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Organisation of Pharmaceutical Producers of India

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Securing the Future: Innovation, IP, and India's Road to a Knowledge Economy

India Readies Biopharma, Trial Network Push, Rolls Out Import Duty Cuts

India Steps Up Regulatory Reform: Simplified Processes, Faster Reviews

Foreword

Anil Matai
Director General, OPPI

Welcome to the seventh edition of the OPPI Newsletter!

With this quarter, the Organization of Pharmaceutical Producers of India (OPPI) enters into its seventh decade of engagement with India's healthcare ecosystem.

This edition comes at a time when the Government of India has released its Union Budget 2026–27, a budget that has wide-ranging implications for the country's pharmaceutical sector. The first article in the newsletter summarizes these.

The budget underscores the pharmaceutical industry's shift from a traditional focus on generics to building capabilities in advanced areas such as biologics and biosimilars. At the same time, the exemption of import duties on select therapies signals a strong policy intent to improve access to cutting edge treatments. This is particularly important as India faces a rising burden of cancer and rare diseases, driven in part by increasing life expectancy, which is bringing disease patterns closer to those seen in developed countries.

At the same time, the global pharmaceutical landscape is being shaped by ongoing geopolitical tensions, including the conflict in West Asia. Disruptions in energy markets, supply chains, and logistics corridors have had ripple effects on the availability and pricing of key raw materials such as Active Pharmaceutical Ingredients (APIs) and intermediates as well as delays in delivery of critical medicines. Heightened uncertainty in shipping routes and around input costs is reinforcing the importance of supply chain resilience and diversification of sourcing. Such issues may impact India's pharmaceutical industry by increasing cost pressures, affecting production timelines, and underscoring the need for greater self-reliance and strategic reserves, while also creating opportunities for India to strengthen its role as a reliable global supplier of medicines.

This edition also looks at the rapid simplification of India's 'T-license' system to enable more rapid approvals and a transition to a notification-based system. In addition, it looks much further ahead at the growing, indeed existential, challenge that antimicrobial resistance could pose to public health, and one of the key means by which the Government proposes to make public health work better: the Ayushman Bharat Digital Mission (ABDM). This initiative could revolutionise how the population and the medical profession interact with each other, though clearly the challenges ahead are formidable.

We hope this edition offers useful context and encourages continued engagement on the issues shaping India's healthcare future.

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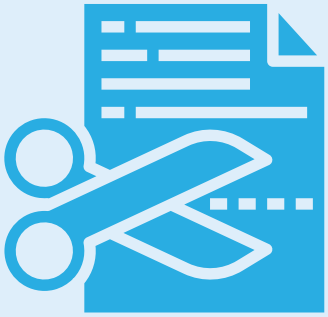

India Readies Biopharma, Trial Network Push, Rolls Out Import Duty Cuts

Anju Ghangurde, Executive Editor of APAC, Citeline

Key Highlights:

- India's Union Budget 2026-27 prioritizes building domestic biopharma capabilities
- The budget addresses the shift toward noncommunicable diseases, proposing the 'Biopharma Shakti' initiative, with an outlay of INR100 billion over five years
- Regulatory capacity at the CDSCO to be enhanced to align with global standards
- Expansion and upgradation of NIPERs and establishing accredited clinical trial sites also planned
- Duty exemptions on cancer drugs and therapies for seven rare diseases announced

India's Union Budget 2026–27 has prioritized building domestic capabilities in biologics and biosimilars, marking a clear recognition that the future of the sector lies beyond traditional strongholds like pure-play generics and that the country needs to act cohesively and fast. The budget also granted import duty exemptions on several therapies for cancer and rare diseases.

Finance minister Smt Nirmala Sitharaman ji referred in her budget speech to the shift in India's disease burden towards non-communicable diseases, such as diabetes, cancer, and autoimmune disorders, noting that biologic medicines were key to "longevity and quality of life at affordable costs". She proposed the roll-out of the 'Biopharma Shakti' (Strategy for Healthcare Advancement through Knowledge, Technology, and Innovation), with a total outlay of INR 100 billion over the next five years.

The program seeks to position India as a global biopharmaceutical manufacturing hub by building a strong and self-reliant ecosystem for the domestic production of biologics and biosimilars. "This initiative will catalyze investments in advanced biomanufacturing infrastructure, promote innovation, and enhance India's capabilities in high-value, next-generation therapies, thereby reducing import dependence and strengthening healthcare security," a government statement added.

Positive Industry Response

The government's sectoral thrust was well received by industry. Mr Anil Matai, Director General, OPPI, said, "The ₹10,000 crore outlay over five years reflects India's clear long-term vision to build a resilient, innovation-driven, end-to-end biopharmaceutical ecosystem – spanning research, advanced manufacturing, regulatory excellence, and patient access."

Some established biosimilar manufacturers similarly emphasized the importance of recognizing non-communicable diseases as the dominant healthcare challenge. They also highlighted the growing role of affordable biosimilars for complex biologic therapies in shaping new standards of care.

"Encouraging investment in advanced manufacturing, building global scale, and strengthening regulatory capacity through a dedicated scientific review cadre at the Central Drugs Standard Control Organization (CDSCO) are all critical to meeting global benchmarks," said the CEO of a leading biopharma organisation.

Smt Nirmala Sitharaman ji also specifically proposed strengthening the CDSCO to meet global standards and approval timeframes through a dedicated scientific review cadre and specialists. Efforts in some of these areas have already been underway and appear set for momentum (see article on regulatory reforms in this edition).

More widely, India's budget mentioned scaling up manufacturing in seven strategic and frontier sectors including semiconductors, electronics components, rare earth minerals, chemicals, and container manufacturing.

Accredited Trials Sites

The Biopharma Shakti initiative also envisages setting up a nationwide biopharma-focused academic and research network. Three new National Institutes of Pharmaceutical Education and Research (NIPERs)

have been proposed to be established, while seven existing institutes are to be upgraded.

The budget further listed plans to create a network of over 1,000 accredited India clinical trials sites, a proposal that was generally lauded by industry, though some experts noted that several fundamental aspects need attention to deliver meaningful gains.

The MD and CEO of a leading pharma organisation said that the expansion of NIPER capacity and the creation of a nationwide network of accredited trial sites further reinforce India's potential as a global biopharma and research hub, while also enabling "broader and more inclusive participation in high-quality clinical research".

Global clinical research organizations too appeared enthused. The CEO of a global CRO said that such initiatives go beyond what was previously seen in China in terms of government-led efforts to support clinical research. The CRO hopes that these 1,000 sites will also support Phase I studies.

"What we've seen in China is growth in early-phase, Phase I-type studies. That creates and builds momentum for greater patient access to new treatments in a country," the executive said.

Another CRO industry veteran, though, referred to multiple challenges that need to be addressed including the fact that few Indian medical professionals, hard pressed for time, are inclined towards conducting high quality clinical research which meets international standards of science and ethics. The general standard of detailed medical documentation is also not always as per global practices, the veteran stated.

A government statement maintained that the large-scale expansion of trial capacity will enhance both the quality and credibility of clinical research in India, while also accelerating drug development timelines. It is also expected to open up opportunities for researchers, medical professionals, and allied sectors, while for patients it could mean improved access to advanced therapies.

Past efforts are also noteworthy, such as the Indian Council of Medical Research (ICMR)-backed Indian Clinical Trial and Education Network (INTENT), which aims to promote high-quality, multi-center, regulation-compliant clinical trials addressing India's health priorities.

In 2024, the ICMR also formalized memoranda of agreements with multiple sponsors under its Network of Phase I Clinical Trials initiative. These included collaborative efforts with Aurigene Oncology for a small molecule for multiple myeloma, partnering for a Zika vaccine development with Indian Immunologicals and CAR-T cell therapy advancement study for a new indication of chronic lymphocytic leukemia with ImmunoACT.

Import Duty Exemptions For Life-Saving Drugs

The Budget also proposed full exemption of basic customs duty (BCD) on 17 life-saving drugs and medicines aimed at bringing relief particularly to cancer patients.

A senior leader maintained that with non-communicable diseases accounting for over 60% of India's disease burden, sustained investment in prevention and timely treatment is critical. "Measures such as exempting basic customs duty on select cancer medicines reflect this patient-centric approach that can improve access and health outcomes," the executive said.

Rare Disease Therapies

In addition, budget 2026-27 also exempts seven rare diseases that are part of India's National Policy for Rare Diseases (NPRD) 2021 from BCD when imported for personal use. The categories are congenital hyperinsulinemic hypoglycemia, familial homozygous hypercholestrolemia, alpha mannosidosis, primary hyperoxaluria, cystinosis, hereditary angioedema, and primary immune deficiency disorders.

Anil Matai, Director General, OPPI, termed the customs duty exemptions as particularly impactful measures and a "strong patient-first intervention" that directly reduces the cost burden of advanced, often life-saving therapies for families facing cancer and rare diseases.

"By easing the financial barriers to accessing complex treatments, the budget meaningfully advances equitable access to care at a time when the burden of non-communicable diseases such as cancer, autoimmune disorders, and diabetes continues to rise," said Matai. It also reinforces India's focus on improving access to cutting-edge therapies while fostering a supportive environment for innovation and global collaboration, he added.

India Steps Up Regulatory Reform: Simplified Processes, Faster Reviews

Anju Ghangurde, Executive Editor of APAC, Citeline

Key Highlights:

- India presses on with regulatory reform, easing processes and optimizing the deployment of resources
- T-license system simplified, enables quicker approvals and transition to a notification system.
- Review timelines reduced from 90 to 45 working days
- Significant capacity building efforts proposed at CDSCO

India has unveiled a raft of regulatory reforms including the transition of the 'T[est]-license' system to a notification approach as part of efforts aimed at improving processes and review timelines, while also optimizing the deployment of resources.

Manufacturing a new drug or an investigational new drug (IND) to conduct clinical trials, bioavailability/bioequivalence studies or for examination, testing, and analysis was not traditionally permitted without obtaining permission from the Central Licensing Authority (CLA). The new rules now enable notification to the CLA.

"Provided that in case of manufacture of new drug or IND for analytical and non-clinical testing (excluding new drug and INDs of the category of sex hormones, cytotoxic, beta-lactam, biologics with live microorganisms, and narcotics and psychotropic drugs) an online application in Form CT-10 to the CLA shall be submitted as prior intimation and the applicant may manufacture such drugs based on the acknowledgment of such intimation," a government notification said in January. Review timelines have also been halved from 90 working days to 45.

Conditions pertaining to such permission continue to remain effective. These include the requirement to use the new drugs manufactured only for the purposes of conducting clinical trials or bioavailability and bioequivalence studies or for examination, test and analysis, and ensuring that no part of it is sold in the market or supplied to any other person, agency, institution, or organisation.

Records of new drugs manufactured and persons to whom the drugs have been supplied for specified purposes must also be maintained.

Quick Processing Taking Place

An industry expert with expertise in clinical operations and regulatory affairs, among other areas, told Citeline that the test licenses have been taken to the Indian regulator's Online National Drugs Licensing System (ONDLS) and were being processed quickly. "I have seen test licenses approved within one week, because these are also processed by the zonal offices," the expert pointed out.

However, the executive alongside underlined that for things to work optimally, pharma too needs to get its act together. Some drug makers apparently rush for submission with incomplete applications "just to get into the system". It has to be "a two-way process," asserted the expert, who has significant experience across foreign multinational and Indian firms.

A similar notification was issued with respect to BA/BE studies. In the case of single-dose, two-period, two-sequence, two-treatment, BA/BE studies in normal healthy adult human volunteers (for export purposes only) of an oral dosage form of a drug (other than those in the cytotoxic, hormone, narcotic and psychotropic substances categories, a drug of narrow therapeutic index or those with highly variable pharmacokinetics) already approved in India or the US, EU, Japan, Australia, Canada, and the UK, the studies may be conducted after submission of an online application as prior intimation in Form CT-05 and its acknowledgement by the CLA.

The revised rule is however subject to conditions, including that the prior intimation be accompanied by an approval of a CLA-registered ethics committee and certain requirements around sample size, as per the notification.

Capacity-Building At CDSCO

Further, India's drugs regulator has outlined striking plans to create a flexi-pool of scientific talent in the Central Drugs Standard Control Organization (CDSCO), while also signalling a sharpening of monitoring and enforcement of quality compliance efforts.

At a recent industry event, Dr. Rajeev Raghuvanshi, Drugs Controller General of India (DCGI), underlined that these changes will save resources for both the regulator and industry. He also noted capacity-building initiatives which will see the CDSCO add around 1,500 personnel to carry out "internal review of scientific matters - mainly the clinical side."

Currently, the regulator depends on external subject expert committees (SECs) for trial-related evaluations and approvals, which is a long-standing prickly area for industry. Dr. Raghuvanshi asserted that unless a regulator has its own internal scientific cadre, it is very difficult to manage such situations because of the "absence of institutional memory," which is not created due to external dependence.

"That is going to be created. We are preparing the file, and we will be moving it for approval. It is going to change the whole system of review and approval of applications," the DCGI said, declaring that he expects the proposed mechanism to be "at par with the US FDA." About 40% of these additional personnel are likely to be on contract or advisors or honorary scientists, he added later.

These initiatives follow a specific mention in India's Union budget 2026-27, where finance minister Nirmala Sitharaman specifically proposed strengthening the CDSCO to meet global standards and approval timeframes through a dedicated scientific review cadre and specialists.

On the compliance front the DCGI, among a string of efforts, emphasized that Schedule M of India's Drugs and Cosmetics Rules, which cover good manufacturing practices (GMP) and requirements pertaining to "premises, plant and equipment for pharmaceutical products," has been in force since January 2026 for "all companies with all the extensions," implying that no further requests for additional time for compliance were being entertained.

Securing the Future: Innovation, IP, and India's Road to a Knowledge Economy

Bhushan Akshikar, President, OPPI and Vice President & Managing Director, GlaxoSmithKline Pharmaceuticals Limited

Key Highlights:

- OPPI President Bhushan Akshikar underscores innovation and R&D as central to building a value-based, knowledge-driven pharma sector in India
- Strong IP and patent systems are essential to drive investment and global competitiveness
- Ongoing government reforms and global trade agreements are strengthening India's IP framework
- Regulatory Data Protection (RDP) is a key missing element needed to advance India's innovation ecosystem

The Prime Minister Shri Narendra Modi, in his address to the nation on the 79th Independence Day, once again delineated his vision for a Viksit Bharat @2047 by underscoring innovation as one of the key pillars of India's economic progress.

The Government of India's vision to shift from a volume to a value-based pharmaceutical industry reflects its commitment to delivering high-quality, innovative healthcare solutions that meet the evolving needs of patients and healthcare providers. Healthcare systems are able to thrive because of continuous research & innovation in the fields of science and technology that results in finding new treatment outcomes to address unmet medical needs.

It is encouraging that India witnessed a significant surge in IP filings between 2020–21 to 2024–25 with 180% increase in patent filings alone. Also encouraging for the research based pharmaceutical industry is the recognition by the Prime Minister during his Independence Day address, on the need to enable researchers and entrepreneurs to secure patents for new drugs and medical technologies.

Several schemes launched by the Government of India such as the Promotion of Research and Innovation in Pharma-MedTech Sector (PRIP) scheme and the National R&D Policy are indeed steps in the right direction. **However, one pillar that stands out as foundational to India's ambition to becoming a global innovation hub is a robust pharmaceutical research and development (R&D) ecosystem, underpinned by a strong, predictable intellectual property (IP) particularly, patent regime.** A robust IP framework along with a streamlined, fair and transparent regulatory mechanism not only incentivizes innovation but also facilitates the development, protection, and commercialization of novel healthcare solutions that meet the evolving needs of patients and healthcare providers.

India's signing of the trade agreements such as EFTA TEPA, India-UK CETA has been contributing to shaping up of its legal framework, including IP laws. Several positive measures have been undertaken by the Government of India to augment its IP framework such as streamlining of the pre-grant opposition process, simplification and reduced frequency to file working statement in Form 27, simplification of the requirements to file information in respect of corresponding patent applications, modernization of IP Offices including increase in the sanctioned strength and working manpower of the Indian Patent Office etc. OPPI member companies look forward to further shaping up of India's patent law as agreed to between India and UK under India-UK CETA such as non-disclosure of confidential information contained in the disclosure (Form 27) in the public domain other than in exceptional circumstances.

On August 13, 2025, the Commerce Minister, Shri Piyush Goyal rightly recognized data exclusivity (also termed as regulatory data protection) as the last missing link before India witnesses an inflow of foreign investment leading to millions of jobs.

For research based pharmaceutical industry, generation of regulatory data generated in the course of developing a drug product (required for making regulatory submissions) is cost and time intensive and also involves significant risks. Since RDP merely provides protection of the data package required to be submitted before a drug regulatory authority from its unfair commercial use by third parties without the originator's concurrence. In this way, RDP systems balance and advance both the development and testing of new medicines and enabling availability of lower-cost alternatives.

RDP does not extend the patent term nor does it create "evergreening". It, in fact, typically overlaps with the patent term without preventing generics

from entering the market through independent effort. Therefore, the apprehension that RDP will slacken growth of generic market is ill-founded.

Indian companies aggressively seek opportunities for generics even in regulated markets mainly the EU, UK and other well-regulated countries. RDP incentivises innovators to invest in R&D, particularly for biologics, which involve greater complexity and cost, and for AYUSH/phyto-products, which may not be patentable but require large investments in generating clinical data.

As an industry association representing R&D based innovative pharma companies, Organisation of Pharmaceutical Producers of India (OPPI) looks forward to discussions on RDP including the deliberations envisaged under the India-EFTA TEPA.

India has the potential to be a global leader in research and development-based industries. Indian scientists have demonstrated their critical research talent in the biotech and pharmaceutical spheres. The country is poised to make important contributions to public health through innovation, not only within India, but globally. To become fully integrated into the larger family of scientists around the world working to bring new therapies and cures to patients, a conducive innovation ecosystem is critical. Also critical is an effective IP enforcement mechanism that enables enforcement of IP rights in a timely and consistent manner instils confidence in the rule of law and provides a fillip to innovation-led investments.

Fostering innovation, enhancing ease of doing business and establishing a clear, strategic framework for a robust IP regime can empower India to realize its full potential as a global centre for innovation. Further, as global IP laws evolve, India's alignment with emerging global IP norms will be crucial for India's competitive growth in the knowledge economy.

With these pillars in place, the country is well-positioned to lead in the 21st-century knowledge economy, driving sustainable growth and achieving our prime Minister's vision of making India a global hub of medical self-reliance and innovation.

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Antimicrobial Resistance: The Great Challenge Of Our Age?

Dr Andrew Warmington, Manufacturing Editor, Citeline

Key Highlights:

- Antimicrobial resistance is a huge and growing public health concern
- India's second National Action Plan was launched in 2025
- Official and private stakeholders are taking initiatives
- The first visible sign is an identifying strip on packages

Antimicrobial resistance (AMR) occurs when antimicrobials cease to work as they are meant to against bacteria, viruses, fungi, and parasites. There are various causes for this but the most important is the excessive and inappropriate use of antibiotics, leading to resistant strains emerging. Indeed, our hon'ble Prime Minister Shri Narendra Modi ji recently quoted an Indian Council of Medical Research (ICMR) report in his Mann Ki Baat address to the entire nation on 29th December 2025 to warn people that antibiotics are not a quick fix and should be taken only on medical advice.

AMR is universally recognized as one of the most pressing public health concerns of our time. A forecast by the Global Research on Antimicrobial Resistance (GRAM) Project in 2024, based on estimates across 204 countries and territories, suggest that AMR will cause 39 million deaths between 2025 and 2050[1]. Other estimates put the total at closer to 10 million[2].

In India alone, according to the Institute for Health Metrics and Evaluation and the University of Washington, over 300,000 lives have been lost on average each year due to AMR since 1990. In 2021, anything between 224,000 and 310,000 deaths were attributable to it and 855,000-1.13 million associated with it[3].

Potential Impacts Vast

Looking forward, the potential impacts of AMR are alarming. Some common infections, such as pneumonia or tuberculosis, could become harder or even impossible to treat. Routine medical procedures could be abandoned because the risk of hospital-acquired infections is too great or they could just become much more expensive.

The economic implications are also extremely grim. In 2023, the World Health Organization (WHO) projected that AMR could reduce global GDP by 3.5-3.8% per year up to 2050. It could also result in US$1 trillion of additional healthcare costs in the same timeframe, reduce labor productivity, and plunge millions more people in low-income countries into extreme poverty[4]. In addition, it also threatens plant and animal health because of the overuse of antibiotics in animals and the spillage or leakage of antibiotics into environment.

India's Double Challenge

India has a double challenge here, as a major supplier of diagnostics, vaccines, and drugs to avert and control AMR, and internally in facing the threat with the health system of a developing country. The complexity of the AMR challenge, it is recognized, must be addressed through a 'One Health' approach with coordination and collaboration among multiple stakeholders beyond the purview of the MoHFW.

India began its first National Action Plan on Antimicrobial Resistance (NAP AMR) in 2017. On 18 November 2025, during WHO's World AMR Awareness Week, the Union Minister for Health and Family Welfare (MoHFW), Shri JP Nadda ji, launched NAP-AMR 2.01[5].

Developed since 2022 via a series of stakeholder consultations, this takes the strategy through to 2029 and aims to address some of the shortcomings of the first plan, whose implementation was partly derailed by COVID-19. The new plan describes six strategic objectives, together with multiple sub-objectives and key activities:

1. Improving awareness and understanding of AMR through effective communication, education, and training
2. Strengthening laboratory capacity for AMR detection, surveillance, and targeted surveillance of antibiotic residues
3. Reducing the incidence of infection through effective prevention and control of infection
4. Optimizing the use of antimicrobial agents in humans, animals, and food through uninterrupted access to and judicious use of antimicrobials
5. Promoting research and innovations by identifying priorities for basic and operational research relevant to AMR
6. Strengthening governance, intra- and inter-sectoral coordination, and collaborations on AMR

NAP AMR 2.0 also includes mechanisms for monitoring its implementation 2.0 within and across various ministries and an evaluation framework with defined outcomes and Key Performance Indicators (KPIs).

Multiple Stakeholders Involved

All of the stakeholders have launched action plans and will develop implementation roadmaps ensuring engagement of private sector, technical institutions, professional groups, industry, cooperatives, NGOs, international partners, and others. They include:

- MoHFW, including the Department of Pharmaceuticals and the National Institutes of Pharmaceutical Education and Research
- Ministry of Agriculture and Farmers Welfare (MoAFW) and the Indian Council of Agricultural Research
- Ministry of Fisheries, Animal Husbandry and Dairying (MoFAHD)
- Ministry of Information Broadcasting (MoIB)
- Ministry of Science & Technology (MoST), via the Department of Biotechnology (DBT), Department of Science & Technology (DST) and Council of Scientific and Industrial Research (CSIR)
- Ministry of Chemical & Fertiliser
- Ministry of AYUSH
- Ministry of Jal Shakti
- Ministry of Education (MoE)
- Prime Minister's Science, Technology, and Innovation Advisory Council (PMSTIAC)

Some positive measures have already been taken. Gujarat and Kerala have banned over-the-counter sales of antibiotics, and some antimicrobials and pesticides have also been banned from use in crops, while various pharmaceutical companies are taking their own initiatives on AMR.

The Thin Blue Line

On 21 January 2026, the MoHFW issued a draft amendment to the Drugs Rules, 1945, Rule 96, Sub-rule (1) by adding a clause stating: "Antimicrobial drugs and their preparations shall bear a conspicuous blue vertical strip on the left side running throughout the body of the label without disturbing the other conditions printed on the label."

The proposal aligns with recommendations of expert panels from the Central Drugs Standard Control Organization (CDSCO). The thinking behind this is that, although these drugs are already subject to strict schedules necessitating red-line warnings and prescriptions, existing labels do not differentiate these drugs from others clearly enough. The blue line would enhance the visibility of antibiotics and help reduce incorrect usage.

References

1. *Nuffield Department of Medicine, Antibiotic resistance could cause 39 million deaths between now and 2050, 17 September 2024: https://www.ndm.ox.ac.uk/news/antibiotic-resistance-could-cause-39-million-deaths-between-now-and-2050#:~:text=Dr.,'*
2. *Ahmed S. K., Hussein S., Qurbani K., Ibrahim R. H., Fareeq A., Mahmood K. A., et al. (2024. c). Antimicrobial resistance: Impacts, challenges, and future prospects. J. Medicine Surgery Public Health 2, 100081. doi: 10.1016/j.glmedi.2024.100081*
3. *IHME/University of Washington, The burden of antimicrobial resistance (AMR) in India: https://www.healthdata.org/sites/default/files/2023-09/India.pdf*
4. *WHO, Antimicrobial Resistance, 21 Nov. 2023: https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance#:~:text=The%20World%20Bank%20estimates%20that,year%20by%202030%20(2)*
5. *https://ncdc.mohfw.gov.in/wp-content/uploads/2025/11/National-Action-Plan-on-Antimicrobial-Resistance-2.0.pdf*

ABDM: A Digital Initiative In Pharmaceutical Innovation

Dr. Andrew Warmington, Manufacturing Editor, Citeline

Key Highlights:

- The Ayushman Bharat Digital Mission aims to create integrated digital health system
- It is closely linked to other health and digitalization initiatives
- Industry has welcomed it as a key part of India's pharmaceutical innovation drive
- Key challenges are data security, confidentiality, and limited public awareness

Our hon'ble Prime Minister Shri Narendra Modi ji announced the National Digital Health Mission (NDHM) on 15 August 2021, the 75th Independence Day of India. Since renamed the Ayushman Bharat Digital Mission (ABDM), this is a highly ambitious mission to create an integrated digital health system that bridges the gaps between different stakeholders. The vision behind it is that every citizen will have a unique health ID, with access to digitized health records and a registry of doctors and health facilities.

The ABDM is part of Ayushman Bharat, the world's largest government-funded healthcare program. As on 28.02.2026, a total of 43.52 crore Ayushman cards have been created, including 1.14 crore Ayushman Vay Vandana cards created for senior citizens aged 70 years and above, and a total of 36,229 hospitals have been empanelled under the scheme across the country, out of which 19,483 are public and 16,746 are private hospitals[1].

The mission uses the software stack of Aadhaar, the national identification number system of India. The building blocks include a unique health identifier called DigiDoctor, a registry of healthcare facilities, a consent manager, and electronic and personal health record standards. These allow for the portability of data so that a patient with a health ID could, in theory, move seamlessly from one healthcare provider to another.

ABDM is also closely linked to Ayushman Bharat Yojana, a program launched in 2018 with the aim of providing free medical assistance to the poorest 40% of the population. It is also integral to Digital India, the flagship program launched in 2015 by our hon'ble Prime Minister Shri Narendra Modi ji "with the vision to transform India into a digitally empowered society and knowledge economy".[2] It is an important pillar in advancing the long-term goal of Viksit Bharat, aimed at building a more inclusive, efficient, and future-ready healthcare ecosystem.

Digital Revolution In Pharma

"Healthcare is set to undergo a revolution, and digitalization will contribute most to this," Forbes magazine commented. "The Indian experiment could be a good way to identify the issues involved in mass rollouts of digital initiatives. Public healthcare officials all over the world should be monitoring India closely".[3]

Writing in 'Essays in Innovation',[4] a recent publication by OPPI, multiple senior figures from the Indian pharmaceutical industry hailed the ABDM as an integral part of the country's innovation drive in this field, alongside Ayushman Bharat as a whole, the Production Linked Incentive (PLI) scheme, the Promotion of Research and Innovation in Pharma-MedTech Sector (PRIP) scheme and an investment-friendly climate in general.

A senior leader noted that the ABDM had already created over 67 crore digital health IDs, "laying the foundation for truly portable and patient-centric care". A stakeholder called the launch of the ABDM "a watershed moment". By creating digital health IDs, interoperable electronic health records (EHRs), and national registries for healthcare professionals and facilities, ABDM aims to establish a robust digital health backbone," he stated.

Another stakeholder said , "This infrastructure not only improves service delivery but also provides data that can fuel AI-driven research, personalized treatment pathways, and more efficient clinical trials. In this way, the digitization of healthcare complements and strengthens the innovation push in pharma and med-tech".[4]

Major Challenges Ahead

Needless to add, the hurdles are formidable in a vast nation with a population of nearly 1.4 billion, where

it is estimated that only 57% of men and 37% of women have ever used the internet, and most still live in rural areas and are accustomed to paying for healthcare out of pocket. One of the most complex is data security, which has already raised many problems for the Aadhar program.

Although the government has commissioned digital building blocks based on a wide range of data, information, and infrastructure services, leveraging open, interoperable, standards-based digital systems with the aim of ensuring the security, confidentiality and privacy of health-related personal information, data privacy is another thorny issue.

As an article in the Journal of Family Medicine and Primary Care in October 2024 showed, public awareness of the ABDM is still very low. A survey of 150 adult outpatients in an urban hospital in Bengaluru found that only 8% knew about it and only 5.3% knew of the related Ayushman Bharat Health Account (ABHA) or the Unique Health ID for Indian Citizens, and only 0.7% already had an ABHA. These people were mostly from the upper strata of society and many of them did know about other government digital services. This suggests that awareness among poorer and rural people will be considerably lower.

More positively, 92% of participants were ready to be part of the ABDM and to have a health ID, while 98.7% agreed with the concept of ABHA. They were very agreeable to the idea of uploading their medical records online, using the health ID to link their medical records, and to use it like Aadhaar.

In addition, their experience of using the COVID-19 vaccination portal, CoWIN, also meant that they view digital health in general favourably. The most significant concerns about the digitalization of healthcare were data safety and privacy, cited by 60%.[5]

Outlook

Nonetheless, the potential for ABDM is sky-high. "By building a national health stack where citizens have digital health IDs, facilities and providers are registered, and records are interoperable, India is laying the groundwork for a more equitable system," said a leader from a leading pharma organisation.

"For patients, this means portability and reduced fragmentation. For researchers and pharmaceutical innovators, it opens the door to using anonymised, consent-based data to generate real-world evidence, design better trials, and track long-term outcomes".[1]

References

1. *https://www.pib.gov.in/PressReleasePage.aspx?PRID=2241085&reg=3&lang=2*
2. *Digital India: https://www.digitalindia.gov.in/about-us/*
3. *Enrique Dans, How India's National Digital Health Mission Is Set To Revolutionize Healthcare, Forbes, 17 Aug. 2020: https://www.forbes.com/sites/enriquedans/2020/08/17/how-indias-national-digital-health-mission-is-set-to-revolutionize-healthcare/*
4. *OPPI, Essays on Innovation, 2025: https://replicaoppi.indiaoppi.com/wp-content/uploads/2025/12/Essays-on-Innovation-1.pdf*
5. *M.C. Arjun, S. Pooruikha, Anura V. Kurpad, Tinku Thomas, Knowledge, Attitude and Practice about Ayushman Bharat Digital Mission and Digital Health among hospital patients, J Family Med Prim Care. 2024 Oct 18;13(10):4476–4481. doi: 10.4103/jfmpc.jfmpc_255_24*

Key Interactions

The UP Pharma Conclave:

Representing OPPI on the panels, OPPI Director General Anil Matai and OPPI President-Elect Amitabh Dube shared perspectives on enabling regulation, research-led growth, and how OPPI member companies' Global Capability Centres are already strengthening India's role across R&D, digital health, and global innovation value chains in conevrsation with Hon'ble UP Chief Minister Shri Yogi Adityanath ji.

Meeting with the DCGI and CDSCO Officials:

The OPPI delegation met with the DCGI Shri Rajeev Raghuvanshi ji and Central Drugs Standard Control Organization team to further collaborate on Ease of Doing Business and Regulatory Policies.

Coffee Table Book

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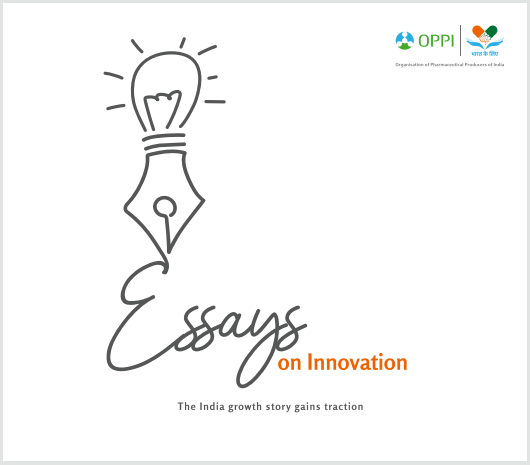
Essays on Innovation



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Thought Leadership Report – Fuelling Innovation, Advancing Equity

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Acknowledgements

We would like to extend our sincere thanks to everyone who contributed to this edition of the OPPI Quarterly Newsletter. This issue reflects a collective effort to examine India's healthcare journey with depth, balance, and perspective.

Special thanks to:

- **Mr. Anil Matai,** Director General, OPPI, for his continued leadership and vision
- **The OPPI Communications Team,** for their editorial oversight, coordination, and execution across this edition
- **The Citeline Editorial Team,** for their expert reporting, editorial partnership, and content development

Your dedication and hard work have been the driving force behind this success.

To our readers, thank you for your continued engagement. We look forward to sharing further insights and perspectives in the next edition as India's healthcare landscape continues to evolve.

Warm regards,

Asawari Sathaye
Director, Communications and Patient Advocacy, OPPI

About Power of Partnership

2025-26 marks a defining chapter for the Organisation of Pharmaceutical Producers of India (OPPI) – our Diamond Jubilee. Since its inception in 1965, OPPI has been the voice of the research based global pharmaceutical companies in India, advocating policies that encourage scientific innovation while ensuring that the patients are always at the centre of all decisions.

For six decades, OPPI has been at the forefront of shaping the Indian pharmaceutical landscape, fostering a patient-centric ecosystem grounded in innovation, ethics, access, and collaboration.

OPPI's journey has been defined not only by scientific and industrial progress but by the Power of Partnership.

Our legacy is rooted in partnerships with multiple stakeholders, i.e., with policymakers to drive regulatory clarity, with academia to nurture innovation, with the media to promote public understanding, and with our member companies to maintain the highest standards of ethics and compliance. This landmark is a reaffirmation of our commitment to India's future in healthcare.

About OPPI

The Organisation of Pharmaceutical Producers of India (OPPI) established in 1965, represents the research-based global pharmaceutical companies in India. OPPI has been an integral part of the healthcare journey of the country. We remain committed to supporting the nation's healthcare objectives, putting patients at the core of all decision making and collaborating with all stakeholders to find sustainable solutions to realize the collective vision of Health for All.

Our member companies have been serving the country's healthcare ecosystem since pre-independence and continue to remain committed to patient safety and providing quality care in the future as well. As an association, our advocacy decisions, patient commitment and work are always keeping the country first and we embody the spirit of working for 'Bharat Ke Liye'; driven with innovation to find solutions for unmet medical needs, collaboration with government stakeholders, and co-creation with partners coming together to address the nation's healthcare challenges. We are committed to the Hon'ble Prime Minister Shri Narendra Modi-ji's clarion call of 'Jai Vigyan and Jai Anusandhan'.

Connect with us on:

OPPI India

@OPPIIndia

Organisation of Pharmaceutical Producers of India (OPPI)

communications@indiaoppi.com

www.indiaoppi.com

#BharatKeLiye ***#PowerofPartnership***

OPPI | भारत के लिए

Organisation of Pharmaceutical Producers of India

Registered Office: 1620, C Wing, One BKC, Bandra Kurla Complex, Bandra East, Mumbai-400051, India.

Delhi Office: Avanta Business Centre, Cabin No. 3.08, 3rd Floor, Ambadeep Building, K. G. Marg, Connaught Place, New Delhi - 110001, India.

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