnership could be a positive step toward enhancing global pharmaceutical sustainability and resilience.

The U.S. has a pressing need to address bottlenecks in its API supply chain. India can be a strong candidate for such a partnership, as a reliable and significant contributor to the US drug supply chain.

Notes on sources

THIS REPORT IS BASED ON THE IQVIA SERVICES DETAILED BELOW

NATIONAL SALES PERSPECTIVES (NSP)™
measures revenue within the U.S. pharmaceutical market by pharmacies, clinics, hospitals and other healthcare providers. NSP reports 100% coverage of the retail and non-retail channels for national pharmaceutical sales at actual transaction prices. The prices do not reflect off-invoice price concessions that reduce the net amount received by manufacturers.

NATIONAL PRESCRIPTION AUDIT (NPA)™
is the industry standard source of national prescription activity for all pharmaceutical products. It measures demand for prescription drugs, including dispensed pharmaceuticals to consumers across three unique channels: retail, mail service, and long-term care pharmacies. From sample pharmacies, IQVIA collects new and refilled prescription data daily. NPA represents and captures over 92% of all outpatient prescription activity in the United States and covers all products, classes, and manufacturers.

Definitions

HERFINDAHL-HIRSCHMAN INDEX (HHI)
is a measure of market concentration and is often used to measure the impact of mergers on competitiveness in a market. The HHI is the sum of the squares of each market participants market share. The U.S. Department of Justice and Federal Trade Commission define markets as unconcentrated when the HHI is below 1,500, moderately concentrated when the HHI is between 1,500 and 2,500, and highly concentrated when the HHI is above 2,500.[40]

GENERIC SAVINGS
is the amount of money in a given period that would have been spent on medicines in the absence of generic competition less the amount of money actually spent in that period on medicines with generic competition at invoice prices. The estimated spending in the absence of generic competition is based on generic medicine volume and brand pre-expiry invoice prices. Generic savings shown here covers 1,283 molecules which have faced generic competition since 1992 and the savings generated between 2013 and 2022.

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Murray Aitken is Executive Director, IQVIA Institute for Human Data Science, which provides policy setters and decisionmakers in the global health sector with objective insights into healthcare dynamics. He led the IMS Institute for Healthcare Informatics, now the IQVIA Institute, since its inception in January 2011. Murray previously was Senior Vice President, Healthcare Insight, leading IMS Health's thought leadership initiatives worldwide. Before that, he served as Senior Vice President, Corporate Strategy, from 2004 to 2007. Murray joined IMS Health in 2001 with responsibility for developing the company's consulting and services businesses. Prior to IMS Health, Murray had a 14-year career with McKinsey & Company, where he was a leader in the Pharmaceutical and Medical Products practice from 1997 to 2001. Murray writes and speaks regularly on the challenges facing the healthcare industry. He is editor of Health IQ, a publication focused on the value of information in advancing evidence-based healthcare, and also serves on the editorial advisory board of Pharmaceutical Executive. Murray holds a Master of Commerce degree from the University of Auckland in New Zealand, and received an M.B.A. degree with distinction from Harvard University.

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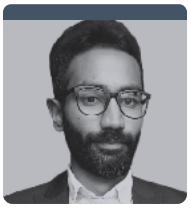
Jamie is an Associate Thought Leadership Director for the IQVIA Institute, managing aspects of IQVIA Institute research projects and conducting research and analysis within global healthcare. Prior to joining IQVIA in 2021, he held positions with the North Carolina Department of Health and Human Services and the Duke Human Vaccine Institute, where he developed skills in understanding and addressing the array of physical, environmental and social contributors to individual health. Jamie uses his experience in public health, health communication, and drug development and research to understand current trends in healthcare and the life sciences industry. He holds B.S. in Animal Science, B.S. in Zoology and a Master of Toxicology from North Carolina State University.



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Vibhu Tewary is a Project Director at the IQVIA Institute for Human Data Science and is based out of New York, NY. His key areas of interest include healthcare policy, global market access, and economic modeling. Vibhu has authored multiple reports on global healthcare policy and market access. Prior to joining IQVIA, he worked as a researcher in a policy think tank in India. Vibhu did his undergraduate studies at the Indian Institute of Technology, Madras, and holds an MBA from Duke University.

About the Institute

The IQVIA Institute for Human Data Science contributes to the advancement of human health globally through timely research, insightful analysis and scientific expertise applied to granular non-identified patient-level data.

Fulfilling an essential need within healthcare, the Institute delivers objective, relevant insights and research that accelerate understanding and innovation critical to sound decision making and improved human outcomes. With access to IQVIA's institutional knowledge, advanced analytics, technology and unparalleled data the Institute works in tandem with a broad set of healthcare stakeholders to drive a research agenda focused on Human Data Science including government agencies, academic institutions, the life sciences industry, and payers.

Research agenda

The research agenda for the Institute centers on five areas considered vital to contributing to the advancement of human health globally:

- Improving decision-making across health systems through the effective use of advanced analytics and methodologies applied to timely, relevant data.
- Addressing opportunities to improve clinical development productivity focused on innovative treatments that advance healthcare globally.
- Optimizing the performance of health systems by focusing on patient centricity, precision medicine and better understanding disease causes, treatment consequences and measures to improve quality and cost of healthcare delivered to patients.
- Understanding the future role for biopharmaceuticals in human health, market dynamics, and implications for manufacturers, public and private payers, providers, patients, pharmacists and distributors.
- Researching the role of technology in health system products, processes and delivery systems and the business and policy systems that drive innovation.

Guiding principles

The Institute operates from a set of guiding principles:

- Healthcare solutions of the future require fact based scientific evidence, expert analysis of information, technology, ingenuity and a focus on individuals.
- Rigorous analysis must be applied to vast amounts of timely, high quality and relevant data to provide value and move healthcare forward.
- Collaboration across all stakeholders in the public and private sectors is critical to advancing healthcare solutions.
- Insights gained from information and analysis should be made widely available to healthcare stakeholders.
- Protecting individual privacy is essential, so research will be based on the use of non-identified patient information and provider information will be aggregated.
- Information will be used responsibly to advance research, inform discourse, achieve better healthcare and improve the health of all people.

The IQVIA Institute for Human Data Science is committed to using human data science to provide timely, fact-based perspectives on the dynamics of health systems and human health around the world. The cover artwork is a visual representation of this mission. Using algorithms and data from the report itself, the final image presents a new perspective on the complexity, beauty and mathematics of human data science and the insights within the pages.

This algorithmic art is based on data on prescriptions by Indian companies to U.S. residents over time

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