Industry Overview

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Notes:

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cost containment, pricing and reimbursement, regulatory affairs, and the operating environment for pharmaceutical companies. Market Prognosis contains economic forecasts from the Economist Intelligence Unit and delivers in-depth analysis at a global, regional and country level, and analyzes dynamics at distribution channel, market segment and therapy class levels.

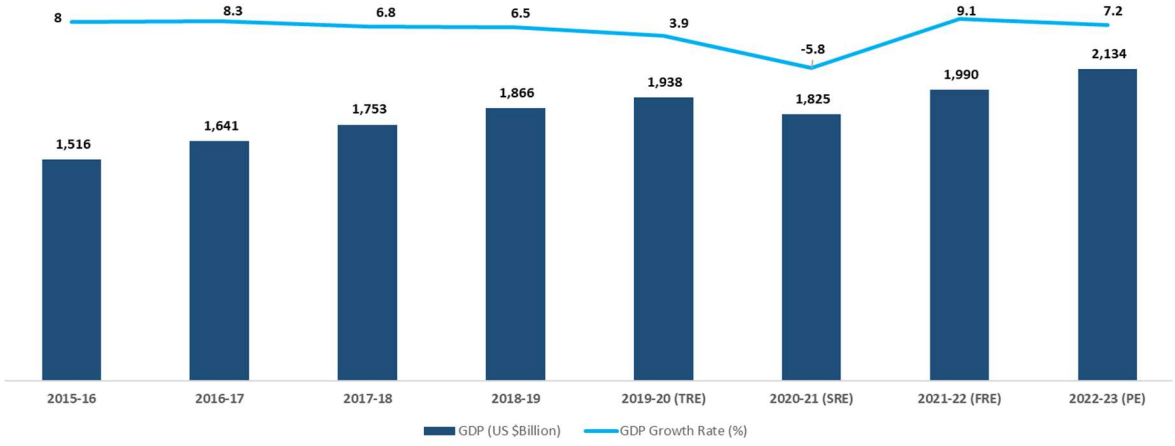
Note: For the purpose of this "Industry Overview" section, US$ is converted to ₹, across the years, using a constant exchange rate of 1 US$ = ₹75.

Macroeconomic Overview of India

Historic GDP growth in India

India ranks 5th in the world in terms of GDP, with an average annual growth rate of approximately 6% since Financial Year 1991. India's real GDP (at constant prices) was US$ 1,990.11 billion (₹ 149,258 billion) in Financial Year 2022 which improved to US$ 2,134.19 billion (₹ 164,064.00 billion) in Financial Year 2023 recovering from the impact of COVID-19. The Indian economy has grown by 7.2% in Financial Year 2023. The RBI's recent Consumer Confidence Survey noted consistent improvement in Consumer Confidence Index since Calendar Year 2022. The Consumer Confidence Index was at 77.3 as of July 31, 2022, which had improved by 1.4 points from May 31, 2022 due to improved rate of employment and household income. Such growth was on account of several factors, such as increased mobility, business activities and trade as COVID-19 situation normalized, strong rebound of end-consumption (in terms of domestic consumption and exports) and policies and measures implemented by the Indian government and the Reserve Bank of India (RBI), which are (a) provision of liquidity window of ₹ 500 billion and (b) an additional liquidity window of ₹ 150 billion for contact-intensive sectors, including restaurants, tourism, and aviation.

Real GDP (in US$ billion) and Growth Rates (in %) (Constant Prices)



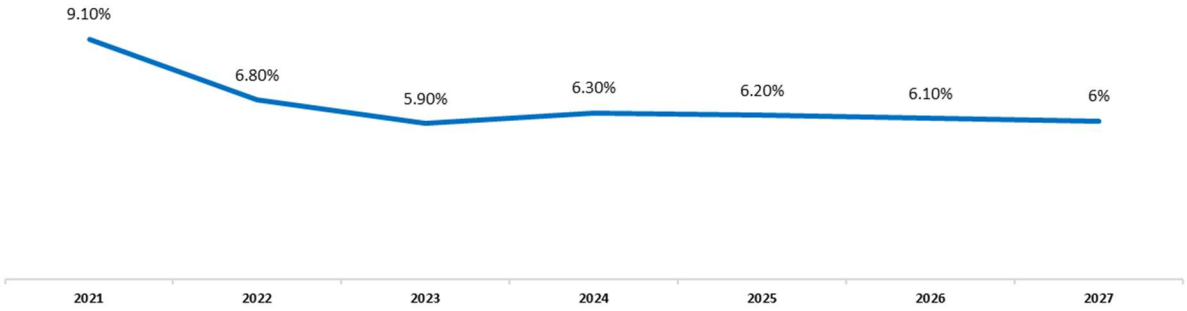
FRE: First Revised Estimates; AE: Advance Estimates; PE: Provisional Estimate
Source: Ministry of Statistics and Programme Implementation
Note: Real GDP data as per 2011-12 series from MoSPI in ₹ is converted to US$ using exchange rate of 1 US$ = 75 ₹

Outlook on India's GDP growth

As per IMF April 2023 data-base, India's GDP has grown at the rate of 6.8% in CY 2022. Further, the growth rate is expected to stabilize at around 6-7% between CY 2023 to CY 2027. Key drivers for India's GDP growth include – (a) rising domestic consumption supported by rising purchasing power of the population, (b) India's push for domestic manufacturing and its impact on creation of jobs locally, and (c) favourable policy support.

Additionally, the Indian government has launched a four-year National Monetization Pipeline (NMP) worth ₹ 6,000 billion for the period starting from Financial Year 2022. The NMP was announced to provide a clear framework for monetization and provide potential investors with a ready list of assets. The NMP will drive private sector investment, which in turn is expected to generate employment opportunities, thereby enabling high economic growth.

Trend and outlook on India's real GDP growth (% year-on-year)

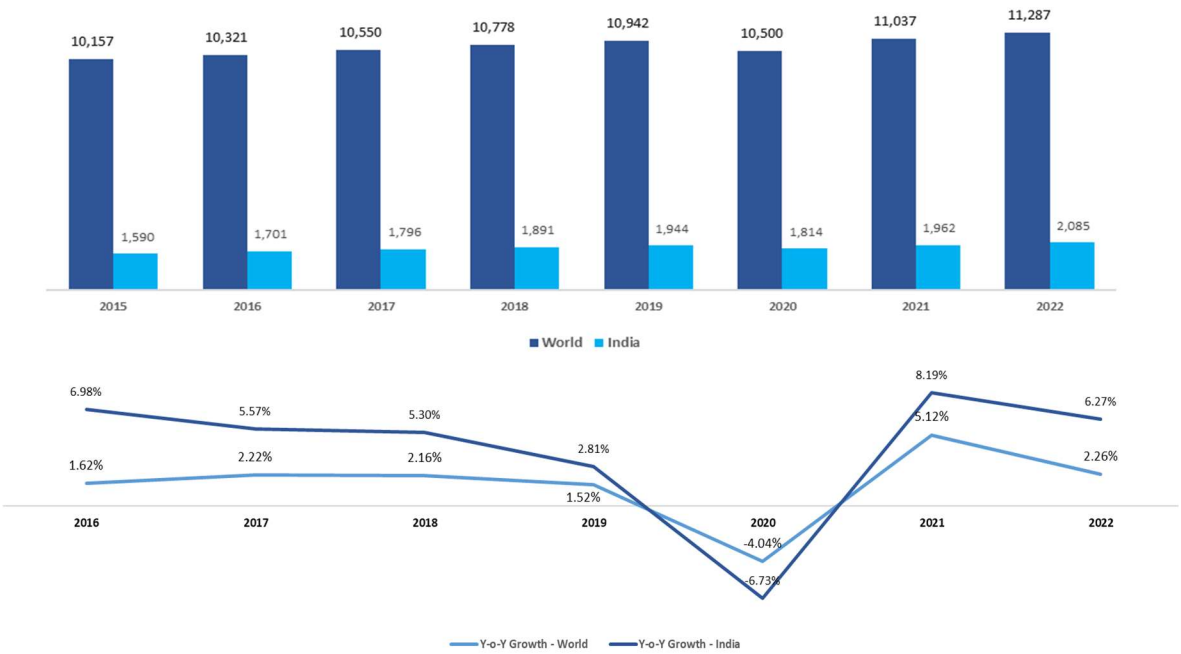


Source: International Monetary Fund
Note: YoY GDP growth forecast in % for 2021-27

Review of GDP Per Capita

Global GDP per capita grew at 1.3% CAGR over CY 15-22, as per the World Bank. During this time period, India recorded a GDP per capita growth of 3.44% (that is - nearly 2.7 times the global GDP growth). With India expected to emerge as one of the fastest recovering economies, the growth in GDP per capita is expected to resume at pre-pandemic levels, over the next 5 years. Between the years 2015 to 2022, the GDP per capita for India has seen the highest growth among the BRICS countries, only second to China, as per the World Bank.

Global and Indian per capita GDP Growth at constant 2015 US$



Source: The World Bank Databank – GDP related datasets
Note: GDP per capita for CY15 to CY22 at constant 2015 US$; YoY growth in GDP per capita of India compared with global numbers

Contrast media

Introduction

Contrast media are chemical agents developed to enhance the contrast of an imaging modality in diagnostic imaging, thereby aiding diagnosis of diseases.

Once inside the human body, contrast media agents are selectively and temporarily taken up by different body tissues. By virtue of their inherent properties, contrast media agents enhance the images, leading to better visualizations of the tissues and organs.

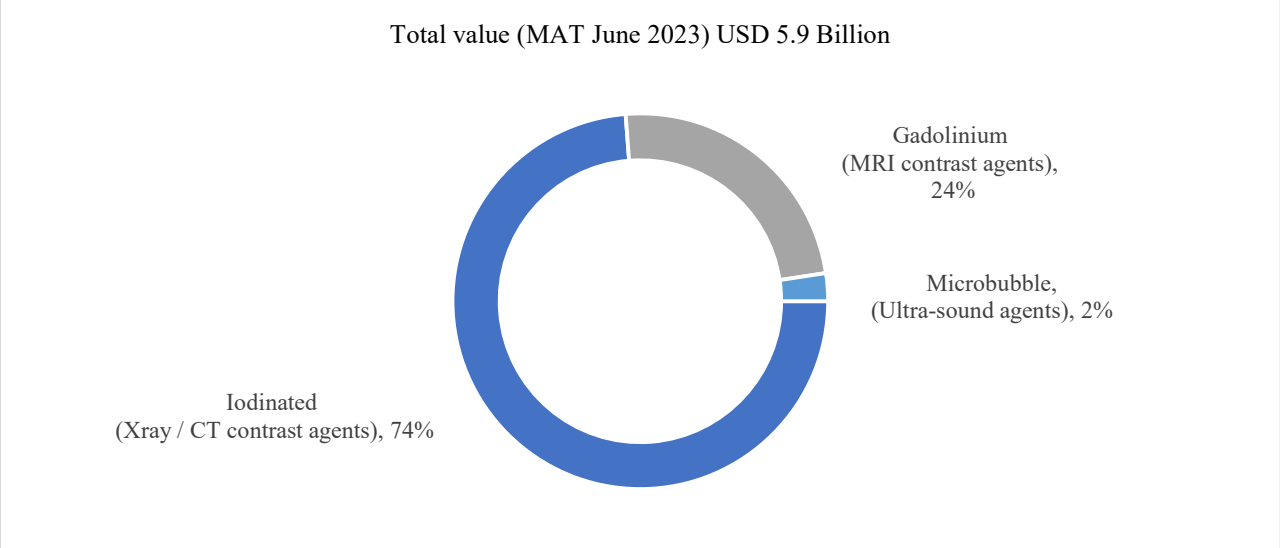
Contrast media – current size and segmentation by imaging modality

Contrast media can be divided into three key segments based on the imaging modality for which they are used. These segments are:

- X-ray / Computed Tomography (CT) contrast agents: these are predominantly iodine-based contrast media agents
- Magnetic Resonance Imaging (MRI) contrast agents: these are predominantly gadolinium based contrast media agents
- Ultrasound (USG) agents: these are stabilized microbubble-based contrast media agents

The size of the global contrast-media formulations market for MAT June 2023 was approx. USD 5.9 Billion (approx.₹ 442.5 billion).

Global Contrast Media Formulations Market, Split by Market Segments (MAT June 2023)



Source: IQVIA MIDAS Quarterly Sales data, MAT June 2023

Note: Thoughtout this report "MAT June" data denotes the moving annual total data starting from July 1of the previous year to June 30 of the year stated. As an example, MAT June 2023 denotes 12 month moving annual total of sales for the period – July 1, 2022 to June 30,2023.

Globally, iodinated contrast agents formed the major segment by value, accounting for approximately 74% of all sales in MAT June 2023. Gadolinium based agents formed the next largest segment, accounting for approximately 24% of the total sales and microbubble forms a srelatively small (approximately 2% share), by value.

Iodine based contrast media (used primarily for X-rays and computed tomography ("CT"))

Iodinated contrast media are primarily used in X-ray based imaging and in CT. This is because:

- Different tissues in the human body have different levels of transparency towards X-rays (for instance, air and fat are more transparent compared to bones) and hence show up as different scales of grey on the final image
- Since iodine has an atomic number that is higher compared to most tissues in the body, it produces more attenuation of X-rays and hence increases contrast of X-ray based images.

Iodine-based contrast agents are divided according to:

  - osmolarity (high, low)
  - ionicity (ionic or non-ionic); and
  - the number of benzene rings (monomer or dimer).

Ionic contrast agents have the propensity to dissociate into ions on dissolution in a polar solvent (such as body fluids). This dissociation results in introduction of multiple particles per molecule of contrast agent and are hence usually high-osmolar.

Non-ionic / low-osmolar contrast agents are associated with significantly lower rates of adverse reactions as opposed to high-osmolar agents. Resultantly, non-ionic/ low-osmolar preparations are most widely used.

The classification of contrast media agents into monomer or dimer corresponds to the number of benzene rings in the structure of the molecule. Benzene ring being a stable structure; dimers are therefore more stable than monomers and are also able to fit more iodine atoms per molecule.

Listed below are the iodine-based contrast media based on their osmolarity, ionicity and whether these are monomer or dimer.[1]

Molecule	Monomer/ Dimer	Ionicity	Osmolarity	Approximate Share of the molecule within iodine based contrast media (as per Global MAT June 2023)**	CAGR (2019 – 2023)
Iohexol	Monomer	Non ionic	Low osmolar	Approx. 31-33%	<0%
Iodixanol	Dimer	Non ionic	Low osmolar	Approx. 12-14%	<0%
Iopamidol	Monomer	Non ionic	Low osmolar	Approx. 15-17%	<0%
Ioversol	Monomer	Non ionic	Low osmolar	Approx. 10-12%	5-6%
Iomeprol	Monomer	Non ionic	Low osmolar	Approx. 10-12%	5-6%
Iopromide	Monomer	Non ionic	Low osmolar	Approx. 10-12%	5-6%
Iobitridol	Monomer	Non-ionic	Low osmolar	Approx. 4-6%	2-3%

[1] Intravascular Contrast Media for Radiography, CT, MRI and Ultrasound, Mar 2, 2016, PG https://radiologykey.com/intravascular-contrast-media-for-radiography-ct-mri-and-ultrasound/

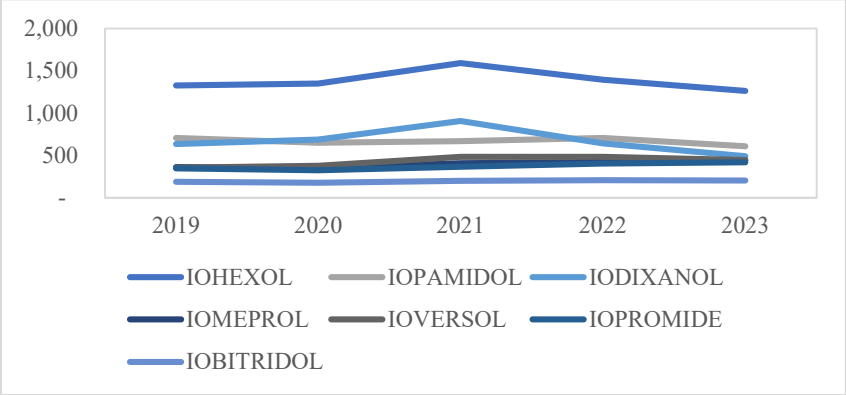
Others	-	-	-	<1%	6 - 7%
Total	-	-	-	**Approx. 100%**	**0 to 1%**

Source: IQVIA MIDAS Quarterly Sales data MAT June 2023; for osmolarity, ionicity and monimer vs dimer related information, IQVIA has relied on secondary sources[2]

** The market share provided is that of the respective molecule within the overall iodine based contrast media market.

As the above table indicates, the key iodinated molecules are non-ionic, low-osmolar agents. All these agents are well established in the market, having gained US-FDA approval on or before year 2000.

Key iodine based contrast media molecules by formulations sales value (millions USD), Global MAT June 2019 – Global MAT June 2023



Source: IQVIA MIDAS Quarterly Sales data, MAT June 2023

Gadolinium based contrast media (used primarily for MRIs)

Gadolinium based contrast agents ("GBCAs") have been approved for intravascular use for MRI over the past 20 years. These agents are injected intravenously. Gadolinium is the molecule of choice for use as an MRI contrast agent, because it has the highest number of unpaired electrons; this property of Gadolinium causes brighter images on MRI scans.

GBCAs are classified based on:

- Ionicity (ionic or non-ionic)) – extent to which the molecule dissociates into ions when dissolved in a polar solvent
- Chelating ligand (macrocyclic or linear) – chemical compounds that are bonded to ions to increase the stability of the compound

Both ionic and non-ionic GBCAs can be used for intravascular injection. Most gadolinium contrast agents are distributed rapidly through the body and eliminated through the kidneys; allergic reactions to GBCAs are relatively rare. Macrocyclic agents are more stable than linear agents and hence are associated with better contrast.

[2] Intravascular Contrast Media for Radiography, CT, MRI and Ultrasound, Mar 2, 2016, PG https://radiologykey.com/intravascular-contrast-media-for-radiography-ct-mri-and-ultrasound/

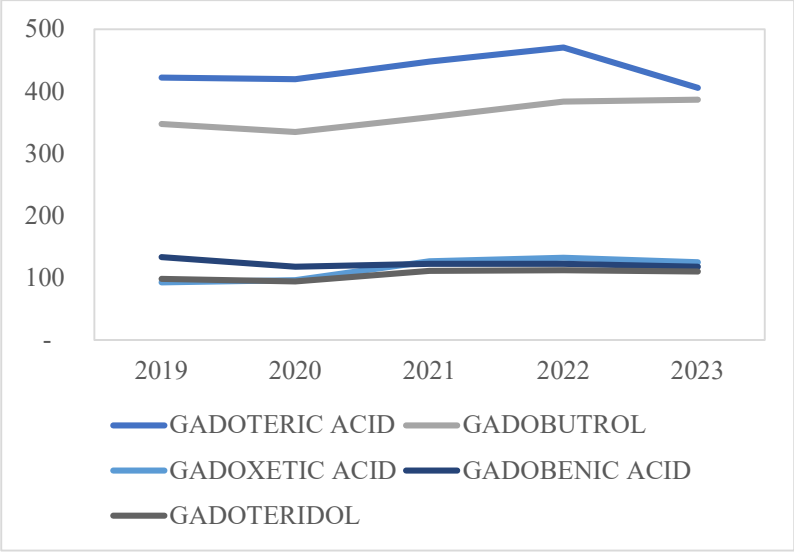
Listed below are gadolinium-based contrast media (used primarily in MRI) based on their ionicity and chelating ligand. [3]

Molecule	Ligand group	Ionicity	Share of the molecule within gadolinium based contrast media (as per Global MAT June 2023)**	CAGR (2019 – 2023)
Gadoteric acid	Non-linear (macrocyclic)	Ionic	Approx. 31-33%	< 0%
Gadobutrol	Non-linear (macrocyclic)	Non-ionic	Approx. 30-32%	2-3%
Gadoxetic acid	Linear	Ionic	Approx. 9-11%%	7-8%
Gadobenic acid	Linear	Ionic	Approx. 8-10%	< 0%
Gadoteridol	Non-linear (macrocyclic)	Non-ionic	Approx. 8-10%	2-3%
Gadopentetic acid	Linear	Ionic	Approx. 5-7%	< 0%
Gadodiamide	Linear	Non-ionic	Approx. 3%	< 0%
Others	-	-	~0.5%	< 0%
Total	-	-	**Approx. 100%**	**1-2%**

Source: IQVIA MIDAS Quarterly Sales data, MAT June 2023

** The market share provided is that of the respective molecule within the overall gadolinium based contrast media market.

Key gadolinium based contrast media molecules by formulations sales value (millions USD), Global MAT June 2019 – Global MAT June 2023



Source: IQVIA MIDAS Quarterly Sales data, MAT June 2023

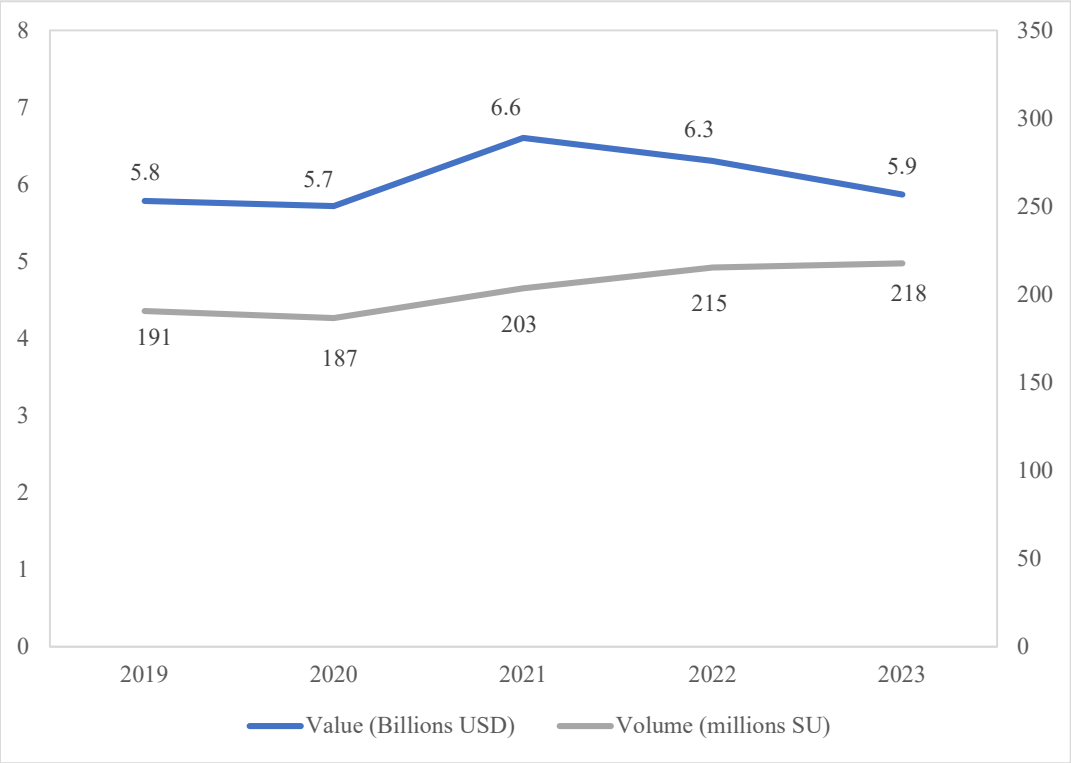
[3] MRI contrast agents: Classification and application, International Journal of molecular medicine, Sep 21, 2016, https://www.spandidos-publications.com/10.3892/ijmm.2016.2744

Gadopiclenol is a new macrocyclic gadolinium-based contrast agent. In Phase 3 clinical trials, the product has shown encouraging results in terms of high relaxivity, minimal / no protein binding, and high kinetic inertness – pointing to potential uses for central nervous system diagnostic studies.

Contrast media: historical trends and forecast size

Contrast media: Historical trends

Global contrast media sales value and volume, MAT June 2019-2023



Source: IQVIA MIDAS Quarterly Sales data, MAT June 2023

The global contrast media formulations market witnessed the following trends between MAT June 2019 and MAT June 2023:

1. The formulations market witnessed a continual increase until MAT June 2021 on account of (a) use of contrast media in COVID-19 related diagnosis and (b) use of contrast media in medical procedures that were initially planned in 2020, but were undertaken in 2021 as various COVID-19 related restrictions eased in early 2021
2. The formulations market witnessed a continual decline post MAT June 2021 on account of various factors such as - (a) supply uncertainty, as factories (especially those in China) remained shut during certain parts of Calendar Year 2022 on account of local COVID-19 restrictions and (b) hospitals across the globe focused on recovery of margins, post the unprecedented drop in revenues they witnessed on account of COVID-19 and hence looked to negotiate / re-negotiate prices of contrast media formulations
3. The contrast media formulations market returned nearly to pre-COVID (MAT June 2019) levels in MAT June 2023

Contrast media: Forecasts

This section is organized into following sections:

- Key considerations underlying the forecasts

- a commentary on key drivers for growth of contrast media.
- current geographic distribution of contrast media market; and
- an estimation of geography-wise growth range for the formulations market for iodine and gadolinium-based molecules.

Contrast media forecasts: Key considerations

The forecasts below **do not consider** the following scenarios:

- COVID-19 continuing to cause serious disruptions in the diagnostic imaging market, going forward
- A significant fluctuation (especially downwards) in prices of contrast media formulations products. That is, keeping in view pre-COVID trends, our analysis considers stable pricing regime for contrast media formulations
- Launch of certain products that are currently in product development stages. Given that the products are in early stages of development and their safety / efficacy over the current set of products is yet to be conclusively proven, this dsocument refrains from making any adjustments for disruption (if any) that such launches may cause in the demand for existing products.

Growth drivers for contrast media

Growing Population and Changing Demographics:

According to the UN estimates, the global population is expected to rise from 7.9 billion in 2021 to 8.5 billion in 2030[4]. The segment of the population aged 65 years and above is estimated to increase from 6.9% of total world population in 2000 to an estimated 10.4% by 2025[5]. An aging population is expected to increase the overall spending on healthcare, including an increased spending on diagnostics.

Growing prevalence of lifestyle diseases:

Globally, factors such as hypertension, smoking, irregular diet patterns, increasing prevalence of diabetes, physical inactivity, obesity etc. in the young population (especially in individuals less than 40 years of age) has led to the emergence of various lifestyle diseases in the early stages of life. This, in turn, is expected to drive increased spend on diagnostics.

Rising Healthcare expenditure

Healthcare expenditure is transitioning globally, with a rapid rise in domestic spending, both out-of-pocket and publicly funded. During the period from 2000-2017, global health expenditure has grown at a CAGR of 3.9% while the global economy grew at a CAGR of 3.0%[6]. This phenomenon (higher domestic spending on healthcare) is expected to increase further[7] due to innovative public and private healthcare financing initiatives undertaken by the countries across the world.

Focus on early diagnosis:

Advancement in diagnostic technologies (such as nuclear imaging, radiographic tests, etc.) coupled with growing public awareness are expected to drive the demand for diagnostic services.

Increased convenience

[4] World Population Prospects - UN Population Division (2019)
[5] World Bank national accounts data
[6] World Health Organization
[7] OECD report (Healthcare at glance)

Convenience (provided to the customers through online booking, and online reporting, etc which result in time-saving for the patient) will be one of the key levers to drive demand for diagnostics services. Diagnostic labs, on their part, are investing in having a stronger network of labs and advanced lab technologies to increase the turn-around time for the tests and further add to the patient convenience.

Increasing demand for preventive healthcare:

Globally, demand for preventive healthcare has increased on account of (a) increased awareness and (b) rising curative costs. Employers across the globe are promoting preventive and wellness tests on a regular basis for their employees, to support the well-being of their employees and potentially reduce absenteeism and other health risks.

Geographic distribution of Global contrast media formulations market

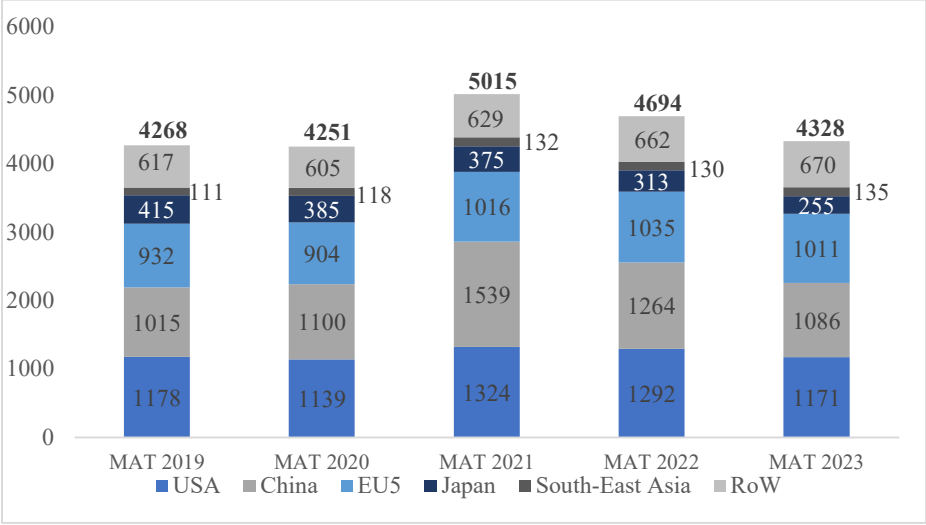
The USA accounts for the largest share of contrast media sales of formulations (by value) with ~USD 1.6 Billion (₹ 125 billion) as of MAT June 2023. China is the second largest market with ~USD 1.41 billion (₹ 106 billion) in MAT June 2023. Among the other regulated markets – Japan and EU5 markets (Germany, France, the UK, Italy, and Spain) together account for approximately 29% of the total market.

Geographic distribution of Contrast media market (millions USD), MAT June 2023

Country / Region	Value (millions USD MAT June 2023)	Value share in % (2023)	CAGR % (2019 – 2023)
USA	1,694	29%	<0%
China	1,410	24%	4-5%
EU 5	1,342	23%	1-2%
Japan	343	6%	< 0 %
South-East Asia	173	3%	5-6%
Rest of the World	908	15%	~2%
Total	**5869**	**100%**	**~0-1%**

Source: IQVIA MIDAS Quarterly Sales data, MAT June 2023

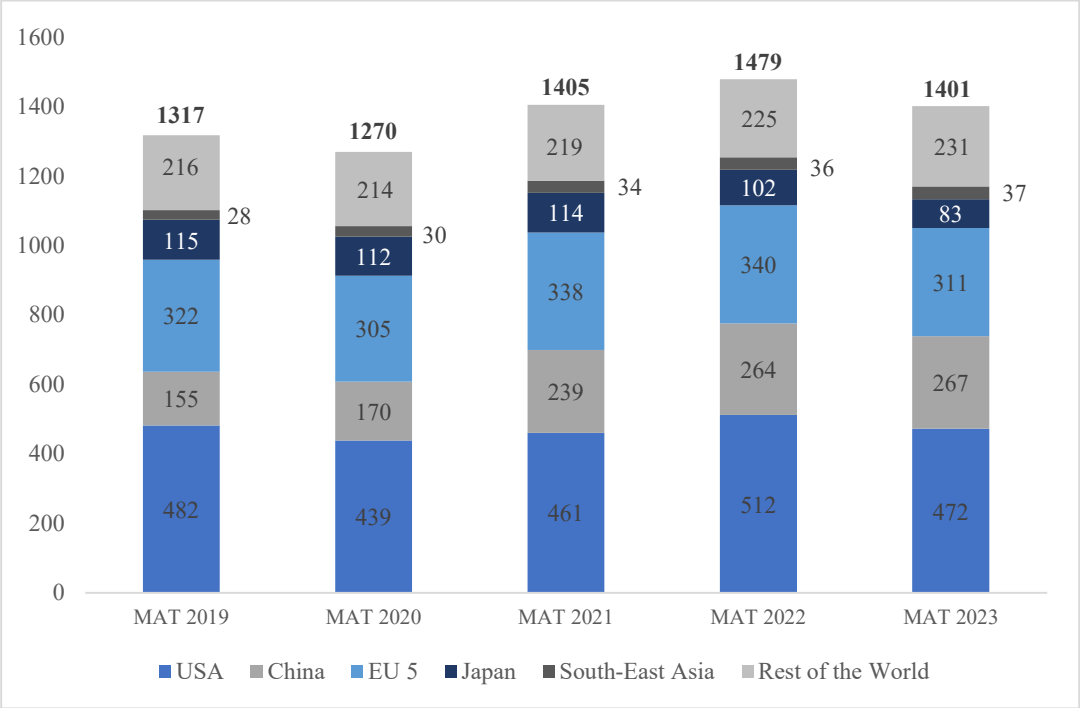
Geographical distribution of Iodine based Contrast Media sales (millions USD), MAT June 2019-2023



Source: IQVIA MIDAS Quarterly Sales data, MAT June 2023

As of June 30, 2023, USA was the largest market for iodinated contrast media accounting for approximately 27% of the formulations market, followed by China and the EU5 accounting for approximately 25% and approximately 23% respectively. South-East Asia is one of the fastest growing market exhibiting a CAGR of ~5% and reaching a value of USD 135 million (approx. ₹ 10.12 billion) in MAT June 2023.

Geographic distribution of Gadolinium-based Contrast Media sales (millions USD), 2019-23



Source: IQVIA MIDAS Quarterly Sales data, MAT June 2023

USA and EU5 together accounted for ~56% of the gadolinium-based contrast media formulations during the period from MAT June 2019 to 2023, reaching USD 783 million (approx. ₹ 58.7 billion) in MAT June 2023.

COVID-19 resulted in delayed elective surgical cases, leading to decrease in volumes of imaging procedures unrelated to COVID (such as MRI, mammography, etc). This, in turn, resulted in de-growth in the demand for gadolinium-based contrast media between MAT December 2019 and MAT December 2020 and subsequent rebound in MAT December 2021.

Growth forecasts for contrast media

Overall contrast media formulations market is forecast to grow at a CAGR of 6-8% between 2023-2025; the growth is expected to be primarily led by volume. The forecast geographic distribution of this growth is estimated to be as under:

Country / Region	Pre-COVID growth (2014-2018)	Historical Value growth (2019-2023)	Forecast Value growth (2023-2025)	Remarks on forecast
Regulated, developed markets (US and EU-5)				

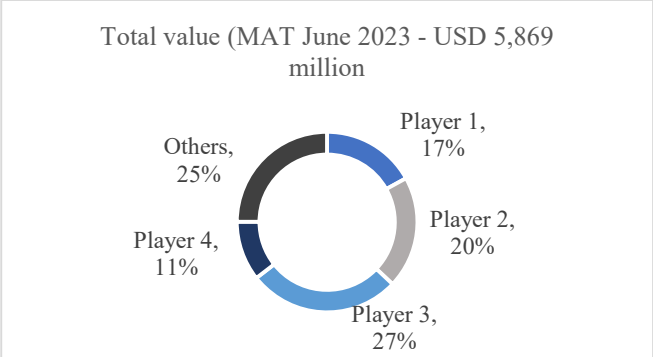
Iodine based contrast media	3-4%	0-1%	2-4%	US and EU-5 are stabilized, matured markets with a sizeable installed base of MRI / CT equipment. With COVID situation normalizing, the market will likely resume historical growth (adjusted for high-base effect)
Gadolinium based contrast media	3-4%	<0%	2-4%	
China				
Iodine based contrast media	12-15%	1-2%	8-10%	China iodine and gadolinimum markets witnessed a sharp decline during 2019-2023 on account of COVID restrictions implemented in the country. With COVID related restrictions lifted and given the focus of the latest 5 year plan on widening healthcare access, the market will likely resume historical growth (adjusted for high-base effect)
Gadolinium based contrast media	16-17%	13-15%	12%-14%	
Rest of the World				
Iodine based contrast media	1-2%	2-3%	3-5%	Headroom for growth exists given (a) ageing population (b) increased spend / reimbursement by several governments
Gadolinium based contrast media	4-6%	2-4%	6-8%	Growth will likely surpass pre-COVID levels, given (a) increased incidence of cancer and cardiovascular diseases - diagnosis of which requires use of MRIs (b) initiatives by countries for increased access

Source: IQVIA MIDAS Quarterly Sales data, MAT June 2023, IQVIA analysis

Key players in the Contrast Media Formulations market

The global contrast media formulations industry is highly concentrated, with 4 players garnering ~75% of global sales of contrast media formulations *(Source: IQVIA MIDAS Quarterly Sales data, MAT June 2023)*. These 4 players (in alphabetical order; not in the order in which these have been depicted in the charts in this document) are: Bayer, Bracco, GE Healthcare and Guerbet.

Global Contrast Media Formulations Market, Key players as per MAT June 2023



Source: IQVIA MIDAS Quarterly Sales data, MAT June 2023

These 4 key players:

- Are the innovators / originators of the respective contrast media formulations products and, as indicated in the charts in this document, continue to hold significant market share of the global contrast media market
- Collectively held approx. 75% of the global contrast media formulations in each of MAT June 2019, 2020,2021, 2020 and 2023
- Either have a forward integration play (that is – they manufacture the MRI / CT / X ray equipment) or have long-standing relationships with existing equipment makers
- Given the capital expenditure associated with these equipment and the criticality of the output in determining patient treatment, end-users of contrast media (such as diagnostics labs and hospitals), typically prefer using the originator's formulation product as contrast media; further, the closed-system nature of the equipment (that is - only a specific contrast media reagent is indicated for a given equipment, to the exclusion of other contrast media agents) has ensured that these 4 players have been able to hold higher than 70% global market share consistently over the past 10 years (MAT June 2013-MAT June 2023).

Global Contrast Media Formulations Market, Key players as per MAT June 2023

Players	Share of iodine-based contrast media %	Share of gadolinium-based contrast media %
Top 4 players combined	**73%**	**81%**
Others	**27%**	**19%**
Total	**100%**	**100%**

Source: IQVIA MIDAS Quarterly Sales data, MAT June 2023

Sourcing of intermediates by contrast media formulations players

Manufacturers of contrast media intermediates supply their products to contrast media API and formulations companies (that is, intermediates players operate with Business-to-Business (B2B) model).

Key charateristics of this B2B model are:

- Steady or predictable cash flow: B2B players generally have long-term supply contracts ranging from three to five years with API / formulations, providing predictability of medium-term revenue.

- Partnership between formulations companies and B2B players are close, given the specialized nature of manufacturing contrast media. These factors help B2B players with an ascertained and agreed minimum order quantity thus giving them a better visibility to cash flow

- *Quality Compliance is one of the most important considerations*: During the last few years, regulatory scrutiny has increased across the board for pharmaceutical products. Good track record of quality, compliance with regulatory requirements and customer inspections provide confidence in supply continuity to contrast media formulations companies.

The aforementioned 4 contrast media formulations players are headquartered in developed markets (namely USA and EU). These players typically source intermediates from select vendors in India and China ("Vendors"). The entry barriers for becoming a Vendor to any of these 4 players are high, on account of the following reasons:

1. **Strict internal standards for product impurity / features profile**:
   Given (a) that the end-use of contrast media is in conducting expensive diagnostic examination and (b) the high level of integration that the contrast media needs to have with the corresponding equipment, the formulations players have very strict standards of impurity / features profile.

   Only those intermediate players that have an established track record and proven technological expertise in manufacturing contrast media intermediates can meet such standards.

2. **Stickiness of relationship**: The key criteria for purchasing contrast media intermediate is whether the intermediate, when converted into API and eventually into formulations, delivers the desired "performance" in the diagnostic lab / clinical setting.

   This necessitates a close co-ordination between (a) contrast media API and formulations players and (b) contrast media intermediate suppliers, over a sustained period of time. The intermediates players do not compete based on ability to provide the product at lowest cost; instead, their focus is on working closely with the formulations players over a sustained period of time to ensure that the formulations product delivers the required performance.

3. **Long-term supply contracts**: Contrast media formulations players typically do not procure intermediates on "spot" basis (that is – procure whichever intermediate is available at the point of time, at the lowest cost).

   Instead, the intermediates players are provided long-term forecasts by formulations players and long-term supply contracts are entered into. Further, when developing a new molecule, the contrast media formulations players typically work very closely with the intermediate suppliers to ensure that (a) the quality / impurity profile is maintained and (b) when the product is launched, issues associated with scale-up of manufacturing are mitigated.

Contrast media API and intermediates landscape

Contrast media intermediates players are primarily based in India and China. Even prior to COVID-19, formulations companies were looking to de-risk their dependence on a single country. COVID-19 has further accentuated this need and formulations companies are increasingly looking to source intermediates from a diverse set of countries (including India), on account of:

- Established credentials of India in pharmaceuticals manufacturing
- Large pool of talent (pharmaceuticals graduates, engineers) available in India
- Established track record in delivering intermediates and APIs that adhere to the quality norms of formulations players and regulatory authorities.

This ought to result in increased demand for intermediates manufactured by established Indian contrast media players considering (a) the stickiness of the customer relationships in the contrast media space, as described above and (b) the trend for de-risking the dependence on a single country.

There does not exist an industry standard / industry recognized data-set that provides the size, market share, quantity supplied, growth trends, competitive landscape of contrast media intermediates. Based on secondary research, the following is noted:

- A limited number of India-based players supply contrast media intermediates to contrast media API / formulations companies based in United States and Europe.

- There exist cases of molecules / intermediates where, for a specific molecule / intermediate level, a single player has supplied greater than 75% of the value of the intermediates exported from India over the past 3 years. One of the examples of this phenomenon - is that of 5-Amino-N,N'-bis(2,3-dihydroxypropyl)isophthalamide (Trade name: ABA), where, over the past 3 calendar years, the Company has supplied over 75% of the value of exports of the intermediate from India (Source: Data on imports to and exports from India, as available in public domain, secondary research)

High-Intensity Sweetener Market

Note: There does not exist an industry standard / industry recognized data-set that provides the size, growth trends, competitive landscape of high-intensity sweetener market in general and saccharine in particular. The information contained in this section is based on information available in public domain (including but not limited to annual reports of companies that market high-intensity sweeteners, analyst reports as well as select publications of Government of India). Accordingly, the data-points stated in this section are not based on a single data-set.

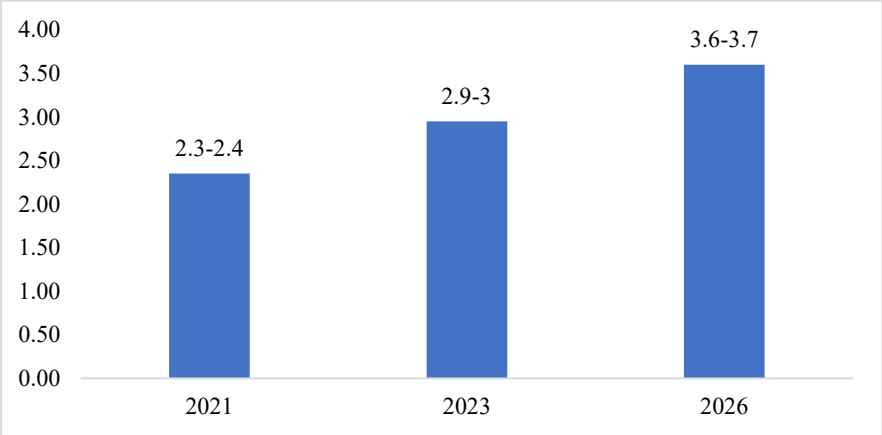
High-Intensity Sweetener Market overview

Saccharine is a 'high-intensity sweetener'. High intensity sweeteners are compounds that are commonly used as substitute for sugar in food, beverages, oral health, and pharmaceutical products ("End Products"). High intensity sweeteners are around 300-500 times sweeter than sugar but contribute negligible / limited calories, when added to food items.

High-Intensity Sweeteners: Market size and growth

In 2023, the global high-intensity sweetener market was estimated to be a US$ 2.9 to 3.0 Billion (approx. ₹ 232 – 240 billion) in size, comprising products such as Sucralose, Aspartame, Saccharine, Stevia and Neotame.

Global High Intensity Sweetener Market (Billions USD)



Source: Secondary research, investor presentations of select high-intensity sweetener focused players

The high-intensity sweeteners market is estimated to grow at a CAGR in the range of 6% to 7% over the next 5 years, on account of the following:

1. Growing incidence of diabetes and obesity and corresponding need for low-calorie foods

   Approximately 537 million adults (i.e., individuals in the age group of 20-79 years) are estimated to be living with diabetes in 2023[8] and the number is projected to rise to 643 million by year 2030. Further, obesity worldwide has nearly tripled since 1975[9]. With the growing burden of diabetes and obesity, the demand from consumers for low-calorie food and beverage products is expected to rise.

2. Shifting consumer preference

[8] International Diabetes Federation (IDF) Diabetes Atlas
[9] World Health Organization (2016)

Consumers previously looking for reduced fat content are shifting their focus towards reduction in consumption of sugar. This trend has led food and beverage manufacturers to develop and market "sugar-free" products, by using high-intensity sweeteners in their formulations.

3. Increase in investment in R&D by manufacturers of End-Products

   Manufacturers of End Products (such as FMCG companies, companies that market beverages and oral care products) are making investments in R&D programs and are setting up innovation labs, to:

   - develop product solutions that address customer feedback such as delay in perceived sweetness, bitter aftertaste, and lack of mouth feel; and
   - evaluate the long-term health impact of artificial sweeteners.[10]

4. Rising urbanization and changing lifestyle resulting in higher consumption of ready-to-eat / processed foods

   High-intensity sweeteners are extensively used in packaged food products such as ready-to-eat foods, beverages, frozen meals, etc. While demand for packaged food and beverage products has historically been driven by developed markets (such as United States, Canada, Western Europe, and Japan), developing economies in South-East Asia / select countries within Africa are expected to drive future growth for convenience food products due to rising urbanization, increase in disposable income, growing middle class population and changing lifestyle patterns.

High-Intensity Sweeteners: segmentation by key products

Summarized below are the most commonly used high-intensity sweeteners:

Parameter	**Sucralose**	**Saccharine**	**Aspartame****	**Stevia**
Year of discovery	1976	1879	1965	1931
Sweetening power compared to sugar (Approx.)	600-650 times	300-500 times	200 times	200-300 times
Metabolic and biological properties	Minimally metabolized and excreted unchanged	Not metabolised and excreted unchanged	Metabolized to its constituent amino acids and methanol	Broken down to steviol in gut and excreted in urine as steviol glucuronide
Caloric value	Calorie-free	Calorie-free	4 kcal/g	Calorie-free

Source: EU Commission Regulation No. 231/2012; Annexure II and II of Regulation No. 1333/2008

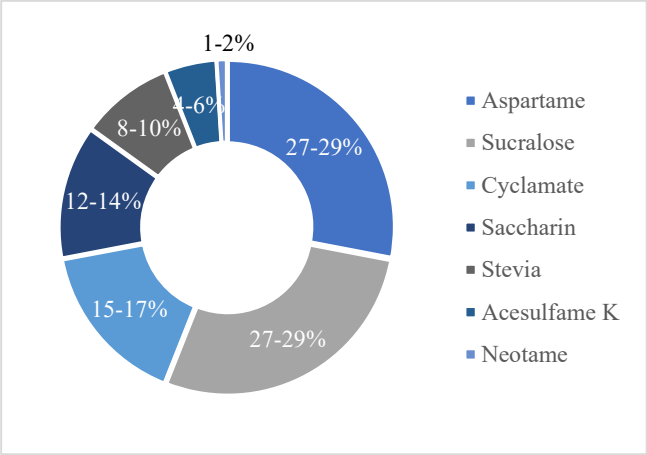
** In July 2023, the International Agency for Research on Cancer (IARC) and the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) Joint Expert Committee on Food Additives (JECFA) released its findings in relation to assessment of health impact of aspartame. Citing "limited evidence" for carcinogenicity in humans, IARC classified aspartame as possibly carcinogenic to humans (IARC Group 2B)

[10] Based on review of investor presentations of listed food and beverage companies

Saccharine Market overview

Saccharine is commercially sold as a granular or powered form artificial sweetener and is primarily used in table-top sweeteners, oral care products such as toothpastes and mouthwashes, beverages (primarily soft-drinks), confectionery products (mints, candies, and bakery products), pharmaceutical products, food supplements and animal feeds etc.

Market share of Global High Intensity Sweeteners (by value)



Source: Secondary research

Saccharine forms 12-14% (by value) and 17-19% (by volume) of the high-intensity sweeteners market[11]. Saccharine is expected to continue holding this share within the high-intensity sweeteners market, on account of the following:

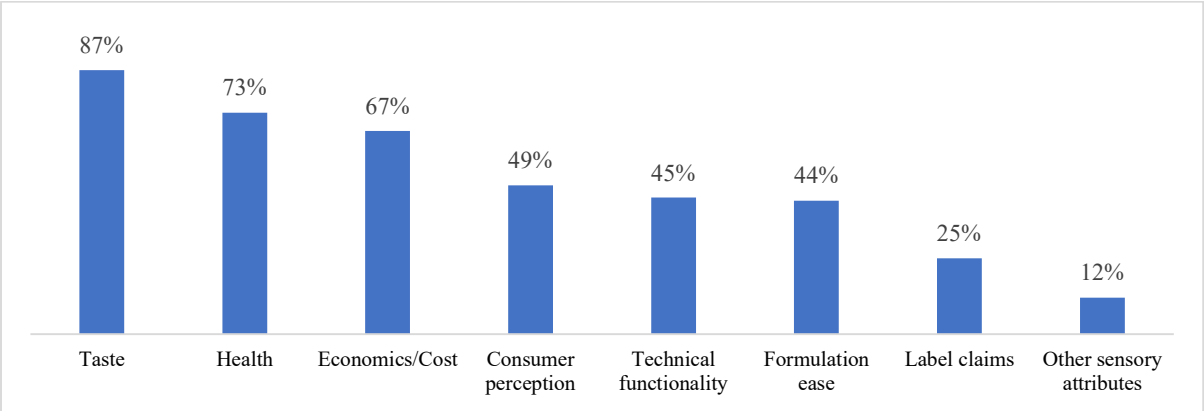
1. Taste consistency
2. Established safety profile
3. Cost effectiveness
4. Versatility

Taste consistency

Selection of high-intensity sweetener by end-users (such as FMCG / Oral health companies) is a function of various factors such as calorific value, cost implications, product positioning, sensory attributes etc. However, "taste" appears to be the primary deciding factor for most food and beverage companies when including high-intensity sweeteners in their product formulations [12]; correspondingly, companies that market products containing high-intensity sweeteners accord highest importance to taste profile when selecting the sweetener.

[11] Secondary research
[12] International Food Information Council survey

Percentage of attributes ranked in top 3 most important attributes by R&D/Product development officials of food and beverage companies



Source: Secondary research

As a result, for products that already contain saccharine and have an established taste profile, FMCG companies are unlikely to substitute saccharine with any other high-intensity sweetener, unless such product delivers exactly the same taste profile as that of saccharine.

Established safety profile

Saccharine has been consumed by humans for more than 100 years and it is one of the most extensively researched food additives. Multiple studies conducted over the past 3 decades have indicated that saccharine is safe for human consumption.[13] As a result:

- In 2001, saccharine was removed from the list of potential carcinogens and, therefore, products containing saccharine do not need to carry a warning label. Both US FDA and EPA have declared saccharine as safe for consumption and it is among the only 6 high-intensity sweeteners approved by US FDA[14] as food-additives in the US.
- Other European and International authorities that have provided approval to saccharine include the European Food Safety Authority (EFSA) and The Joint FAO/WHO Expert Committee on Food Additives (JECFA). In the European union, 11 sweeteners including saccharine are approved for use in food and beverage products.
- Saccharine has been approved in more than 100 countries worldwide.[15] The timeline showcasing growing acceptance of saccharine as a sugar substitute is highlighted below:

Timeline in relation to safety profile of saccharine

Year	Institution	Decision/Recommendation on Saccharine
1993	World Health Organization (WHO)	Declared as a safe artificial sweetener for human consumption
1995	The Scientific Committee on Food (SCF) of the European Commission	Established Average Daily Intake (ADI) and reconfirmed its safety
1998	International Agency for Research on Cancer (IARC)	Deleted from list of carcinogens

[13] A. Bassoli, L. Merlini, in Encyclopaedia of Food Sciences and Nutrition (Second Edition), 2003
[14] US FDA website
[15] Touyz, Louis Z G. "Saccharine deemed "not hazardous" in United States and abroad." Current oncology (Toronto, Ont.) vol. 18,5 (2011)

2000	National Toxicology Program (NTP), USA	Deleted from list of carcinogens
2001	Food and Drug Administration (FDA), USA	Declared as safe for human consumption
2010	Environmental Protection Agency (EPA), USA	Saccharine removed from list of toxic materials

Source: Information available on WHO, US FDA and EPA Websites

Cost effectiveness

Saccharine is one of the least expensive high-intensity sweeteners available. Saccharine is also blended with other high-intensity sweeteners, in order to lower the per unit product costs while ensuring the sweetness profile of the end-product.

Cost comparison of sweetening 1000 cups of coffee/tea from various high-intensity sweetener alternatives

Sweetener	Cost of sweetener for 1000 cups of coffee or tea (in USD)
Saccharine	20.0
Sugar	23.9
Aspartame	36.5
Sucralose	54.9
Rebaudioside A (Reb-A)	107.3

Source: Sugar and Sweetener Outlook by Economic Research Service, USDA

Versatility

- Saccharine remains stable at temperatures up to 250 degrees and is therefore used widely in making bakery and confectionery products that require food ingredients to withstand high temperatures during the preparation process.
- Furthermore, saccharine does not react with other food ingredients and hence considered suitable for cooking and baking processes. It has a long shelf life and can be conveniently used in packaged food products.

Key considerations when selecting vendors for provision of saccharine

Food and beverage manufacturers source saccharine from select vendors. The vendors are selected based on:

1. **Strict internal standards for impurity profile**: Given the end-use of saccharine in food and beverage products, oral care products, nutrition supplements and pharmaceutical applications, saccharine manufacturers need to have a very strict standards of impurity profile. Quality was ranked as the most important factor used in purchasing decisions by US purchasers of saccharine.[16]

   Top players in beverages, bakery and confectionery industries prefer to source saccharine from a small set of vendors having manufacturing facilities that observe high standards of compliance. High levels of backward integration in terms of procurement of raw material is required in order to ensure consistency in quality, taste and impurity profile of saccharine produced.

2. **Stickiness of relationship**: Given stringent regulations on use of ingredients in food / beverages by regulatory agencies, saccharine purchasers prefer long-term stability in supply chain operations and hence work with a few selected ingredient suppliers over a sustained period of time, thereby developing long-term

[16] Source: Company websites, U.S. International Trade Commission

relationships.[17][18] Saccharine is generally sold via annual contracts[19] and lead time to secure a contract with a global food and beverage customer for a saccharine supplier is at least 3-5 years.

Saccharine manufacturing landscape

Global demand for saccharine is estimated to be around 37,000-40,000 MT per annum. Saccharine manufacturers are primarily based in Asia with majority of production capacity being concentrated in China.

The largest China based player has saccharine manufacturing capabilities exceeding 7,000 MT per annum. JMC, a leading Korea based manufacturer has installed capacity of ~ 3500 MT per annum. Only a select set of Indian players have comparable capacities. The Company has the installed capacity of approx. 3000-4000 MT per annum, while some of the other India head-quartered players have capacity ranging between 1200 to 1500 MT per annum.[20]

Considering the trend in the end-use sectors to reduce dependence on China, should there be a switch of source from China to India, these leading India based players would be able to garner a substantial part of this demand.

Overview of End-Product industries

Provided below is a brief profile (in terms of growth drivers and key players) of select industries where saccharine is used.

Oral care

The oral care market (in value) is expected to grow at a CAGR of 5% to 6% during the 2023-2026 period, on account of the following:

- Increased awareness: Awareness levels in consumers regarding benefits of good oral hygiene has been consistently rising
- Companies that market oral health products have been adding innovative products to their product portfolio, in order to meet specific requirements of customer segments. For example, specific oral care products are now available for consumers suffering from diabetes; similarly, products with natural ingredients have entered oral care space
- Availability of multiple distribution channels (general trade, modern retail, e-commerce etc.) has improved the accessibility of oral care products in rural regions thereby supporting the growth of the overall market

The market is reasonably concentrated with Top 5 players (these players are arranged in alphabetical order; not in the order of their market share: Colgate, GSK, Johnson & Johnson, Proctor & Gamble and Unilever) commanding nearly 60% of the market.

Non-alcoholic beverages

The global non-alcoholic beverages market includes carbonated soft-drinks, juices, energy drinks, sports drinks, bottled water and ready to drink tea and coffee. This market (in value) is expected to grow at a CAGR in the range of 6% to 8% during 2023-2026 period on account of the following:

- Shift in consumer preference towards premium beverages

[17] Public announcements made by Cargill
[18] Source: Ingredion and S&W Seed company enter supply agreement for US stevia production
[19] Source: Company websites, U.S. International Trade Commission
[20] Source: Company websites, U.S. International Trade Commission

- Growing demand for functional beverages and energy drinks: as consumer preference for wellness products increases, global beverage companies are focusing on launching new products that have a reduced content of sugar and / or use high-intensity sweeteners extensively.

Within the non-alcoholic beverages market, the carbonated soft drinks segment is dominated by 2 players (PepsiCo and Coca Cola Company) with a combined revenue share of nearly 75%.

Bakery and Confectionery

The global bakery and confectionery market comprises buns, biscuits, gums, jellies, mints, toffees etc. The market (in value) is expected to register a CAGR of 5% to 6% during 2023-2026 on account of the following:

- Confectionery industry is witnessing premiumization and hence demand for low-calorie sweeteners is growing
- Changing lifestyle and growing demand for ready-to-eat / packaged products

The bakery and confectionery market is fragmented. Key players include Mondelez Group, Mars Group and The Hershey Company (for confectionery segment), and Bimbo group, Mondelez Group, Yamazaki Baking and Flowers Foods (for bakery segment).

Vitamins and Dietary Supplements

The vitamins and dietary supplements market is expected to continue to grow in value (expected CAGR is between 4% and 6% over 2023-2026). Key demand drivers include:

- Consumers are becoming more attentive to their health needs and focusing more on prevention of diseases (especially on account of COVID-19)
- Availability of a wider product line to meet customization requirements of different segments of population
- Increasing consumer awareness regarding nutritional gaps that need to be bridged via intake of food supplements

The vitamins and dietary supplements market is fragmented. Key players include Amway Corporation, Bayer AG GlaxoSmithKline Plc and Nestle SA.

Pharma excipient

Saccharine, among other sweeteners (sucrose, sorbitol, aspartame), are added to liquid and chewable medications in order to make medicines palatable. The global medicine market (based on amount spent purchasing medicines from manufacturers before discounts and rebates) is expected to grow (in value) at 4% -6% CAGR over 2023-2026.[21]

Key demand drivers include:

- Increasing burden of lifestyle diseases such as diabetes, cardiovascular disease etc.
- Increase in the penetration of private healthcare insurance
- Government initiatives to provide universal health coverage (UHC) to improve access to treatment and medication
- Increase in uptake of biopharmaceuticals and generic drugs following patent expiries of blockbuster drugs

[21] Global Medicine Spending & Usage Trends: Outlook to 2025 (IQVIA Institute for Human Data Science, April 2021)

The global pharmaceutical excipients market is fragmented. Key players include BASF FE, Evonik Industries AG, The Lubrizol Corporation, Archer Daniels Midland Company and Du Pont.

Agrochemicals

Saccharine is used as an intermediate in production of select fungicides that are used for preventing the growth of certain fungi (especially rice blast and Zymoseptoria tritici) that impact rice and wheat. Some of the leading rice agrochemicals include Tricyclazole, Azoxystrobin, Difenoconazole, Isoprothiolane and Probenazole. One of the key fungicides prepared using saccharine is Probenazole, the world's first systemic acquired resistance type fungicide[22]. The market is expected (in value) to register a CAGR of 3% to 4% during 2023-2026. Key demand drivers for such fungicides include:

- Shrinkage of landmass available for agriculture due to urbanization puts pressure on farmers to use agrochemicals for ensuring crop health and increasing land productivity
- Increase in demand for novel ingredients for crop protection with rise in number of harmful organisms affecting crop yield.
- Increase in awareness levels of farmers regarding the benefits of agrochemicals and its safe usage in improving agricultural productivity and preventing soil degradation. Agrochemical companies are also training farmers in pesticide selection, choosing the appropriate application methodology and suggesting quantity to used based on identified pest problems

The agrochemicals market is fragmented. Key players include Meiji Seika Pharma Co. Ltd., Nufarm Ltd., Wuhai He Ye Chemical Engineering Co Ltd., Bayer AG, Adama Co Ltd and FMC Corp.

Saccharine sodium API landscape

There does not exist an industry standard / industry recognized data-set that provides the size, growth trends, competitive landscape of ingredients used in manufacturing of FMCG products. Based on our secondary research, the following is noted:

There exist cases of molecules / intermediates where, for a specific molecule / intermediate level, a single player has supplied greater than 70% of the value of the intermediates exported from India over the past 3 years. One of the examples of this phenomenon - is that of saccharine sodium, where, over the past 3 years, the Company has supplied over 70% of the value of exports of the intermediate from India (Source: Data on imports to and exports from India, as available in public domain, secondary research)

[22] Mitsui Chemicals Press Release (10th September 2021)

Pharmaceuticals intermediates

Overview of pharmaceuticlas intermediates manufacturing and key trends

Pharmaceutical intermediates are compounds that form building blocks of pharmaceutical products. In terms of value-chain, pharmaceutical intermediates are synthesized into active pharmaceutical ingredients (APIs) and these APIs are then formulated into final pharmaceutical formulations such as tablets, capsules, injections, etc. Volume growth in pharmaceuticals intermediates is therefore positively correlated to the demand for the corresponding pharmaceutical products.

For pharma intermediates, 3 key growth drivers are:

- Increased propensity to outource manufacturing by innovators and generics companies
- Increased propensity to de-risk dependence on China for supply of APIs and intermediates and drive self-sufficiency
- Overall growth drivers for the global pharmaceuticals market

Key trend 1:Increased propensity to outsource manufacturing of intermediates and APIs

Both innovator companies and generics companies have been increasingly outsourcing manufacturing of intermediates to contract development and manufacturing organizations (CDMOs) on account of the following:

Innovators – key reasons for outsourcing of pharma intermediates manufacturing to CDMOs

- Over a period of time, CDMOs have developed specific skills / proprietary platforms that enable such CDMOs to develop and supply the requisite intermediates to innovators
- Innovator companies are increasingly preferring asset-light models, wherein innovator companies specialize in (a) product ideation and (b) marketing of drugs, while CDMOs carry out the activities, ranging *from* intermediate / API development, clinical testing, small-scale (for clinical trials) manufacturing *to* commercial scale (for commercial launch) manufacturing
- Venture capital backed start-ups that look to develop novel products typically do not have the manufacturing infrastructure

Generics companies – key reasons for outsourcing of pharma intermediates manufacturing to CDMOs

- In the highly competitive generics industry, outsourcing of intermediate / API manufacturing can provide cost advantage on account of the economies of scale that CDMOs offer (an intermediate manufacturer supplies to multiple API / formulations companies)
- As the product basket increases, managing of supply-chain for the products becomes increasingly difficult; this necessitates outsourcing to CDMOs

Given the above and as innovator companies continue to (a) incur research and development expenditure to develop their product pipeline and (b) continue to outsource manufacturing of intermediates and APIs to CDMOs, the size of the addressable market for pharma intermediates CDMOs is expected to continue to increase.

Key trend 2: de-risking of dependence on China by global API and formulations players

In late 1990s / early 2000s, China significantly stepped-up its efforts to become the leading player for active pharmaceuticals ingredients (APIs) and intermediates. Key reasons for China's competitive advantage included – the setting up of dedicated Special Economic Zones (SEZs), providing subsidized energy and providing subsidized loans and access to roads / ports, etc to entrepreneurs looking to set-up API / intermediates plants in China.

However, in the recent past:

- COVID-19 has accentuated the need to reduce dependence on China and has led several countries to announce initiatives to (a) actively look for sources other than China for sourcing APIs and intermediates and / or (b) drive self-sufficiency for critical APIs. This is especially applicable for key anti-infective products
- China has implemented stricter environment control laws and has witnessed a rise in wages; both these factors have adversely affected competitive advantage held by China-based firms.

Key trend 3: self-sufficiency

Government of India has stepped-in to provide impetus to India's API and intermediate industry by announcing (a) a production linked incentives scheme for select APIs where India has significant dependence on China and (b) dedicated bulk drug parks that can provide centralized infrastructure (such as power, effluent treatment, etc), thus reducing the time and cost of setting-up a new manufacturing unit. Key details of these incentive schemes are as under:

- Department of Pharmaceuticals (DoP) had announced the first PLI scheme in July 2020 with incentives worth ₹ 69.4 billion to boost domestic manufacturing of identified Key Starting Materials (KSMs), drug intermediates, and APIs to attract large investments in the sector and to reduce India's import dependence in critical APIs.

- The investment thresholds for availing the incentives under the PLI scheme are as follows:
  - Fermentation based 4 KSMs / Drug Intermediates – ₹ 4,000 million
  - Fermentation based 10 niche KSMs / Drug Intermediates / APIs – ₹ 500 million
  - Key chemical synthesis based 4 KSMs / Drug Intermediates – ₹ 500 million
  - Other 23 Chemical Synthesis based KSMs / Drug Intermediates / APIs – ₹ 200 million

- The COVID-19 pandemic highlighted both the high degree of reliance on API imports and the limited capabilities of the domestic industry to produce complex, high-value drugs. In March 2021, the DoP announced a new PLI scheme, with incentives worth ₹ 150 billion, to encourage local investment in both areas.

- Incentives will be based on a percentage of annual increases in company revenues for three product types:
  - Category 1 – complex generics, patented drugs, cell-based or gene therapy drugs and orphan drugs.
  - Category 2 – APIs, key starting materials (KSMs) and intermediates.
  - Category 3 – repurposed drugs, including autoimmune products, antidiabetics, anti-infectives, antiretrovirals, cancer, cardiovascular and psychotropic drugs.

India as the leading destination for CDMO services

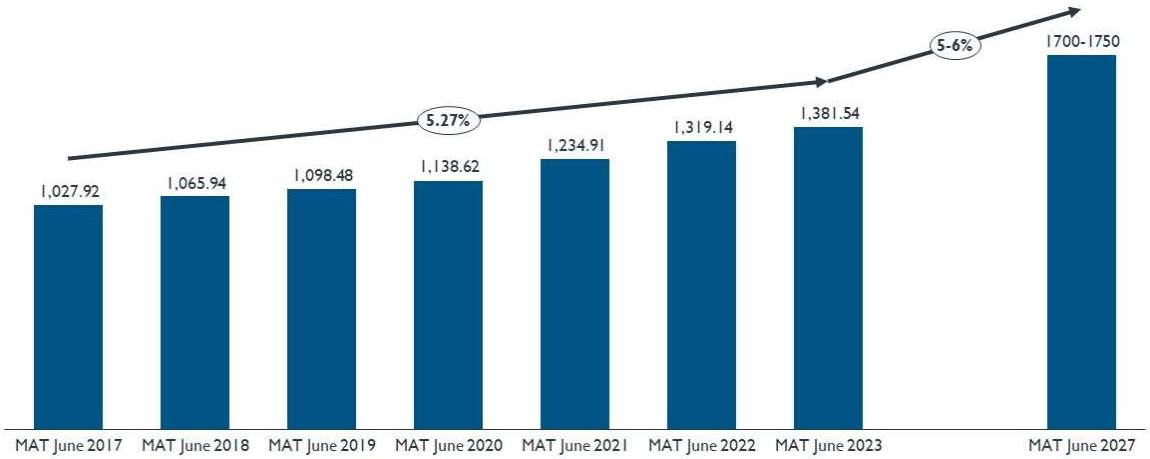
The above trends point towards the need for a destination for sourcing pharmaceuticals intermediates. India is well-positioned to become the leading choice for sourcing of APIs and intermediates, on account of the following:
- Proven credentials for quality and compliance in global pharmaceuticals space
- Proven skills in process chemistry over a sustained time period, as is evident in India's share in global pharmaceuticals supplies
- Strong educational ecosystem (in terms of pharmacy and engineering colleges)
- Track record of supply reliability and IP protection leading to long-term relationships
- Indian Government's focus and support for local manufacturing of APIs and intermediates, as outlined above

Key trend 4: Overall growth in Global Pharmaceuticals market

The global formulation market was estimated at US$ 1,381.54 billion (₹103,615.5 billion) in MAT June 2023 *(Source: IQVIA MIDAS Quarterly Sales Data, MATJune 2023)* and is expected to grow at a CAGR of 5-6% to reach US$ 1,700-1,750 billion (₹ 127,500=131,250 billion) by MAT June 2027 *(Source: IQVIA Market Prognosis Global – May 2023 (MAT June 23- June 27 analysis recalculated based on IQVIA MIDAS MAT June 2023 figures).*

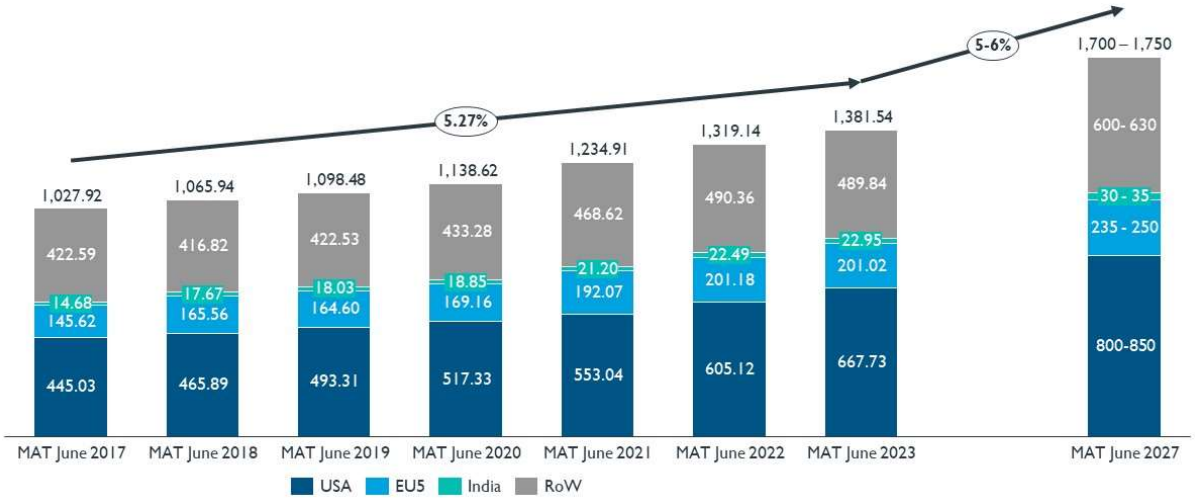
Growth in the global pharmaceutical market is a function of (a) the launch of novel therapies, including biologics, (b) the expansion of existing therapies into newer geographies and adjacent indications (c) growing demand for generic medicines and (d) initiatives taken by pharmaceutical companies and governments globally for accelerated access to drugs.

Global Pharma Market (US$ billion)



Source: IQVIA MIDAS Quarterly Sales Data MAT June 2023, IQVIA Market Prognosis Global – May 2023 (MAT June 23- June 27 analysis recalculated based on IQVIA MIDAS MAT June 2023 figures)

Global Pharmaceuticals Market – By Region (US$ billion)



Source: MIDAS Quarterly Sales Data, MAT June 2023, IQVIA Market Prognosis Global - May 2023 (MAT June 23-June 27 analysis recalculated based on IQVIA MIDAS MAT June 2023 figures)
Note: Regional contribution to global pharma market in % for MAT June 2017 to 2023

In terms of geographical distribution:

Developed Markets

- The US formed 48.33%of the global pharmaceuticals market in MAT June 2023. The US is expected to remain the key contributor to growth in the major developed markets and is expected to grow at a CAGR of 5-6% over MAT June 2023-2027. *(Source: IQVIA MIDAS Quarterly Sales Data, MAT June 2023, IQVIA Market Prognosis Global – May 2023 (MAT June 23- June 27 analysis recalculated based on IQVIA MIDAS MAT June 2023 figures))*

- EU5 formed 14.55% of the global pharmaceuticals market in MAT June 2023. Within EU5, UK is expected to be the fastest growing economy at a CAGR of 5-6% over MAT June 2023-2027, followed by Germany, Italy, and Spain at 5-6% CAGR over the same period. *(Source: IQVIA MIDAS Quarterly Sales Data MAT June 2023, IQVIA Market Prognosis Global – May 2023. MAT June 23-June 27 analysis recalculated based on IQVIA MIDAS MAT June 2023 figures)*

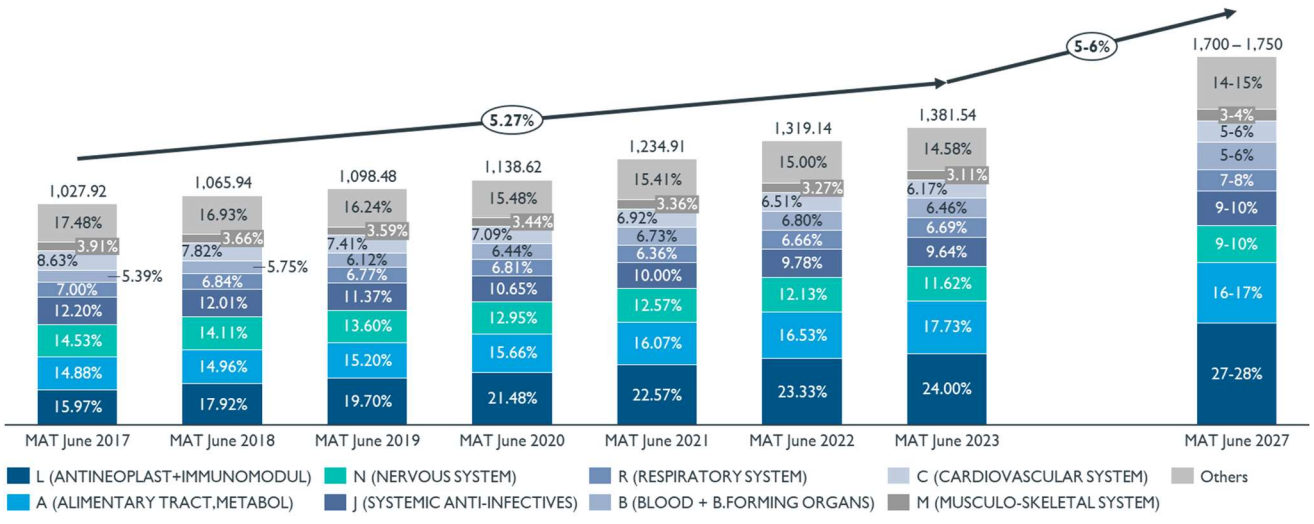
Pharmerging Markets

- China currently forms 8.21% of the global pharmaceuticals market; it is amongst the largest of the 15 pharmerging markets and is expected to grow at a CAGR of 4-5% over MAT June 2023 - June 2027 *(Source: IQVIA MIDAS Quarterly Sales Data MAT June 2023, IQVIA Market Prognosis Global – May 2023. MAT June 23-June 27 analysis recalculated based on IQVIA MIDAS MAT June 2023 figures)*

- Two pharmerging markets, namely Brazil and India, together form 3.83% of the global pharmaceuticals market. Both Brazil and India pharmaceutical markets are forecast to grow at 10-11% CAGR over MAT June 2023-MAT June 2027, which is one of the fastest growth rates among the pharmerging markets*(Source: IQVIA MIDAS Quarterly Sales Data MAT June 2023, IQVIA Market Prognosis Global – May 2023. MAT June 23-June 27 analysis recalculated based on IQVIA MIDAS MAT June 2023 figures)*

Global Pharma market: segmentation by therapy areas

Global Pharmaceuticals Market – By Therapy Areas(US$ billion)



- Source: MIDAS Quarterly Sales Data, MAT June 2023, IQVIA Market Prognosis Global - May 2023 (MAT June 23-June 27 analysis recalculated based on IQVIA MIDAS MAT June 2023 figures)

For select therapies, growth drivers are:

- **Oncology**: The global oncology market is the largest therapy market, contributing to ~24% of the total formulations market in MAT June 2023. The oncology market will continue to witness growth on account of (a) introduction of novel treatments, and (b) increased incidence of cancer on account of lifestyle factors

  Central nervous system (CNS) therapy area formed ~12% of the formulations market in MAT June 2023. Besides already well established sub-therapies (such as epilepsy, anti-depressants, and mood stabilizers), pharmaceutical companies are focusing on areas such as Alzheimer's and Parkinson's disease, to drive growth in this therapy area.

- **Diabetes and cardio-vascular** therapy areas are expected to continue to witness growth on account of increasing incidence of obesity, sedentary lifestyle, and rising geriatric population.

Features of a typical arrangement in relation to supply of intermediates to innovators of NCEs

A typical arrangement between innovators (that is, companies that develop patented, innovative new chemical entities "NCEs") and Intermediates CDMO partners (that is, companies that develop pharmaceuticals intermediates that are eventually used in sysnthesis of the final product) entails the following:

- **Revenue and capacity utilization predictability for the CDMO**: Innovators typically form close partnerships with their CDMO partners on account of:
  - the confidentiality of the projects;
  - novelty of the underlying chemistry / processes and the need for custom-development of compounds / processes)

  This close partnership typically starts from very early stages of product development and runs up to clinical trials / commercialization (depending on factors such as the scale at which the CDMO partner operates, outcomes of clinical trials, etc.).

  Given the above and limited competition when supplying for manufacturing of NCEs, there is greater visibility in terms of revenues and capacity utilization to the CDMO partners.

- **Higher realizations per unit sold**: In relation to NCEs, the key criteria for selection of the CDMO partner are:

  - CDMO / its key management's expertise / track record in the underlying chemistry; and
  - track record of the CDMO in working in the similar therapy area with the same / other innovators.

  Cost competitiveness is typically not the most important consideration in selection of CDMO partners for supply of intermediates for NCEs. Resultantly, CDMOs that supply intermediates for NCEs typically earn higher realization per unit (per gram or kilogram of material supplied) than in the case of other supplies (such as supplies once the product has genericised).

Key end-use molecules for pharma intermediates manufactured by the Company

Note: The names of the end-use molecules below have been provided to IQVIA by the Company. The data set used for size of the molecule / size of the therapy is IQVIA MIDAS Quarterly Sales data MAT June 2023.

Nilotinib

- Nilotinib is a tyrosine kinase inhibitor used in the treatment of chronic myelogenous leukaemia. It falls under the category of protein kinase inhibitors, which is a subsegment of anti-neoplastic drugs. Nilotinib was approved by the US-FDA in 2007.

- Global Nilotinib sales reached approx. USD 1.78 billion (₹ 133.5 billion) as of MAT June 2023, exhibiting a CAGR of ~1.5% between MAT June 2019 and MAT June 2023. Global anti-neoplastic drugs market exhibited fast growth in recent years and stands at approx. USD 183 billion (₹ 13,725 billion) as of MAT June 2023. The protein kinase inhibitor segment is one of the fastest growing subsegments and had sales of USD 55 billion (₹4,125 billion) as of MAT June 2023.

- The global anti-neoplastic market is dominated by USA, which accounts for nearly 45% of total sales, while EU5 accounts for 21% of sales in MAT June 2023. Japan is the next biggest market, accounting for ~6%. China is the 4th largest and exhibiting a CAGR of ~12% from MAT June 2019 – 2023, owing to increased healthcare expenditure by the government in recent years and low base compared to China's large population.

Sertraline

- Sertraline belongs to a class of anti-depressant drugs called selective serotonin reuptake inhibitors, or SSRIs. Sertraline is used in the treatment of major depressive disorders, obsessive compulsive disorders, social anxiety disorders and post-traumatic stress disorders. Sertraline was approved by the US-FDA in 1990.

- Sertraline global sales is approximately USD 1.4 billion (₹ 105 billion) molecule as of MAT June 2023. Sertraline had a CAGR of ~5% from MAT June 2019 – June 2023.

- USA dominates the anti-depressive market with ~29% market share as of MAT June 2023 and EU5 accounts for approximately 12%. Brazil, China, and Canada are the next three biggest markets with 9%, 5% and 5% market shares respectively.

Pregabalin

- Pregabalin belongs to the class of drugs called anti-epileptics or anti-convulsants. These drugs act on the central nervous system by slowing down the impulses that cause seizures. Pregabalin acts through modulation of presynaptic calcium channels that are involved in the propagation of seizures and neuropathic pain. Hence, besides epilepsy, Pregabalin is also used in the treatment of neuropathic pain, fibromyalgia and as an add-on drug in certain partial seizures.

- Pregabalin received FDA approval and was launched in the USA in 2004.

- The global anti-epilepsy market was ~ USD 18.6 billion (₹ 1,395 billion) in MAT June 2023. Pregabalin registered sales of ~USD 2.5 billion (₹ 187.5 billion) as of as of MAT June 2023.

- USA dominates the global market with ~37% market share as of MAT June 2023, while EU5 accounts for 15%. Japan and China the next biggest markets accounting for 4% share individually.

Clopidogrel

- Clopidogrel belongs to the class of anti-thrombotic drugs called anti-platelet aggregating drugs. Clopidogrel is used in the prevention of strokes and heart attacks in persons with increased risk for such conditions.

- Clopidogrel was approved by the FDA and launched in the US in 1997.

- The global anti-thrombotic market grew by ~8% CAGR during the period from MAT June 2019 – June 2023, to reach ~USD 61.7 billion (₹ 4,627 billion) as of MAT June 2023. Clopidogrel (monotherapy) had a market of ~USD 2 billion (₹ 150 billion) as for MAT June 2023.

- USA dominates the anti-thrombotic market with ~49% market share as of MAT June 2023 and EU5 accounts for 15% of sales. China and Japan are the next biggest markets, accounting for ~5 and 4% each.

Bempedoic acid

- Bempedoic acid is a novel non-statin drug used to treat hypercholesterolemia. It lowers LDL by inhibiting the cholesterol biosynthesis pathway in the liver.
- Bempedoic acid is among the recently launched products in the products indicated for hypercholesterolemia. It was launched in the USA in March 2020 and registered sales of approx. USD 120 million (₹ 9 billion) as of MAT June 2023.
- The global lipid regulating drugs market had sales of approx. USD 23.5 billion (₹ 1,762 billion) as of MAT June 2023. USA and EU5 account for ~26% and 15% of global lipid-regulating drugs market respectively, followed by China and Japan, constituting ~6% and 5% respectively.

Opicapone

- Opicapone is an O-methyltransferase inhibitor that is used in the treatment of Parkinson's disease as an adjuvant to levodopa/carbidopa (which are the key drugs of choice for treating Parkinson's disease).
- Opicapone was launched in Europe in 2016 and reached sales of over ~USD 134 million (₹ 10 billion) as of MAT June 2023. Anti-Parkinson's drug market reached sales of ~USD 4.6 billion (₹ 345 billion) as MAT June 2023.
- EU5 accounts for 22% of total anti-Parkinson's drug market and USA accounts for 18% as of MAT June 2023. Japan is the 3rd largest market, accounting for 12% of total sales value. China is 4th largest marke,t growing with a CAGR of ~7% from MAT June 2019– June 2023, and is expected to continue this growth for the near future, which can be attributed to two factors: (a) the low base of existing market size in China compared to its population and (b) its large aging population and inverted age pyramid.

Escitalopram

- Escitalopram belongs to the class of anti-depressants drugs called selective serotonin reuptake inhibitors (SSRIs). These drugs are used to restore serotonergic function in the treatment of depression and anxiety.
- Escitalopram received FDA approval and was launched in the USA in2002.
- Escitalopram registered sales of ~USD 1.9 billion (₹ 142 billion) as of as of MAT June 2023, growing at a CAGR of ~1.6% from MAT June 2019 - 2023.
- Anti-depressive drug market reached sales of ~USD 15.6 billion (₹1,170 billion) as MAT June 2023.
- USA dominates the anti-depressive market with ~29% market share as of MAT June 2023 and EU5 accounts for approximately 13%. Brazil, China, and Canada are the next three biggest markets with 9%, 5% and 5% market shares respectively.

Docusate

- Docusate is a laxative / drug used in treatment of constipation. It has been approved by the US FDA as a "generally recognized as safe" (GRAS) additive. Docusate registered sales of ~USD 110 million (₹ 8 billion) as of as of MAT June 2023
- The global market for constipation drugs was ~ USD 7.4 billion (₹ 555 billion) in MAT June 2023. USA dominates the market with ~40% market share as of MAT June 2023, while EU5 accounts for ~11%. Japan and China are the next biggest markets accounting for 7% and 3% respectively.