#### HEALTHCARE ROUNDUP FOR

August 2024



### India boosts emergency readiness with indigenous RT-PCR Kit for Mpox detection

On 27th August 2024, India made significant strides in the fight against the Mpox (Monkeypox) virus with the development of its indigenous RT-PCR testing kit, the IMDX Monkeypox Detection RT-PCR Assay, created by Siemens Healthineers. The kit, which received manufacturing approval from the Central Drugs Standard Control Organisation (CDSCO), marked an important achievement for the "Make in India" initiative.

This advanced diagnostic tool targeted two regions in the viral genome, enabling the detection of both Clade I and Clade II variants of the virus. The assay was platform-agnostic, seamlessly integrating into existing lab workflows without the need for new instruments, effectively leveraging India's COVID testing infrastructure. The kit was to be manufactured in Vadodara, with an annual production capacity of 1 million reactions.

Siemens Healthcare emphasised the urgency of precise diagnostics during the ongoing Monkeypox public health emergency, declared by the World Health Organization. The assay, validated by ICMR-National Institute of Virology, Pune, boasted 100% sensitivity and specificity, providing results in just 40 minutes—significantly faster than traditional methods. Hariharan Subramanian, Managing Director of Siemens Healthcare, noted that the development of this assay kit represented a proactive step in improving access to care and combating the disease.





#### Make in India: AIIMS Delhi and Osaka University collaborate to set up centre for medical devices

A delegation from Osaka University, Japan, along with officials from the Japan International Cooperation Agency (JICA), visited AIIMS Delhi on 27th August 2024 to discuss establishing a National Centre for Medical Device Development, Validation, and Skill Training. The high-level meeting, chaired by AIIMS Director M Srinivas, focused on a project aligned with India's "Make in India" initiative for medical devices. The delegation also visited the proposed site at AIIMS Delhi's Jhajjar campus.

This visit marked a continuation of collaborative efforts initiated nearly a decade ago following the joint statement by Prime Minister Narendra Modi and the late Japanese Prime Minister Shinzo Abe during their 2014 summit in Tokyo. As a result of that summit, AIIMS and Osaka University signed a Memorandum of Understanding (MoU) on October 13, 2014, to develop novel and affordable surgical instruments, marking the first R&D collaboration between medical institutions in India and Japan.

This innovative project aims to reduce India's reliance on imported medical devices and promote the development of high-quality, affordable medical devices, with Japan's support in technology and knowledge transfer being crucial to its success.



# Economic Survey 2023-24 flags obesity as a growing concern in India

The Economic Survey 2023-24 emphasized that India's achievement of its long-term goal to become a developed economy relied heavily on improving the health of its population, particularly through weight loss. The report flagged obesity as a growing concern, citing data from the National Family Health Survey 5 (NFHS-5), which showed a significant rise in obesity rates among both men and women. Obesity among men aged 18-69 increased from 18.9% to 22.9%, while for women, it rose from 20.6% to 24.0%. Experts highlighted the urgent need for the government to address this health crisis to boost India's economic prospects.

Obesity was linked to non-communicable diseases such as diabetes, heart disease, and cancer, which undermine the potential of India's working-age population. Experts called for government intervention and individual responsibility to promote balanced diets and physical activity. Dr. Devi Prasad Shetty identified obesity as the root cause of many health problems and stressed the importance of regular health checkups. Dr. Rajeev Jayadevan advocated waist circumference as a simple, cost-effective health metric. The report and experts underscored the need for preventive measures, education on healthy lifestyles, and policy changes to curb obesity and support India's economic growth.



#### **USAID** and **Jhpiego launch Udaan to improve youth sexual** health in India

The U.S. Agency for International Development (USAID), in partnership with Jhpiego, launched the Udaan Collaborative under the MOMENTUM Country and Global Leadership: India-Yash project on 13th August 2024. The initiative aimed to enhance access to quality Sexual and Reproductive Health (SRH) services and information for youth across India. The project brought together over 900 obstetrician-gynecologists, 600 general physicians, and 7,200 pharmacists, focusing on urban and rural areas in Jharkhand, Odisha, Chhattisgarh, and Madhya Pradesh.

The Udaan Collaborative supported young people in making informed health decisions by providing a digital platform with comprehensive SRH information and products. Michelle Lang Alli, Director of the USAID/India Health Office, highlighted the collaboration with the Indian government and the private sector to enhance family planning and reproductive health goals. Dr. Jaydeep Tank, President of the Federation of Obstetric and Gynaecological Societies of India, emphasized the initiative's role in uniting healthcare providers to drive change and empower youth.

Somesh Kumar, Country Director of Jhpiego India, noted Udaan's alignment with Jhpiego's vision of empowering individuals in healthcare decisions. The initiative also featured a digital platform integrating chatbots, helplines, and online consultations to promote safe SRH practices and informed decision-making.



## India eases drug approval process, lowering costs and expanding access to new therapies

On 9th August 2024, India's Drug Controller General (DGCI) issued a significant order waiving the requirement for local clinical trials for new drugs already approved by top regulatory authorities in the US, UK, Japan, Australia, Canada, and the EU. This order applied to drugs for weight loss, Alzheimer's, cancer, rare diseases, gene and cellular therapies, and pandemic-related treatments. Pharma companies could now obtain regulatory clearance in India by demonstrating that their drugs offered a "significant therapeutic advance" over existing treatments.

Previously, even globally approved drugs needed local trials in India. The new rules aimed to expedite access to innovative therapies, benefiting patients with rare diseases or specific cancers. The waiver was included in the 2019 New Drugs and Clinical Trial Rules but was only now implemented, specifying which countries' approvals could be recognized.

The move was expected to speed up the availability of blockbuster drugs like GLP-1 receptor agonists for diabetes and obesity, and cancer therapies. However, these drugs would still need to undergo Phase IV post-marketing surveillance in India. The DGCI's Subject Expert Committee retained the authority to require local trials if scientific evidence suggested the drug might behave differently in the Indian population. This change was also anticipated to reduce drug prices by lowering development costs.

#### New study by HelpAge India reveals India's aging population faces rising health & social security risks

The recent study by HelpAge India, titled "Ageing in India: Exploring preparedness & response to care challenges," highlighted the severe lack of healthcare facilities and social support for India's elderly population, particularly those aged 60 and above. The report underscored the growing risks related to health, environment, and social security for senior citizens. It revealed that only one in four elderly individuals received financial support from family, pension schemes, or provident funds, leaving the majority with little to no economic security. Many older adults, especially those working in the unorganized sector, lacked pension and insurance coverage, placing a heavy financial burden on their families.

The study also brought attention to the increasing prevalence of multiple morbidities among the elderly, with 54% of senior citizens reporting more than one chronic condition such as hypertension, high cholesterol, and diabetes. Furthermore, the report exposed the disturbing issue of elder abuse, with 7% of the elderly experiencing abuse, primarily at the hands of sons and daughters-in-law. HelpAge India called for urgent action to address these social challenges by improving access to affordable healthcare, increasing financial security, and raising awareness to support the aging population better.





#### Health Ministry urges states to implement nationwide standard treatment guidelines

On 31st July 2024, The Union Health Ministry urged all states to implement 157 Standard Treatment Workflows (STWs) across 28 medical specialties, as developed by the Indian Council of Medical Research (ICMR). These STWs were designed to standardize care in hospitals and promote the rational use of essential drugs and diagnostics. In a letter to state health secretaries and the National Medical Commission (NMC), Union Health Secretary Apurva Chandra emphasized the need for healthcare providers to stay updated with medical advancements. The STWs provided a simplified, one-page app-based tool to guide physicians at all levels of care.

Developed in collaboration with the National Health Authority (NHA) and the World Health Organization's India Country Office, the STWs covered common and serious diseases encountered across the Indian Public Health Care system. Union Health Secretary highlighted that these workflows were essential for establishing uniform care standards and encouraging the rational use of resources.

The STWs were made available on the ICMR website and as a mobile app, and Union Health Secretary called for state health departments to ensure their widespread use among physicians. The implementation of these workflows aimed to improve patient outcomes by providing clear, accessible guidelines and streamlining healthcare practices nationwide.



# API & ICP release new guidelines to improve hypertension care in India

On 5th August 2024, the Association of Physicians of India (API), in collaboration with the Indian College of Physicians (ICP), released new guidelines for managing hypertension in Indian patients with Type 2 Diabetes Mellitus (T2DM). Recognizing the high cardiovascular risk of T2DM, the guidelines recommended dual antihypertensive therapy, particularly combining Angiotensin Receptor Blockers (ARBs) with Calcium Channel Blockers (CCBs), to reduce blood pressure and prevent cardiovascular complications effectively.

A significant update in the 2024 guidelines was the inclusion of newer CCBs, with a focus on Cilnidipine. Introduced in India in 2007, Cilnidipine was highlighted for its benefits in reducing blood pressure and protecting vital organs, especially the kidneys. The guidelines suggested combining Cilnidipine with ARBs while considering patient-specific factors. Renin-angiotensin system (RAS) blockers were also recommended for their proven efficacy in preventing diabetic kidney complications. The guidelines encouraged the use of newer anti-diabetic agents like SGLT2 inhibitors and GLP-1 receptor agonists for better glycemic control and vascular protection.

Additionally, the guidelines emphasized multiple methods to detect and measure hypertension, including home BP monitoring, and advocated for lifestyle modifications, such as yoga, as adjunct therapy. These recommendations were published in the Journal of the Association of Physicians of India (JAPI).



## **Union Health Minister JP Nadda inaugurates First Policy Makers' Forum in New Delhi**

Union Minister of Health & Family Welfare and Chemicals & Fertilizers, Shri J.P. Nadda, inaugurated the 'First Policy Makers' Forum' in New Delhi on 19th August 2024. The forum brought together an international delegation of policymakers and drug regulators from 15 countries, hosted by the Indian Pharmacopoeia Commission (IPC) in collaboration with the Ministry of Health & Family Welfare and the Ministry of External Affairs.

During the event, Shri Nadda underscored India's role as the "pharmacy of the world," highlighting the country's contribution to treating diseases like malaria, HIV-AIDS, and tuberculosis in developing nations through affordable generic drugs. He also emphasized India's leadership in vaccine production, which supplies 60% of the global demand, including during the COVID-19 pandemic under the Vaccine Maitri Programme.

A key highlight of the forum was the launch of two groundbreaking digital platforms: the Indian Pharmacopoeia Online Portal and the Adverse Drug Reaction Monitoring System (ADRMS) software. These initiatives aimed to enhance drug standards accessibility and strengthen pharmacovigilance infrastructure in India. The forum featured in-depth discussions on India's flagship Janaushadhi Scheme, promoting the use of affordable, high-quality generic medicines internationally. Delegates also explored India's healthcare facilities and manufacturing capabilities, reinforcing India's commitment to improving global health through collaboration and innovation.

#### Pharmarack and IPA release report on Indian pharma supply chain

Pharmarack Technologies, a leader in pharmaceutical digital supply chain and market intelligence, in collaboration with the Indian Pharmaceutical Alliance (IPA), released a report titled "Changing Dynamics of Indian Pharma Supply Chain." The report examined the transformation of India's pharmaceutical supply chain over the past decade, with a focus on changes driven by the COVID-19 pandemic and recent regulations like Good Manufacturing Practices (Revised Schedule M) and Good Marketing Practices (UCPMP).

The report highlighted the critical importance of compliance throughout the entire supply chain, starting with the doctor's prescription. It was based on a comprehensive research methodology that combined data from Pharmarack's advanced analytics platform, which gathered real-time data from over 200,000 chemists and 12,000 distributors across India, with in-depth interviews from key stakeholders, including top pharmaceutical companies, distributors, retail chemists, and industry experts. The report also drew on global best practices, identifying areas where India could learn from more developed markets.

Key recommendations included upskilling and digitising pharmacies, strengthening drug quality compliance to enhance patient safety, increasing transparency to combat counterfeit drugs, and leveraging digital technologies to build supply chain resilience. Dhruv Gulati, CEO of Pharmarack Technologies, emphasized the need to focus on patient welfare and optimize the distribution network through technology and empowerment of pharmacists.



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