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Organisation of Pharmaceutical Producers of India

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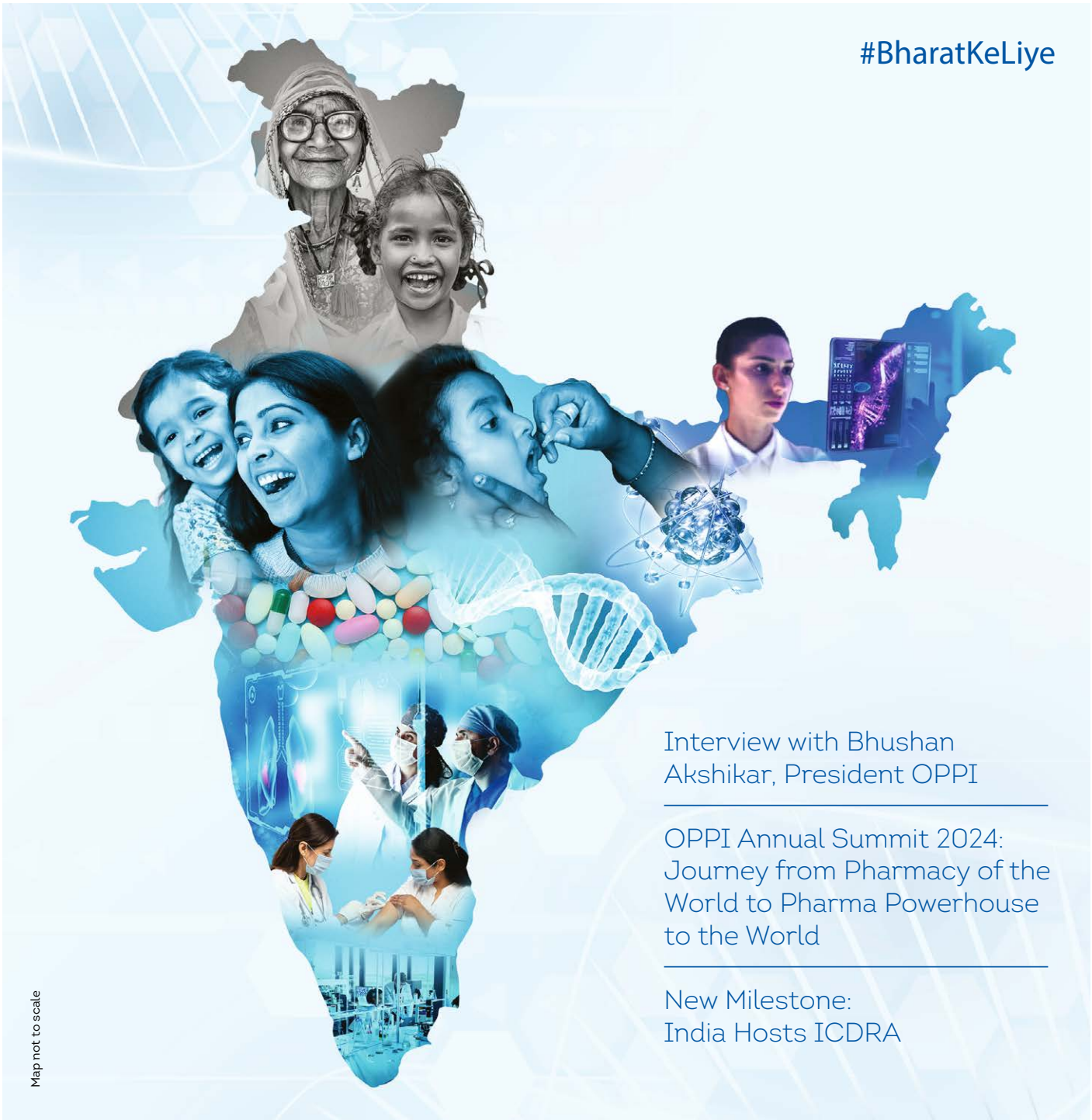

Interview with Bhushan Akshikar, President OPPI

OPPI Annual Summit 2024: Journey from Pharmacy of the World to Pharma Powerhouse to the World

New Milestone: India Hosts ICDRA

Foreword

Anil Matai
Director General, OPPI

Welcome To The Second Edition Of The OPPI Quarterly Newsletter!

As we release the second edition of the Organisation of Pharmaceutical Producers of India's (OPPI) quarterly newsletter, I am grateful for your engagement and enthusiasm for this initiative.

This quarter, we explore key milestones shaping our industry, including regulatory advancements, transformative policy initiatives and strides in innovation and patient care. These developments underscore India's evolution from the "pharmacy of the world" to a "global pharmaceutical powerhouse."

Highlights from this edition include:

- A Q&A with OPPI President, Bhushan Akshikar, on his vision for India's healthcare future
- Insights from the OPPI Annual Summit 2024 on accelerating reform and inclusive healthcare
- Updates on regulatory pathways and their global implications
- A look at Ayushman Bharat's expanded health coverage and its impact
- The role of Regulatory Data Protection (RDP) in fostering innovation

The year 2024 has been a pivotal chapter for India's healthcare landscape, setting the stage for a transformative journey toward a more patient-centric and innovation-driven future. Landmark initiatives like the expansion of the Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (PM-JAY) and the modification of guidelines for PRIP scheme for promotion of domestic manufacturing of KSMs and API have demonstrated the government's unwavering commitment to fostering an inclusive healthcare ecosystem. The notification of the Patent (Amendment) Rules 2024, waivers for Phase 3 clinical trials for certain categories of drugs already approved in well-regulated markets, including the USA, UK, Japan, Australia, Canada, and the EU and the government signing the much-awaited Trade and Economic Partnership Agreement (TEPA) with European Free Trade Association (EFTA) states comprising Iceland, Liechtenstein, Norway, and Switzerland reflect India's progressive strides toward creating a dynamic, globally competitive pharmaceutical sector that is driven by innovation. While the functioning of SEC requires more streamlining, it surely has become more structured and efficient.

As we move forward, collaboration will remain the cornerstone of our efforts. By working with industry leaders, policymakers and and all relevant stakeholders, we can address challenges, seize opportunities and elevate India's healthcare landscape.

Thank you for your support and engagement. I hope you find this edition insightful and inspiring.

Index

15

India Builds Health Coverage For Elderly, Opportunities In Store For Pharma

The expansion of Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB PM-JAY) to cover all senior citizens aged 70 and above, regardless of their income is expected to provide better healthcare and treatment opportunities for the silver generation. It is also seen expanding market opportunities for pharma in the long term.

18

The Role of Regulatory Data Protection in Incentivizing R&D

Regulatory Data Protection (RDP) incentivizes innovation by safeguarding proprietary data submitted in support of marketing registrations for pharmaceutical products. Concerns that RDP can stymie the growth of the generic market and lead to 'evergreening' of patented products are unfounded.

Interview with Bhushan Akshikar, President OPPI

By Izabela Chmielewska,
Managing Editor, Custom Content at Citeline

Key Highlights:

- Leading OPPI during a transformative period in India
- OPPI's evolving role to strike a balance between fostering innovation, ensuring patient access & navigating regulatory challenges
- Collaborating with the Indian Government to transform healthcare access & innovation
- Importance of robust IP protections in fostering innovation
- Generative AI's role in transforming the pharmaceutical landscape

In this Q&A, Bhushan Akshikar, recently appointed President of the Organisation of Pharmaceutical Producers of India (OPPI), shares his vision for the organisation and the strategic priorities shaping the future of the Indian pharmaceutical industry.

He discusses OPPI's role in fostering a collaborative culture and driving policy advocacy to advance innovation, while ensuring that the highest ethical standards are followed.

Bhushan highlights key areas of focus, including intellectual property (IP) protection, patient access, regulatory reform and the adoption of cutting-edge technologies like generative AI. He also provides insights into the opportunities and challenges that lie ahead for India as it transitions from being the 'pharmacy of the world' to a global leader in pharmaceutical innovation.

Role As President of OPPI

As the newly appointed President of OPPI, what are your primary goals for the organization over the next two years and how will you engage its stakeholders to foster a collaborative culture and drive action toward innovation?

It is an honor to lead OPPI during this transformative time as India progresses towards positioning the nation as a global leader by 2047. Our pharmaceutical sector is renowned as the 'pharmacy of the world,' a role underscoring India's impact and global significance.

To meet the growing healthcare demands, OPPI is committed to advocating for policies that incentivize robust Research and Development (R&D). By empowering our member companies to pioneer innovative solutions, we can address critical, unmet medical needs and drive substantial improvements in patient care. Our overarching vision is to guide India's transformation from a renowned pharmacy to a true global pharma powerhouse, ultimately strengthening both public health and economic growth.

Collaboration is at the core of this endeavor. We are dedicated to actively engaging OPPI members, government bodies, regulatory authorities and healthcare leaders to foster a culture that champions shared expertise and collective action. Through these alliances, we aim to shape policies prioritizing affordability, accessibility and sustainability in healthcare. In doing so, we can establish India's pharmaceutical industry as a global archetype of affordable, high-quality healthcare.

Upholding OPPI's mission, supporting India's health systems and expanding patient access will remain priorities. As an industry, we are steadfast in our commitment to the nation and the patients we serve. We are committed to strengthening India's healthcare infrastructure, advocating for sustainable investments in capacity building, healthcare delivery, and public health initiatives. Through these efforts, OPPI aims not only to meet the current healthcare needs but also to strengthen the foundation for a more resilient, accessible and future-ready healthcare system.

How do you see OPPI's role evolving in India's healthcare system, particularly in addressing the balance between innovation, patient access, and regulatory challenges?

OPPI's role is evolving to strike a critical balance between fostering innovation, ensuring patient access and navigating regulatory challenges. While our longstanding mission has been to ensure that high-quality healthcare is accessible to all since before India's independence, we are now placing an even greater emphasis on advocating for a regulatory framework that supports industry involvement while upholding the highest ethical standards and prioritizing patient safety.

Our approach involves moving from volume-driven to value-driven healthcare solutions, where innovation not only improves patient outcomes but also enhances the economic and social well-being of communities. In this way, OPPI intends to guide the industry toward global leadership while strengthening the foundations of healthcare delivery at home.

Collaboration & Advocacy

How do you envision OPPI collaborating with the Indian Government and other stakeholders to improve access to innovation and patient outcomes?

OPPI is committed to collaborating with the Indian Government to transform healthcare access and innovation. Recent policy initiatives, including the National Policy on Research & Development and various health research programs launched under the government's 100-day agenda, present valuable opportunities for partnership in public and private sectors.

Key focus areas include supporting government initiatives like the Pradhan Mantri – Ayushman Bharat Health Infrastructure Mission, advocating for policies incentivizing R&D investment, and creating Centers of Excellence. We're particularly excited about initiatives like the 'First in the World' challenge and efforts to develop drugs for rare diseases. Through these collaborations, we aim to position India at the forefront of global health research and innovation, aligning with the vision of a 'विकसित भारत'.

Our member companies have already demonstrated their commitment by establishing Global Capability Centers (GCCs) that employ over 90,000 highly skilled professionals, as well as setting up innovation hubs that not only leverage advanced technologies – ranging from Generative AI, Augmented and Virtual Reality (AR/VR) and Internet of Things (IoT) – but also collaborate closely with leading academic institutions, including the Indian Institutes of Technology (IITs) and the National Institutes of Pharmaceutical Education and Research (NIPERs).

By nurturing talent and working hand-in-hand with the government, OPPI is confident these partnership efforts are redefining the contours of drug discovery and development. They enable a shift from volume-based care toward volume-based outcomes while fostering a sustainable and innovative pharmaceutical ecosystem.

What are your thoughts on how OPPI can better advocate for more substantial intellectual property (IP) protections to encourage innovation in the pharmaceutical industry?

As India aspires to transition from 'Make in India' to 'Discover in India', OPPI recognizes the critical importance of robust intellectual property (IP) protections in fostering innovation. We are positioned at a pivotal moment as the world's third-largest pharmaceutical market by volume, and we understand that transitioning from volume to value requires a supportive IP environment.

Our advocacy focuses on creating a balanced IP regime that rewards innovation while maintaining accessibility. This includes supporting policies that protect confidential business information, provide regulatory data protection and streamline regulatory processes. Currently, Indian pharma companies are investing 7-8% of revenue in R&D, and we believe a strong IP framework is essential to encourage this continued investment. By protecting the rights of innovators and combating counterfeiting, we aim to establish India's reputation for not just affordability but excellence in quality and innovation.

OPPI Member Companies have been present in India for over 100 years. Can you highlight the legacy of these companies and the way ahead?

OPPI member companies have a profound legacy of healthcare contributions dating back to pre-independence India. Their enduring commitment extends far beyond merely producing pharmaceuticals – they are pioneers of innovation, continually developing groundbreaking therapies that address unmet medical needs and enhance patient outcomes.

Today, these companies are at the forefront of technological adoption, investing heavily in R&D while embracing cutting-edge technologies like AI and advanced data analytics. Beyond product development, OPPI members emphasize transparency and accountability, ethical interactions and educational initiatives for healthcare professionals. By focusing on educational partnerships and responsible collaboration, these companies remain key contributors to a more robust healthcare ecosystem that can address the healthcare challenges of tomorrow.

How do you foresee the role of Gen AI and technology in the pharma sector?

Generative AI is rapidly transforming the pharmaceutical landscape, offering unprecedented

capabilities in drug discovery, personalized medicine and patient care management. By analyzing vast datasets, AI algorithms can identify promising drug candidates more efficiently, significantly accelerating the development of new treatments for various diseases.

The technology's potential extends to personalized medicine, where AI can integrate genetic profiles, lifestyle factors and medical histories to create tailored treatment plans. This approach minimizes adverse effects and maximizes treatment efficacy. Additionally, AI plays a critical role in enhancing patient safety by monitoring patient data to detect early signs of potential complications and promoting medication adherence.

While challenges exist, including initial implementation costs and potential hesitancy among healthcare professionals, the future looks promising. Continued collaboration between pharmacists, AI developers and healthcare providers will be crucial in refining these tools and driving innovation prioritizing patient care.

Challenges & Opportunities

What are the biggest opportunities for the pharmaceutical industry today, and how can OPPI support the industry in furthering these opportunities?

Today's pharmaceutical industry is on the cusp of significant growth, driven by opportunities emerging in digital health, personalized medicine and preventive care. Reducing dependency on imported APIs and creating a holistic, self-sufficient ecosystem will be vital to fostering long-term resilience. Additionally, embracing value-based care models, enhancing manufacturing standards and strengthening IP protections will help India's market expand its global footprint.

OPPI supports these developments by advocating for regulatory environments that stimulate innovation and research. We aim to facilitate knowledge sharing and best practices through strategic alliances between pharmaceutical companies, healthcare providers and governmental bodies. Our commitment to ethical standards and transparency will be instrumental in building public trust in new therapies.

By acting as a catalyst for collaboration and policy reform, OPPI helps position the industry to seize emerging opportunities. It delivers impactful healthcare solutions that benefit patients, strengthening India's global standing and drives sustainable growth.

OPPI Summit: Govt, Leaders Chart Path To Viksit Bharat - Accelerate Reform, Innovation, Inclusive Healthcare

Byline: Anju Ghangurde,
Executive Editor APAC at Citeline

Key Highlights:

- India seeks to foster a collaborative environment for innovation and production
- Policy support, regulatory reform part of government efforts to spur innovation
- Collaborative approach needed to improve healthcare access in India
- GCCs playing a role in creating a dynamic innovation ecosystem

The Annual Summit of the Organisation of Pharmaceutical Producers of India (OPPI) saw top government functionaries, industry leaders and other stakeholders deliberate a range of key topics including policy support and the pivotal role of innovation as India seeks to transform from the pharmacy of the world to the pharma powerhouse to the world.

Addressing the conference, Hon'ble Union Minister of State for Health and Family Welfare Smt. Anupriya Patel underlined that the Indian government is steadfast in improving "ease of doing business" through simplified policies, streamlined approvals and fostering a collaborative environment for both innovation and production.

"These measures aim to make India a preferred global destination for pharmaceutical as well as healthcare investments," Minister of State emphasized at the summit.

She referred to a slew of initiatives including the Scheme for Promotion of Research and Innovation in Pharma-MedTech sector (PRIP), which aims to help the sector shift gears from cost-based to innovation-based growth by strengthening the country's research infrastructure, and the Production Linked Incentive (PLI) scheme.

Smt. Anupriya Patel
Hon'ble Union Minister of State for Health & Family Welfare and Chemicals & Fertilisers

"We do have a robust pharmaceutical ecosystem now. The government is giving a great push to research, innovation and skilling. You have all types of support, including regulatory support," she underlined.

Dr. Arunish Chawla, Former Secretary, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, in his address, underscored that the government is a "responsive" and "listening" administration.

He referred to the recently announced Scheme for Strengthening the Medical Device Industry which comes with interesting elements, including sub schemes pertaining to marginal investment for reducing import dependence and common facilities for medical device clusters, etc.

Dr. Chawla also noted that the Scheme for Strengthening of the Pharmaceutical Industry is now entering its last year and that the time had come to "re-envision and revamp" it.

'We need to think of a post-PLI framework that will make India not just a reliable pharmacy in the world, but actually a pharma powerhouse of the world," he said. The government intends to engage in stakeholder consultations, including with industry, in the coming months. Dr Chawla has just been appointed as Secretary, Department of Revenue, Ministry of Finance

The Indian pharmaceutical industry, which was valued at approximately $50bn in 2023, is estimated to grow at a CAGR of 9% to $450bn between 2030 and 2047.

Bhushan Akshikar, President OPPI and Vice President and Managing Director, GlaxoSmithKline Pharmaceuticals Limited underlined that alliances will be critical in driving policies and initiatives that make healthcare more inclusive, innovative, and comprehensive in India. OPPI's role, he said, is crucial in this journey and member companies were dedicated to addressing unmet medical needs and advancing innovation for better health outcomes.

Dr. Arunish Chawla
Former Secretary, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers

Dr. Rajeev Singh Raghuvanshi
Drugs Controller General of India, Central Drugs Standard Control Organization (CDSCO)

Anil Matai, Director General OPPI, similarly stressed that India stands at the cusp of a remarkable transformation in healthcare, and the pharmaceutical industry is set to play a pivotal role in realizing the vision of विकसित भारत@2047.

"Moving forward, we must continue fostering an environment that values research, innovation and resilient healthcare infrastructure," Mr Matai underscored.

Four key reports were also released at the summit namely:

- विकसित भारत@2047 – Transforming India from Pharmacy of the World to Pharma Powerhouse to The World
- Winning in Indian Healthcare
- Bilingual FAQs on Value of Innovation
- FAQs on Over The Counter (OTC) Drugs.

Regulatory Reform

Dr Rajeev Singh Raghuvanshi, Drugs Controller General of India (DCGI), highlighted a number of initiatives that the regulator is implementing to ensure optimal resource use, while also seemingly tightening certain procedures around areas like clinical trial-related clearances.

Dr Raghuvanshi indicated that the regulator has stopped "re-deliberations" in subject expert committee (SEC) meetings unless an applicant furnishes fresh data, a move he believes, would help the regulator, and the applicant save resources and time, which can be used in "much more value-added work".

The DCGI also referred to quicker clearances for export no objection certificates (NOC) for the manufacture of 'unapproved' drugs, a process which was centralized earlier this year.

While historically it required between 20 to 60 days to give such NOCs, currently "hard data" indicates it takes less than four days, with the CDSCO doing the activity digitally, he pointed out.

Optimism About India

The summit also featured high-profile panel discussions on a range of key topics.

Bhushan Akshikar
President OPPI

Anil Matai
Director General, OPPI

Experts weighed in on the huge opportunities opening up in India with expanding health cover and rising affluence, among other factors, in a panel discussion on "Winning in Indian Healthcare: The Impact of Global Pharma Companies on Indian Healthcare and the Road Ahead".

Industry leaders pointed to the "growing optimism" about India in boardroom discussions against the backdrop of a range of favourable factors as the country emerges as one of the fastest growing economies of the world. India's large aging population would mean greater healthcare needs in addition to the disease burden in areas ranging from obesity and diabetes to cancer.

Changing consumption patterns as rising income levels encourage the growing middle class to invest more on health and wellness and improving health infrastructure, supported by both public and private investment flows, were some of the other factors discussed.

Reference was also made to the rising affluence in India – about 25% households (80m) are projected to be affluent by 2030 (5x in 20 years) per the OPPI-BCG report unveiled at the summit.

Consumption growth in India is expected to be stronger in Tier 1-4 cities versus metros over the 2020-2030 period, the report noted. With significant consumption in India already getting driven in that segment, it could have immense implications for global pharma companies as "they think of what products to bring, when to bring them," one panellist observed.

Accessing those segments directly could, however, be challenging for global pharma players in the current setup and may require them to either "transform completely" or then consider the partnering route.

The panel also touched on growing public sector insurance, though the penetration of private insurance in India is not "where it should be, but there's no way, but to go up" a panellist observed.

Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB PM-JAY), India's massive publicly funded health assurance scheme, was recently expanded to cover all senior citizens aged 70 and above, regardless of their income.

While there are areas for improvement, given the policy reforms in the last decade or so, India continues to go up the "priority list" when it comes to pharma board room discussions, an industry head added during the discussion.

AB PM-JAY - Impact

Importantly, the AB PM-JAY is also seen changing healthcare dynamics in the country.

While more than 20 million people are estimated to receive free treatment every year under the assurance scheme, experts underscored that coverage and treatment are "only part of the story".

Panelists from Panel 1 discussed on Winning in Indian Healthcare: The impact of Global Pharma companies on Indian Healthcare and the road ahead

AB PM-JAY, a panellist emphasized, is transforming the health system in "a very fundamental way".

Importantly, most of those receiving treatment under the scheme may not be able to access any treatment without it, the expert said, adding that these patient numbers will only increase. More people entering the treatment funnel will have a knock-on effect on the pharma sector.

Additionally, while most of the patients tapped the informal sector or were going to 'one doctor' clinics, Ayushman Bharat had resulted in a trend of consolidation, and some of these facilities were getting "larger or merged". As a result, the very structure of health services and the health system in India was changing in a fundamental way because of Ayushman Bharat, the panellist maintained.

Collaborative Strategies

Collaborative strategies to improve access to healthcare in India were at the core of another panel discussion. The session highlighted the multidimensional aspects involved in improving healthcare access in India, especially post-COVID 19, amid a growing thrust on wellness, patient-centric solutions, and the integration of various healthcare devices and diagnostics.

The panellists emphasized that all stakeholders in the ecosystem need to combine forces to ensure healthcare access across the country. One expert referred to 'Antyodaya' (which essentially means ensuring the rise and development of the last person in society) as the goal as India looks towards a वकसित भारत@2047.

विकसित भारत@2047 envisions India as a developed nation by the centenary of its independence in 2047.

The role of voluntary licensing (VL) in facilitating wider access to critical treatments was also highlighted with a panellist pointing to many successful VL examples in the pharma sector.

Advances in India's IPR landscape are also expected to facilitate innovation and access to medicines. Panellists noted that the Indian patent office granted over 100,000 patents in the last year (15 March 2023 to 14 Mach 2024) and the statement of working of patents in Form 27 had been made "much easier", among other aspects. India had earlier notified the Patents Rules, 2024 with several provisions to simplify patent prosecution and maintenance.

Design And Make in India

Industry leaders also underscored the role of innovation in a discussion around India's efforts to move beyond its traditional stronghold as the pharmacy of the world to emerge as the pharma powerhouse to the world.

While innovation is fundamental to the pharma sector, an industry head noted that India had fared well in the generics space but acknowledged that its share in innovation of drugs is currently negligible.

One panellist asserted that India needs to go from "make in India to design and make in India" and highlighted the role of CRDMOs in moving the innovation needle.

Others maintained that while the entire ecosystem is in place in India, it is functioning in "isolation and in bits and pieces". It, though, requires just one instance that can demonstrate that the entire ecosystem has contributed to deliver an innovative drug which is successful, one panellist stated.

Parallels were drawn with the initial slow traction of Global Capability Centres (GCCs) in India, which has since seen momentum, and almost all the major big pharma companies now have GCCs in the country.

One expert urged OPPI member companies to try and create an "environment of trust" about India among their principals. Various stakeholders need to work together so that the principals consider investing in India across "all areas".

GCCs Are "Big Incubators"

An industry captain also emphasized that GCCs are the "big incubators" so to speak of creating an innovation ecosystem in India.

Over 90,000 jobs are estimated to have been created as a result of these centres, with

Panelists from Panel 2 discussed on विकसित भारत@2047 *- Transforming India from Pharmacy of the World to Pharma Powerhouse to the World*

Panelists from Panel 3 discussed on Collaborative Strategies to Improve Access to Healthcare in India

roles across early R&D, protocol development, biostatistics and machine learning, among others.

The executive also pointed out that most global pharma companies are keen to bring their innovative drugs to India "sooner than later" and some of the recent regulatory changes such as the trial waiver under Rule 101 of New Drugs and Clinical Trials Rules 2019, among others, augur well and will only "incentivize" industry to move forward.

The summit also recognised Dr. Gullapalli N. Rao Founder Chair, L. V. Prasad Eye Institute with the OPPI Lifetime Achievement Award 2024.

Other awardees were:

- OPPI Young Scientist of the Year: Rachit Agarwal, Associate Professor, Indian Institute of Science.
- OPPI Woman Scientist of the Year: Prajakta Dandekar Jain, Co-ordinator, M.Tech. Pharmaceutical Biotechnology Program, UGC Assistant Professor in Engineering Sciences, Institute of Chemical Technology, Mumbai
- OPPI Scientist of the Year: Arun Kumar Shukla, Professor and Sonu Agrawal Memorial Chair, Indian Institute of Technology, Kanpur.
- OPPI Excellence in Innovation Award for Healthcare Start-up of the Year 2024: Neodocs

The OPPI Annual Summit covered India's transformative journey toward becoming a global pharmaceutical powerhouse by 2047 and highlighted the vision of the government officials and industry leaders. The discussions ended on a positive note, with the speakers highlighting the factors that would enable India on its journey towards विकसित भारत@2047.

To access the complete summit report, kindly scan the QR code.

New Milestone: India Hosts ICDRA

Byline: Anju Ghangurde,
Executive Editor APAC at Citeline

Key Highlights:

- Focus on frameworks to strengthen global regulatory systems, harmonize practices.
- String of policy and regulatory advances made in India
- Stakeholders deliberate role of accelerated pathways, regulatory reliance

Regulators, policymakers, and health officials from across the world, at a recent conference in India, discussed strategies, priorities and frameworks to strengthen global regulatory systems and harmonize practices.

Addressing the 19th International Conference of Drug Regulatory Authorities (ICDRA), India's Union Minister of Health and Family Welfare, Shri. Jagat Prakash Nadda, said that the ICDRA platform provides an opportunity to share knowledge, foster partnerships, and develop regulatory frameworks that ensure the safety, efficacy, and quality of medical products worldwide.

The minister emphasized the need for a shared commitment to enhance global healthcare standards and safeguard public health.

Underscoring India's resolve to advance global health, Shri. J.P. Nadda referred to the "3 Ss (skill, speed, and scale)" that the country has focused on, enabling it to meet the increasing demand for pharma products while adhering to global quality standards.

"We are prepared to address pressing challenges, from antimicrobial resistance to ensuring equitable access to life-saving treatments. We are not just participants in this dialogue; we are partners in building a healthier, safer, and more resilient world," Shri. J.P. Nadda declared at the conference hosted by India's Central Drugs Standard Control Organization (CDSCO) in collaboration with the World Health Organization (WHO).

Malebona Precious Matsoso, co-chair of WHO's Intergovernmental Negotiation Body, South Africa, said that regulation of medical products is one of the most crucial aspects currently, and the impact of regulatory decisions can be seen not only at the national or global level but also "in the hospital rooms."

"Public health interventions and response can be shortened through efficient regulation and oversight," she pointed out.

Matsoso referred to India's tag of being the pharmacy of the world but cautioned that the moniker comes with "certain expectations and capacities".

The ICDRA, which was held for the first time in India, covered a range of key topics including a plenary session on "smart regulation" focused on the evolving landscape of regulatory reliance and the World Listed Authorities (WLA) framework, the quality of pharmaceutical starting materials, regulation of advanced therapy medicinal products, and the role of artificial intelligence in improving regulatory oversight, pharmaco-vigilance, and clinical trials, while also addressing the challenges related to data privacy and implementation.

The conference, which ran from October 14-18, brought together regulators, policymakers, and health officials from over 194 WHO member states. The five-day event included two days designated as pre-ICDRA open sessions for engagement with stakeholders, including inter-government organizations, industry, academia, research organizations, NGOs, and non-profits.

Representatives from OPPI, IFPMA, EFPIA and officials from CDSCO during the Pre-ICDRA Side Meeting

India Regulatory Advances, Digitization

The conference also heard India's apex regulator and government officials highlight some of the policy and regulatory advances made in the country recently.

Dr Rajeev Singh Raghuvanshi, Drugs Controller General of India (DCGI), referred, among other aspects, to the approval of India's first indigenously developed CAR T-cell therapy.

"We are continuously upgrading our skills and capacities in our systems and are on a path towards high execution," Dr Raghuvanshi said.

The Indian cell and gene therapy company, ImmunoAdoptive Cell Therapy (ImmunoACT) received the go-ahead from the CDSCO in 2023 for its CD19-targeted CAR-T cell therapy, which reported low toxicity and the absence of neurotoxicities in clinical trials.

At an industry event earlier this year, the DCGI also outlined plans for a massive digitization effort that is expected to cover the "complete regulatory value chain in the country," along with a regulatory rationalization initiative that aims to examine both internal processes and redundancies in the regulatory framework.

At the ICDRA conference, Shri. J.P. Nadda maintained that more than 95% of regulatory processes have been digitized at the CDSCO, bringing "transparency and increasing trust among stakeholders."

Hon'ble Union Minister of State for Health and Family Welfare, Smt. Anupriya Patel, drew attention to India's New Drugs and Clinical Trial (NDCT) Rules 2019 and the Medical Device Rules 2017, which have "promoted scientific and ethical research at par with global expectations and international practices".

India is also collaborating with international organizations such as the International Medical Device Regulators Forum (IMDRF), ISO, WHO, and regional networks like SEARN [South-East Asia Regulatory Network] to harmonise regulatory requirements in the medical devices and diagnostics area. India was recently recognised as an affiliate member of the IMDRF, she stated.

"Recognition of the Indian Pharmacopoeia by the Pharmacopoeial Discussion Group (PDG) is another milestone marking harmonization and recognition of regulatory standards," Smt. Anupriya Patel pointed out.

The Indian Pharmacopoeia Commission, which joined the PDG as a member in October 2023, is expected to benefit from the exchange of information and best practices with PDG members. The collaboration is also seen helping India's efforts to align its regulatory processes and practices with global standards.

Meanwhile, pre-ICDRA side meetings saw local and global stakeholders deliberate the role of well-defined pathways to expedite the regulatory approval process, ensuring faster patient access to crucial treatments and the importance of regulatory reliance in public health emergencies and other situations.

OPPI had organized a pre-ICDRA side meeting with CDSCO officials, along with the IFPMA and EFPIA, to discuss the role of accelerated regulatory pathways in ensuring timely patient access to critical treatments and collaboration in areas like regulatory reliance. While digital tools, namely secure cloud-based platforms, have the potential to accelerate the implementation of more efficient reliance-based processes, the meeting also deliberated the role of data analytics and real-world evidence as technologies evolve and provide distinct product insights beyond clinical trials.

Regulatory & Compliance Spotlight

India Builds Health Coverage for Elderly, Opportunities In Store For Pharma

Byline: Anju Ghangurde,
Executive Editor at Pink Sheet (APAC)

Key Highlights:

- AB PM-JAY extends free health cover to all senior citizens aged 70 years and above
- Expansion of AB PM-JAY to open new opportunities for pharma

The expansion of India's mammoth publicly funded health assurance scheme, Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB PM-JAY), to cover senior citizens widens the net for better healthcare and treatment opportunities for the elderly, but sub-optimal infrastructure and gaps in the core initiative need attention to ensure sustained gains.

In September 2024, the government extended AB PM-JAY to all senior citizens aged 70 and above, providing health coverage, regardless of their income. The move is expected to benefit around 45 million families, including 60 million senior citizens, ensuring free health insurance coverage of up to INR500,000 per family.

Importantly, senior citizens within families already covered by the AB PM-JAY will receive an additional top-up cover for themselves of up to INR500,000 per year, which won't have to be shared with other family members under the age of 70. Seniors covered by private health insurance policies or the Employees' State Insurance scheme would also be eligible to benefit from AB PM-JAY, per a government note.

A senior pharma industry expert noted that beyond the potential "electoral dividends" of the expanded initiative, its successful implementation would be a boon to most families. "This is not limited to the lower strata, and it operates in an area where private health insurance is impossible or extremely expensive to procure," the expert told Citeline.

The AB PM-JAY is seen as the cornerstone of India's path towards Universal Health Coverage and appears to now recognize the sharp anticipated shift in demographics in the coming years. India's population aged 60 and above stood at around 149 million as of July 2022, comprising around 10.5% of the country's population.

But by 2050, this number is projected to climb to 347 million (with the population share of older persons set to double to 20.8%) as per a United Nations Population Fund (UNFPA) report, bringing with it huge associated healthcare costs around geriatric care.

Payment Cycle, Reimbursement Rates

While experts welcomed the latest elder cover expansion plan under AB PM-JAY, they underlined that it could strain an already stretched infrastructure unless wider existing challenges are addressed. Pricing-related concerns for some procedures and delayed payment cycles remain a sticking point with hospitals.

AB PM-JAY covers over 1,900 procedures across 27 specialties spanning both secondary and tertiary hospitalization, as per data from the 2022-23 annual report of the National Health Authority (NHA), the apex body responsible for implementing the scheme. Top procedures under the scheme in 2023 include haemodialysis and cataract-related procedures.

It's not immediately clear whether the Green Channel Payment (GCP) mechanism rolled out by the NHA for hospitals with a "clean background" has made a material difference. Under the GCP, hospitals can receive 50% of claims amount upfront without complete adjudication of claims and the NHA believes that it could ensure active participation of hospitals. Introduced as a pilot in the state of Uttar Pradesh in January 2022, the NHA expects to expand the GCP initiative more widely across the country.

Over 29,000 hospitals have been empanelled under AB PM-JAY and the healthcare scheme has authorized a total of 77.9 million hospital admissions, translating to INR1071.25bn ($12.7bn) in financial coverage till 9 September, per a government statement. Data as of 14 November indicates that 30,743 hospitals have been empanelled, of which 13,659 are private facilities, though distribution among the states remains patchy (Uttar Pradesh leads the pack with over 5,800 empanelled hospitals, followed by Karnataka (3,901) and Gujarat (2,670), while some other states like Maharashtra (1,037) and Punjab (774) had fewer empanelled hospitals.

Roll Out of 'Modicare'

Formally launched by India's Prime Minister, Narendra Modi, in September 2018, AB PM-JAY, also dubbed "Modicare," at the time, aims to provide health insurance cover of up to INR500,000 per family per year. Over 500 million beneficiaries – around the size of the population of the EU – are to be covered for secondary and tertiary care at all public and empanelled private hospitals in India, making it the world's largest government-funded health care program by the number of beneficiaries.

The scheme was subsequently extended to cover 3700,000 Accredited Social Health Activists (ASHAs), Anganwadi Workers (AWWs), and Anganwadi Helpers (AWHs) and their families, providing them with free healthcare benefits.

A key prong of the Ayushman Bharat program also entailed the creation of Health and Wellness Centers (HWCs) to bring healthcare closer to the homes of people. Now renamed as Ayushman Arogya Mandirs (AAMs), these centres offer a

broad spectrum of healthcare services, including preventive, promotive, rehabilitative, and curative care. As of 12 September 2024, there were 174,453 AAMs across India.

Positive Impact For Pharma

Pharma is keeping a close eye on how things are evolving with AB PM-JAY, given the implications for market expansion and potential partnering opportunities down the line.

An EY- FICCI report earlier this year noted that the AB PM-JAY scheme, coupled with the improvement in penetration of private health insurance, increased the proportion of the insured population in India to 52% in 2017-18, from 37% in 2014-15. Health insurance coverage in India is further projected to grow close to 70-75% by 2025, the report added.

Experts said that insurance companies in India will also likely need to think differently as the government finds it easier to reimburse Ayushman Bharat expenses rather than pay for premiums.

"They [insurance companies] will need to think about preventive medicines. They will, for example, have to provide for vaccines. Vaccines are going to be fascinatingly big in this country," the MD of the Indian firm declared.

A robust AB PM-JAY could bring marked gains for pharma in the longer term. It could mean more people getting into the treatment net or accessing better treatment.

The Role of Regulatory Data Protection in Incentivizing R&D

By Anil Matai,
Director General, OPPI

Key Highlights:

- Regulatory data protection helps incentivise innovation
- Apprehensions around 'evergreening' of patented products misplaced
- Role for RDP as India ascends innovation value chain

Regulatory Data Protection (RDP) is a unique mechanism that stimulates research and drug development in medical innovation and incentivizes innovators to recoup their investments in developing safe and effective medicines.

Generating this data requires considerable effort, time, money and involves significant risks. RDP protects the proprietary pre-clinical and clinical data generated and submitted by innovators to regulatory authorities in support of marketing registrations of their pharmaceutical products are protected.

Article 39.3 of the World Trade Organization's (WTO) agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) includes this as a mandatory obligation of all members from January 1, 2000. It requires WTO members to protect undisclosed information or other data must be submitted to approve the marketing of pharmaceutical or agricultural chemical products that utilize new chemical entities. The protection to be provided is against "unfair commercial use" in recognition that the origination of such data involves considerable effort.

In addition, members are also required to protect such data against disclosure, except where necessary, to protect the public, unless steps are taken to ensure that the data is protected against "unfair commercial use".

In India, the regulatory ecosystem is based on similarity. The extant New Drugs & Clinical Trials Rules 2019 (NDCT) require a new drug applicant to submit a complete clinical data package (Table 1 of the Second Schedule) for products that are proposed to be marketed for the first time in India and have not been marketed for an extensive period outside of India.

A smaller package of clinical data for products that have already been approved in India is required for a subsequent new drug applicant under NDCT. This abridged requirement provides subsequent new drug applicants (generic drug producers) with an unfair commercial advantage over the innovator's new drug applicant.

The apprehension that the growth of the generic market will slacken is ill-founded. RDP does not prevent generic manufacturers from submitting their own pharmacological, toxicological and clinical data within RDP period and thus gain marketing approval for their products.

In fact, India has the potential to achieve its vision of Amrit Kal India 2047, i.e., to become a 'Vishwaguru' in research and innovation-based industries. Indian scientists have demonstrated their critical research talent in the biotech and pharmaceutical spheres, and, with the right commercial incentives, can help bring Research and Development (R&D) to India. The country is poised to make important contributions to public health through innovation, not only within India, but to become fully integrated into the larger family of scientists around the world working to bring new therapies and cures to patients. RDP will help speed up the revolution.

Indian companies are aggressively seeking opportunities for generics even in regulated markets, mainly the European Union and the US. Co-licensing and co-marketing arrangements between Indian companies and companies in these markets will depend upon recognition and implementation of a fully compliant TRIPs regime, including data protection.

RDP is independent of protection, distinct from patents and focuses on information and specific regulatory action, i.e., trade secret information generated in the course of developing a drug product required to be submitted to a drug regulatory authority is not shared with the competitors of the innovator. RDP does not lead to 'evergreening' for patented products as it runs at the same time as the patent term, and it typically lasts for only half the length, or less, of the time of the patent term.

Continuing to build its advocacy in this area, OPPI recently released the bilingual booklet on FAQs on the Value of Innovation, emphasizing the critical role of R&D and Innovation in the biopharmaceutical sector.

The book highlights the costs and timelines associated with drug development and the importance of strengthening the Intellectual Property Rights (IPR) framework.

Scan QR code to read the Hindi booklet

Scan QR code to read the English booklet

Key Interactions

OPPI had the honor of meeting with Union Minister of Commerce and Industry, Shri. Piyush Goyal, to discuss how the pharmaceutical sector can drive progress. Our discussions centered on key areas such as advancing innovation, expanding patient access, generating employment, and enhancing skills to build a stronger India.

OPPI recently met with Prof. Ajay Kumar Sood, Office of the Principal Scientific Adviser to the Government of India. During the meeting, Prof. Sood keenly heard about the significant contributions of OPPI and its member companies to the pharmaceutical sector. The discussion also highlighted the critical role of innovation in improving accessibility and enhancing the quality of healthcare products.

Report Releases

OPPI Annual Summit Report

Viksit Bharat@2047 – Transforming India from Pharmacy of the World to Pharma Powerhouse to the World

Over the Counter Drugs FAQ

Winning in Indian Healthcare

Value of Innovation FAQ (Hindi/English)

Scan QR code to read this Publications

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'.

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