



A Sense of Urgency and Bold Ambition Needed: Reimagining India's Pharmaceuticals and Biotechnology Industry

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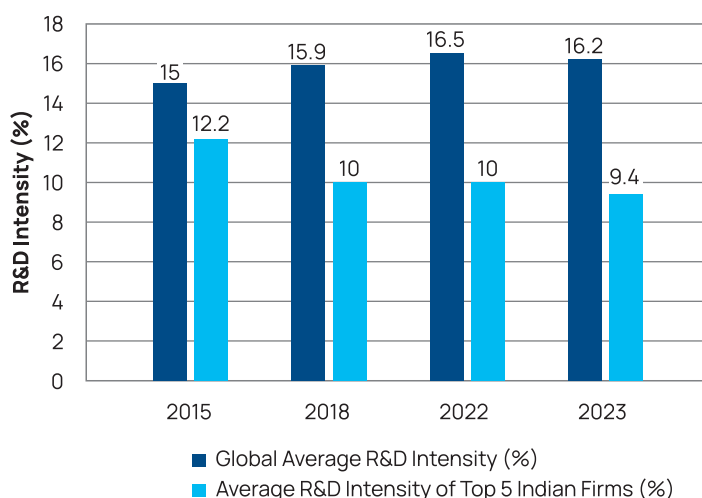
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We are grateful to the participants of the CTIER Ananta series on India's R&D Ambitions: Challenges and Imperatives for Innovation in India's pharmaceuticals & biotechnology sector and CTIER-World Without GNE Myopathy (WWGM) roundtable on Innovation and Policy for Rare Diseases Drug Development in India for their insights at roundtables conducted in 2023 and 2024.

The Indian pharmaceutical industry is currently valued at USD 50 billion and has set itself an ambitious target of growing to USD 450 billion by 2047 (Department of Pharmaceuticals, 2024; IBEF, 2025). It supplies 60 percent of global vaccines and 20 percent of global generic drugs (Press Information Bureau, 2023). In volume terms, it is the third largest pharma industry accounting for around 10 percent of the global market. However, in value terms it accounts for a mere 1.5 percent (RBI, 2021). Although India’s contribution to global vaccines and generic drugs is impressive, a worrying trend is the drop in the average R&D intensity of India’s top pharmaceuticals & biotechnology firms since 2015. The average R&D intensity for the top 5 Indian pharmaceutical firms has declined from 12.2 percent in 2015 to 9.4 percent in 2023 (see Figure 1). If the target of USD 450 billion by 2047 is to be achieved, a sense of urgency and bold ambition is needed from India’s pharmaceuticals & biotechnology industry as well as from our policymakers.

Technology in this sector is changing rapidly. Over the period from 2015 to 2023, we have seen the average global R&D intensity rise from 15 percent to 16 percent (see Figure 1). Indian pharmaceuticals & biotechnology firms need to increase their investments in R&D significantly to be able to compete globally. To spur innovation, there is a need to reform the regulatory framework, bring about better coordination between agencies and put in place well informed regulators. There is a need to create greater access to biological research infrastructure. Focusing on joint industry-masters and industry-PhD programmes with substantial government research funding will help build a strong talent pipeline that is needed by industry.

Figure 1 R&D Intensity of Top Pharmaceuticals & Biotechnology Firms (%)



Source: EU Industrial R&D Investment Scoreboard (various years); Centre for Technology, Innovation and Economic Research (CTIER)

■ **Realigning the Regulatory Framework**

In recent years, the pharmaceuticals & biotechnology sector has seen a shift in focus from chemistry to biology. This transition has triggered calls from industry to reform the regulatory framework by introducing biotechnology regulations alongside existing pharmaceutical regulations. With more products emerging from cutting edge technologies like cell and gene therapy, industry has been urging policymakers to ensure that regulations are in-line with international standards. Such reforms will help fast track processes and ensure global best practices within the sector.

There have been some positive developments that suggest an intent on the part of policymakers to ensure that regulations are being streamlined with international standards. The revised guidelines on similar biologics released in early May 2025 is one such example (CDSCO, 2025). The recent changes to the guidelines are in close alignment with similar regulations by the US Food and Drug Administration (FDA), European Medicines Agency (EMA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA) (Niazi, 2025). China has already proven the merit of reforming its regulatory processes in-line with global standards. By streamlining its processes with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines, it has ensured that domestic clinical trials conducted in China are recognised globally (Tong et al., 2024).

Given the rapid pace of technological changes impacting the industry, from the likes of gene therapy and artificial intelligence, the regulatory framework would need to become more systematic and transparent.

■ **Better Coordination Across Various Agencies and Better Equipped Regulators Needed**

There is a need for improved coordination between multiple agencies as well as regulators who are up to date with global strategies and guidelines for drug development and clinical trials. We highlight through a few examples the ambiguity and lack of clarity in some of the recent guidelines

and the urgency of reform required on multiple fronts.

Continuing with the earlier example on guidelines on similar biologics, it is worth noting that these guidelines were first introduced in 2012, followed by revisions in 2016 and 2025 (Thacker & Dandekar, 2025). The 2025 guidelines remain in draft stage, with no clear timeline for finalisation. To keep pace with the evolving industry landscape, it is essential to reduce the intervals between regulatory updates and ensure ongoing review and oversight.

Another example is the draft National Guidelines for Gene Therapy Product Development and Clinical Trials, introduced in 2019 by the Ministry of Health & Family Welfare and Ministry of Science and Technology. Comments and suggestions were invited prior to 1 August 2019, but no updates have been provided since on the status of these guidelines. In 2024, the government announced that India had successfully conducted her first gene therapy trial for Haemophilia by BRIC-inStem2 (Press Information Bureau, 2025). Though the New Drugs and Clinical Trials Rules (2019) introduced by Central Drugs Standard Control Organisation (CDSCO), Ministry of Health & Family Welfare, include gene therapeutic products within the definition of new drugs (CDSCO, 2019), the regulatory landscape remains fragmented. Better coordination between departments and ministries, along with greater clarity on rules governing clinical trials for gene therapy would immensely benefit the industry.

Indian regulators should closely track developments around guidelines for drug development in other countries. For instance, the US FDA in 2021 introduced guidelines for N of 1 trials (Age, 2022). The N of 1 trials is an approach, especially beneficial for rare diseases trials, wherein multiple clinical trials are conducted over a period of time on a single patient (Lillie et al., 2011). Such forward looking strategies should be explored in India for which appropriate guidelines would need to be put in place. This would enable industry to carry out trials using newer approaches especially for drug development for rare diseases.

■ **Creating a Robust Biological Infrastructure**

Focusing on the infrastructure needs of the sector will greatly benefit the research ecosystem. Much work needs to be done on biobanks in

India, increasing the number of clinical sites, enabling easy access to biological infrastructure and boosting domestic production of regular research material.

Calls for the development of platforms similar to the National Center for Biotechnology Information (NCBI) in the US and the UK Biobank are yielding results. This is evident with the inauguration of the National Biobank at the Council of Scientific & Industrial Research-Institute of Genomics and Integrative Biology (CSIR-IGIB), fashioned after the UK Biobank framework (Press Information Bureau, 2025). India has 19 other biobanks belonging to various government organisations like the Department of Biotechnology (DBT), Indian Council of Medical Research (ICMR) and Council of Scientific and Industrial Research (CSIR). Better coordination between these biobanks and the recently announced National Biobank would vastly improve access to large amounts of data and samples to researchers across the country.

Furthermore, there is a need to expand the number of clinical sites. This can be achieved by transforming medical schools and hospitals into active research sites. Better accessibility to research infrastructure is equally important. Increased communication and coordination between public institutions like National Institute of Pharmaceutical Education and Research (NIPER), Department of Biotechnology (DBT) and others will help scale up access to public research infrastructure. There was much excitement following the Union Budget FY2023 announcement of opening up of ICMR research facilities to researchers at universities and private sector (Mascarenhas, 2023). However, a recent study conducted by the Centre for Technology, Innovation and Economic Research (CTIER) and Confederation of Indian Industry (CII) under the aegis of the Office of the Principal Scientific Adviser to the Government of India (O/o PSA) shows that the research and testing facilities of around 4 percent of ICMR labs were utilised by industry in FY2023. Follow up measures to promote wider utilisation of the public research facilities, along with government support to enable access to private laboratory infrastructure, would significantly benefit startups emerging in this sector.

Indigenous manufacturing of research material for cell culture and monoclonals will also help accelerate research. It is important that raw materials crucial for development of biologics are readily available to smaller players at affordable prices.

■ **Nurturing a Talent Base Equipped for Industry Needs**

A revamp of academic curriculums at higher education institutions is needed to align them with industry requirements. It would be essential for academia to stay updated with the rapid changes in technology in the global economy. Investments in programs that bring together information technology and biotechnology (IT-BT) will help the sector immensely. Collaborative programs like joint Industry-masters and industry-PhDs through government support will also help build a robust talent pipeline.

The government currently spends just 6 percent of its central R&D budget towards healthcare, supporting research in the autonomous laboratories belonging to DBT and ICMR. This is low when compared to some of the other economies like the US and the UK where healthcare research receives more than 20 percent of their respective government R&D budgets (Panjwani, 2023; Research America, 2022). As a first step, the government should look to increase the amounts allocated to health care research. By shifting a significant portion of this funding into universities and integrating the work done in the DBT and ICMR laboratories with the higher education sector will also bolster the talent output and stimulate innovation within the pharmaceutical industry.

■ **Lessons from China and South Korea**

There are lessons to be learnt from countries like China and South Korea who have introduced policies to provide support in infrastructure, finance and regulations. They have helped establish bulk drug parks, expand contract development and manufacturing organisations (CDMOs) and adopt a cluster approach to increase collaborations to boost their position in the global pharmaceuticals & biotechnology supply chain.

China has dedicated policy initiatives to establish bulk drug parks which are supported by common utilities such as electricity, steam, chilled water and effluent treatment systems. These clusters have been strategically located to optimise operating costs and ensure ancillary industries provide a continuous supply of raw materials for API production. This infrastructure-first approach, combined with necessary

utilities and financing, has lowered unit costs and made China a globally competitive manufacturing base (CII & KPMG, 2020). India is currently setting up bulk drug parks in Andhra Pradesh, Telangana, Gujarat and Uttar Pradesh (PTI, 2025). These should be monitored closely to ensure they are equally effective in pushing India's R&D ambitions in the pharmaceuticals & biotechnology sector.

Important learnings can also be gleaned from how Chinese CDMOs have positioned themselves as global service providers offering scale and proximity to key markets. The Chinese CDMOs increased their presence overseas by building integrated R&D and biologics manufacturing facilities, aimed at serving regional markets and meeting regulatory requirements more efficiently (Algazy et al., 2022). A similar CDMO push in India, where AI/ML tools can be built along with drug discovery support, biologics and other kinds of services, will help better integrate with the global pharmaceutical research ecosystem.

Through its Bio-Vision 2016 policy, South Korea provided a vital policy push to enter the global biotechnology supply chain. It was a ten year roadmap launched in 2006 that aimed to strengthen domestic capabilities in R&D, infrastructure, human capital, bio-clusters and international collaborations (Hyeon et al., 2008). South Korea's dedicated bio-clusters have enabled close coordination between regulators and industry. These bio-clusters house various national agencies including the Korea Disease Control and Prevention Agency and the Ministry of Food and Drug Safety (Invest Korea, 2022). The important lesson for India here is that having these agencies close to industry has allowed regulatory processes to support research and commercial activities in a seamless manner.

■ **Towards a World-Leading Pharma & Biotech Hub**

Realising the pharmaceuticals & biotechnology sector's long term ambition of growing to USD 450 billion by 2047 will require a coordinated and strategic push towards regulatory reform, strengthening research infrastructure, a focus on talent development and global integration. This calls for a diverse and capable group of researchers, policymakers, academic leaders and industry professionals to facilitate knowledge exchange, foster investment and co-create forward looking solutions.

India already has the key pieces in place. What is needed is urgency and bold ambition to ensure that regulatory frameworks keep pace with emerging technologies like gene therapy and AI-driven drug discovery, biological infrastructure must be made accessible, curriculums are revamped and academia-industry linkages are enhanced to address evolving skill requirements.

The time has come for India to become a hub for high value pharmaceuticals & biotechnology innovation.

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