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nds D&C Rules to revise ns for ASU, Homoeo drugs

that the manufacturing plant should have the receiving and storing space for packaging material along with the existing norms on the raw material. It also revises the general requirement for the manufacturing plant, including the location and surroundings, buildings, water supply, disposal of waste and effluent, cleaning of containers, storage area including the requirement for raw material, packaging, and finished goods storage.

It also specifies the quality standards for the working space, health clothing, sanitation and hygiene and medical services for workers, standards on machinery and equipment, with emphasis on documentation of each of the process and record keeping procedures. It elaborates on the standards for batch manufacturing records, distribution records, detailed requirements for quality control, training and internal audits, among others. It also substitutes the existing provisions with revised standards on manufacturing process, and product quality control including product recalls.

"The amendments made to this Schedule by the Drugs (Eleventh Amendment) Rules, 2026 shall be complied 'within such time, not later than the 31st day of July, 2029," said the Ministry's notification.

Revision has also been made to Schedule M-I of the Drugs Rules, which specifies the GMP for Homoeopathic drugs. Amendment revised various provisions under the general requirement including the building, rooms, water, disposal of waste, medical services, safety measures, among other specifications. Rules related to plant and equipment including quality control division and raw materials, among others has also been revised and updated with the latest specifications. ◆

document on MDSW

net-of-things, and data analytics using AI, which are covered under the definition of MDSW.

For instance, a digital platform, using Internet-of-Things (IoT), and intended for use in conjunction with connected devices (like smart glucometers) to track chronic conditions such as diabetes, cardiovascular conditions, etc., to offer real-time AI-driven data analytics and interventions to mitigate acute health episodes, and a behaviour-change and digital therapeutics platform intended to mitigate the progression of chronic diseases such as type 2 diabetes, hypertension, etc. through remote coaching and digital tracking, would be covered under the MDR, 2017, it says.

However, software such as for Enterprise resource planning (ERP), used in the design, testing, component acceptance, manufacturing, labelling, packaging, distribution, complaint handling, or to automate any other aspect of a medical device quality system are not to be considered as MDSW.

The firms should refer to the risk-based classification list published by the CDSCO to follow particular requirements, and if the particular software is not listed in the list, the company should submit an application with the CDSCO MD online portal for obtaining the risk class of the device.

The final document also expands significantly on the quality management system (QMS) requirements for medical device software, elaborating that an MDSW QMS should ensure that the software is developed consistently, risks are controlled, changes are traceable, validation is documented, defects are managed, cybersecurity is maintained, and patient safety is protected. The QMS expectation is primarily based on IS/ IEC 62304 (software lifecycle), IS/ISO 14971 (risk management), and IS/IEC 82304-1 (health software safety). ◆

Focus shifts from generics to innovation-led growth

Dr Sanjay Agrawal

THE Indian pharmaceutical industry has emerged as one of the world's most influential healthcare sectors, earning global recognition as the "Pharmacy of the World." India supplies over 20 per cent of the world's generic medicines by volume and plays a crucial role in ensuring affordable healthcare across developed and developing nations.

While the industry initially built its reputation on manufacturing high-quality, cost-effective generic drugs, the focus is now gradually shifting towards research and development (R&D), innovation, and value-driven pharmaceutical solutions.

R&D has become the cornerstone of the next phase of India's pharmaceutical growth. With increasing global competition, evolving disease patterns, rising healthcare demands, and advancements in biotechnology, Indian pharmaceutical companies are investing significantly in scientific research, novel drug discovery, biosimilars, vaccines, speciality medicines, and digital healthcare technologies.

Today, India is no longer viewed merely as a manufacturing hub. It is steadily becoming an innovation ecosystem capable of contributing to global drug development, precision medicine, biologics, artificial intelligence-enabled research, and advanced therapeutics. Government support, academic collaborations, skilled scientific talent, and growing private investments are collectively accelerating this transformation. This article explores the evolution of R&D in the Indian pharmaceutical industry, its current landscape, major investment areas, challenges, opportunities, emerging technologies, government initiatives, and the road ahead.

Understanding pharmaceutical R&D

R&D refers to the systematic process of discovering, developing, testing, and commercialising new medicines, therapies, vaccines, and healthcare technologies. It involves multidisciplinary scientific efforts spanning chemistry, biology, pharmacology, biotechnology, data science, clinical research, and regulatory science.

The pharmaceutical R&D lifecycle is a structured, multi-stage process that begins with basic scientific research to understand diseases and identify potential therapeutic approaches. This is followed by drug target identification, where specific biological targets associated with a disease are selected, and lead molecule discovery, during which promising compounds are identified and optimized.

Once suitable candidates are found, they undergo pre-clinical studies to evaluate their safety and efficacy in laboratory and animal models. Successful candidates then progress through clinical trials (Phases I–IV), where they are tested in humans to assess safety, effectiveness, dosage, and long-term outcomes.

After demonstrating favourable results, the drug is submitted for regulatory approvals to ensure it meets the required standards for quality, safety, and efficacy. Following approval, the drug enters commercial manufacturing for large-scale production and distribution. Finally, post-market surveillance is conducted to continuously monitor the drug's safety, effectiveness, and any rare adverse effects after it reaches the market.

Developing a completely new drug is a long and expensive journey. Globally, it may take 10–15 years and investments exceeding US$ 1–2 billion before a medicine reaches patients. Therefore, efficient R&D strategies are critical for ensuring scientific success while managing costs and risks.

Evolution of pharma R&D in India

Following the enactment of the Indian Patent Act of 1970, India adopted a patent regime that emphasized process patents rather than product patents. This policy enabled domestic pharmaceutical companies to manufacture affordable versions of patented medicines by developing alternative production processes.

As a result, the industry concentrated on reverse engineering, process optimization, cost-efficient manufacturing, and the development of generic drugs. These strategic efforts strengthened the country's pharmaceutical capabilities and established India as a global leader in the production and export of generic medicines.

The TRIPS Era

The introduction of the WTO's TRIPS Agreement in 2005 marked a significant turning point for the Indian pharmaceutical industry. With the adoption of product patent protection, pharmaceutical companies were encouraged to shift their focus from producing generic imitations to developing innovative medicines. Since then, Indian pharmaceutical firms have steadily increased their investments in research and development, particularly in areas such as new chemical entities (NCEs), novel drug delivery systems, biosimilars, biologics, specialty pharmaceuticals, and precision medicine. As a result, the industry's strategic emphasis has evolved beyond manufacturing and generic production toward innovation, research, and knowledge creation.

Current R&D landscape in India

Today, India hosts one of the world's largest pharmaceutical R&D ecosystems. The country is home to more than 3,000 pharmaceutical companies and thousands of manufacturing facilities, including hundreds of WHO-GMP-approved plants that meet international quality standards. India also boasts one of the world's largest pools of pharmaceutical scientists, supported by strong biotechnology research capabilities and a rapidly expanding clinical research infrastructure. Together, these strengths position India as a global leader in pharmaceutical innovation, manufacturing, and drug development.

Major Indian pharmaceutical companies invest between 6% and 15% of their annual revenues in R&D, depending on their strategic priorities. Several companies now maintain dedicated innovation centres focusing on oncology, immunology, metabolic disorders, infectious diseases, neuroscience, and rare diseases.

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Sustainability becomes key priority in pharma R&D

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Key areas of pharma R&D

New drug discovery

Drug discovery represents the highest level of pharmaceutical innovation, involving the identification of biological targets associated with diseases and the design of molecules capable of modifying these targets safely and effectively. Indian pharmaceutical companies are increasingly collaborating with international universities, biotechnology startups, research institutes, and global pharmaceutical firms to accelerate innovation. Major areas of research include cancer therapies, diabetes, cardiovascular diseases, autoimmune disorders, neurological diseases, and rare diseases.

Biosimilars

Biologics have revolutionized the treatment of complex diseases but remain costly for many patients. India has emerged as a leading developer of biosimilars, which are highly similar versions of approved biologic medicines that offer comparable safety and efficacy at significantly lower costs. Indian biosimilar research focuses on monoclonal antibodies, insulin, growth hormones, immunotherapies, and oncology biologics. The increasing global demand for affordable biologics presents substantial export opportunities for the Indian pharmaceutical industry.

Vaccine research

India demonstrated its vaccine development capabilities during the Covid-19 pandemic by rapidly developing, manufacturing, and supplying vaccines to millions of people worldwide. Building on this success, current vaccine research and development focuses on advanced technologies such as mRNA and DNA vaccines, as well as universal influenza vaccines, malaria vaccines, tuberculosis vaccines, and HPV vaccines. These efforts are strengthening India's vaccine innovation ecosystem beyond pandemic preparedness.

Novel Drug Delivery Systems (NDDS)

Pharmaceutical R&D increasingly emphasizes not only the discovery of new medicines but also the improvement of drug delivery methods. Novel Drug Delivery Systems (NDDS) enhance drug absorption, improve patient compliance, increase treatment effectiveness, and reduce side effects. Technologies under development include sustained-release tablets, liposomal formulations, nanotechnology-based drug delivery systems, transdermal patches, injectable long-acting formulations, and targeted drug delivery systems.

Precision medicine

Precision medicine is an emerging approach that tailors treatments according to an individual's genetic makeup, lifestyle, environmental factors, and disease biomarkers. Indian pharmaceutical companies are increasingly partnering with genomic research institutions to develop personalized therapies. As advances in genomics and biotechnology continue, precision medicine is expected to experience significant growth over the next decade.

Artificial intelligence in drug discovery

Artificial Intelligence (AI) is transforming pharmaceutical R&D by significantly reducing the time required for drug discovery and development. AI applications include molecule screening, drug repurposing, clinical trial optimization, toxicity prediction, biomarker identification, and protein structure prediction. Indian startups and pharmaceutical companies are increasingly integrating AI with conventional laboratory research to improve efficiency and accelerate innovation.

Clinical research in India

Clinical trials form the backbone of pharmaceutical R&D by evaluating the safety and effectiveness of new medicines. India offers several advantages for clinical research, including a large and diverse patient population, highly qualified investigators, modern hospitals, cost-effective research infrastructure, and an English-speaking scientific workforce.

Government support for R&D

The Government of India has introduced several initiatives to promote pharmaceutical innovation and strengthen domestic research capabilities. The Production Linked Incentive (PLI) Scheme supports the domestic manufacturing of Active Pharmaceutical Ingredients (APIs), Key Starting Materials (KSMs), and high-value pharmaceutical products, reducing import dependence while encouraging innovation.

The National Biopharma Mission promotes biotechnology innovation, vaccine research, medical device development, translational research, and industry-academia collaboration. The Biotechnology Industry Research Assistance Council (BIRAC) provides funding for startups, academic research, biotechnology innovation, and the commercialization of scientific discoveries, thereby fostering pharmaceutical entrepreneurship.

In addition, India is strengthening domestic API manufacturing through research in green chemistry, continuous manufacturing, process optimization, and advanced synthesis technologies to enhance supply chain resilience.

Role of academia and research Institutions

India's pharmaceutical innovation ecosystem increasingly relies on strong partnerships between academia and industry. Leading research institutions contribute significantly to drug discovery, medicinal chemistry, biotechnology, genomics, nanotechnology, and clinical pharmacology. These collaborative efforts accelerate the commercialization of scientific discoveries while improving the overall quality and impact of pharmaceutical research.

Biotechnology and pharma convergence

The distinction between pharmaceutical and biotechnology companies is gradually diminishing as both sectors increasingly collaborate in advanced healthcare research. Emerging areas of convergence include gene therapy, cell therapy, regenerative medicine, CRISPR gene editing, synthetic biology, and RNA therapeutics. India's rapidly growing biotechnology ecosystem complements pharmaceutical research and development, creating new opportunities for innovation and strengthening the country's position in the global life sciences industry.

Role of startups in pharma innovation

India's startup ecosystem has emerged as a significant driver of pharmaceutical R&D, with health-tech and biotechnology startups playing a pivotal role in advancing innovation. These startups contribute across diverse areas, including AI-based drug discovery, digital therapeutics, diagnostics, genomics, bioinformatics, and remote clinical trials.

Emerging trends shaping future of pharma R&D in India

The future of pharmaceutical R&D in India will be defined by a combination of scientific innovation, digital transformation, sustainability, and global collaboration. As healthcare challenges become more complex, pharmaceutical companies are increasingly adopting multidisciplinary approaches to accelerate drug discovery and improve patient outcomes.

One of the most significant emerging trends is the integration of digital technologies into pharmaceutical research. Technologies such as Artificial Intelligence (AI), Machine Learning (ML), cloud computing, big data analytics, and digital twins are transforming the traditional R&D process.

AI-powered algorithms can analyze millions of chemical compounds within hours, identify potential drug candidates, predict toxicity, and optimize clinical trial designs. These technologies significantly reduce research timelines, lower development costs, and improve the probability of success in drug development.

Another rapidly growing area is real-world evidence (RWE) and real-world data (RWD). Pharmaceutical companies are increasingly utilizing data collected from electronic health records, wearable devices, patient registries, and mobile health applications to better understand disease progression, treatment effectiveness, and long-term patient outcomes. This data-driven approach supports regulatory submissions, post-market surveillance, and personalized treatment strategies.

Sustainability has also become a key priority in pharmaceutical R&D. Companies are investing in green chemistry, environmentally friendly manufacturing processes, waste reduction technologies, and energy-efficient production facilities.

Sustainable R&D not only minimizes environmental impact but also enhances operational efficiency and aligns with global Environmental, Social, and Governance (ESG) goals. India has the opportunity to become a leader in sustainable pharmaceutical manufacturing by combining innovation with responsible production practices.

Collaborative innovation is another important trend driving the industry forward. Pharmaceutical companies are increasingly partnering with biotechnology firms, contract research organizations (CROs), academic institutions, hospitals, and technology companies to share expertise and accelerate research.

Open innovation models enable faster problem-solving, reduce duplication of efforts, and promote the commercialization of breakthrough discoveries. Such collaborations are particularly valuable in areas such as oncology, immunotherapy, gene therapy, and rare disease research.

India is also witnessing significant growth in Contract Research and Development Services (CRDMO). Global pharmaceutical companies are outsourcing research activities to Indian organizations due to the country's highly skilled scientific workforce, advanced laboratory infrastructure, and cost advantages. This trend not only strengthens India's position in the global pharmaceutical value chain but also provides local researchers with exposure to cutting-edge scientific projects.

Furthermore, increasing investments in genomics, pharmacogenomics, and biomarker research are paving the way for precision medicine. As genetic testing becomes more accessible and affordable, researchers can develop therapies tailored to individual genetic profiles, improving treatment effectiveness while minimizing adverse effects. This personalized approach is expected to revolutionize the management of chronic diseases, cancer, and rare genetic disorders.

Looking ahead, India's pharmaceutical R&D ecosystem will continue to evolve through innovation, strategic investments, and stronger global partnerships. By leveraging its scientific talent, expanding research infrastructure, and embracing emerging technologies, India is well positioned to move beyond its traditional role as a global supplier of generic medicines and establish itself as a leading centre for pharmaceutical innovation.

This transformation will not only strengthen the country's economy but also contribute significantly to advancing global healthcare by delivering safer, more effective, and more accessible medicines for millions of people worldwide.

Despite significant progress, pharmaceutical R&D continues to face several important challenges. Drug discovery requires substantial financial investment, often with uncertain outcomes, making it a high-risk endeavour.

In addition, bringing a new medicine to market typically takes more than a decade due to the extensive stages of research, testing, and regulatory approval. The evolving nature of global regulatory standards further in-

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Future presents significant opportunities for pharma R&D

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creases the complexity of ensuring compliance across different markets.

The industry also faces growing competition for highly skilled researchers, making talent retention increasingly difficult. Protecting intellectual property while ensuring affordable access to innovative medicines remains another critical challenge. Furthermore, although applied research has expanded considerably, there is still a pressing need for greater investment in fundamental scientific research to support future breakthroughs.

Despite these challenges, the future presents significant opportunities for Indian pharmaceutical R&D. India is well positioned to become a leading global supplier of affordable biosimilars, while increasing awareness of rare diseases is creating new opportunities for orphan drug development.

The adoption of artificial intelligence in drug discovery has the potential to reduce development costs and accelerate innovation. At the same time, advances in genomics are driving the growth of personalized medicine, creating demand for customized therapies. Innovation-led products can further strengthen India's position as a global pharmaceutical leader and expand export opportunities.

Future of pharmaceutical innovation in India

Over the next decade, India's pharmaceutical industry is expected to transition from a predominantly generic manufacturer to a globally recognized innovation hub. This evolution will be driven by increased investment in advanced research, stronger industry-academia partnerships, adoption of digital technologies, and greater participation in international drug development programs.

Emerging technologies such as artificial intelligence, machine learning, big data analytics, quantum computing, and automation will redefine every stage of pharmaceutical R&D—from target identification and molecule design to clinical trials and post-market surveillance.

Biologics, biosimilars, cell and gene therapies, RNA-based medicines, and precision medicine are likely to become major pillars of future growth. At the same time, India's expertise in cost-effective manufacturing and process optimization will remain a strategic advantage, enabling the country to deliver innovative therapies at accessible prices.

As regulatory frameworks continue to mature and public-private partnerships expand, India has the potential to become a preferred destination for high-value pharmaceutical research, contract development, clinical innovation, and global healthcare solutions.

Conclusion

R&D has become the defining force shaping the future of the Indian pharmaceutical industry. What began as a sector known primarily for producing affordable generic medicines is now steadily evolving into an innovation-driven ecosystem capable of discovering new therapies, advancing biotechnology, developing biosimilars, and contributing meaningfully to global healthcare.

This transformation is supported by a robust scientific workforce, expanding research infrastructure, favourable government initiatives, increasing private investment, and a thriving startup ecosystem. Although challenges such as high development costs, regulatory complexities, and long innovation cycles remain, the industry's commitment to research continues to strengthen.

By embracing cutting-edge technologies, fostering collaboration between academia and industry, and prioritizing patient-centric innovation, India is well positioned to emerge as a global leader in pharmaceutical R&D. The country's ability to combine scientific excellence with cost efficiency offers a unique competitive advantage, ensuring that future breakthroughs not only improve health outcomes but also make advanced treatments more affordable and accessible worldwide.

As the pharmaceutical landscape continues to evolve, sustained investment in research and innovation will remain the key to India's long-term growth, global competitiveness, and contribution to a healthier future for all. ◆

(The author is pharmaceutical consultant)

Anthem Biosciences, leading integrated CRDMO

ANTHEM Biosciences is an integrated CRDMO (Contract Research, Development & Manufacturing Organisation) headquartered in Bengaluru, with multiple GMP-compliant manufacturing facilities. Anthem is one of the few CRDMOs in India with genuine strength across both small-molecule and large-molecule modalities, spanning target identification through commercial-scale supply.

Anthem as a company is 2500 people strong, of which >70% belong to scientific community, 400 fume cupboards across 40 labs and expanding.

Core service lines of the company include:

- ***Small molecules*** — Medicinal chemistry, process chemistry, custom synthesis, and cGMP manufacturing (mg to multi ton)
- ***TIDES*** - Peptides, lipids, oligonucleotides and complex conjugates
- ***Biologics*** — Recombinant proteins, monoclonal and bi specific antibodies, and enzymes via mammalian expression platforms
- ***Fermentation & specialty ingredients*** — Large-scale microbial fermentation, enzymes, probiotics
- ***High-potent APIs*** — Capabilities in ADCs
- ***Green chemistry*** – Biotransformation, flow chemistry, micellar and pincer for greener, more efficient routes
- ***Emerging modalities*** – Photochemistry, electrochemistry and mechanochemistry
- ***Full CMC & regulatory support*** — Analytical R&D, process validation, IND/CTA-enabling packages, and late-stage/commercial manufacturing
- ***A single, connected CDMO system*** — Reducing fragmentation across vendors, accelerating technology transfer, and giving one accountable partner from candidate to clinic to commercial supply ◆