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Innovation Takes Centre Stage in

PAEDIATRIC HEALTH CARE

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"Collaborative efforts between countries and institutions are shaping the R&D landscape in genomic medicine in APAC"
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Acknowledgement/ Feedback

Thank you so much for the wonderful feature on 'Why multi-use real estate is in demand for life sciences companies'.

- Corrie Fisher, US

Thank you BioSpectrum Asia for the interview feature on Lindström in the June edition, and for highlighting our focus on sustainability, operational excellence, and customer satisfaction, all crucial in the biopharma and pharmaceutical industries.

- Manas Kumar, India

The interview feature on Nona Biosciences looks great. Thank you.

- Helence, China

Thanks much for publishing Jeremy Cao's article- 'How Thai Biotech is Thriving with Innovations'.

- Jaxon, China

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Letter from Publisher

Ravindra Boratkar
Publisher &
Managing Editor,
MD, MM Activ Sci-Tech
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Dear Readers,

A recent joint report by UNICEF, the WHO, the UN Population division and the World Bank group reveals that children dying under five years of age declined by two thirds in two decades in South Asia. The number has come down from 5 million in 1990 to 1.3 million in 2022. Even the death probability for under five years of age has reduced by 72 per cent since 1990.

In any society, paediatric healthcare is an important issue and in a welfare state it is also of major priority in terms of healthcare. The entire healthcare sector is experiencing a major shift from old medical technologies to a new one driven by Artificial Intelligence (AI) and novel techniques. Paediatric healthcare is no exception with the dawn of a new era of paediatric medicine innovations.

A hospital in Vietnam recently announced the introduction of AI driven machines for early detection of myopia risk for children. A hospital in India launched a paediatric prohealth programme to combat the increasing trend of non-communicable diseases among children. Overall, in the APAC region innovations in paediatric healthcare driven by new technologies as well as collaborative efforts are rapidly advancing. All this is indirection to enhance child healthcare. Our content team has tried to find out what innovations are shaping up and what collaborative efforts are on in APAC in paediatric healthcare. I am confident that it will give you a good insight into the subject.

Our second article is on the issue of obesity drug development. The topic assumes a very serious concern with an estimated one billion people worldwide to be affected by obesity by 2030. Pharma companies are showing interest and making significant investments in combating obesity.

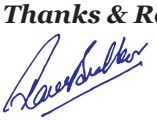
In addition, we are also taking stock of the progress of the Asia Pacific region towards achieving 2030 targets for elimination of another serious disease, hepatitis, on the occasion of the World Hepatitis Day on July 28. It is important to look at it when the disease is claiming 3,500 lives each day and 254 million people are living with Hepatitis B and 50 million with Hepatitis C.

According to the WHO, projections indicate a shortfall of over 15 million health workers by 2030, underscoring the urgent need for action. In this regard, we have covered an expert article on how the Philippines is revolutionising medical education by providing affordable and value-for-money learning options at a fraction of the cost and its curriculum matched with US standards, ensuring seamless integration into foreign jobs, particularly in North America.

As the life science industry continues to evolve, strategic partnerships between startups and large corporations will become increasingly crucial for driving innovation and bringing new therapies to patients faster. We have touched upon this issue in an expert article wherein the author explains that the collaborative efforts between nimble startups and resource-rich corporations ensure that innovation remains at the forefront of the industry, ultimately benefiting patients and advancing global health outcomes.

I am sure you will find this edition a great read.

Thanks & Regards,



Ravindra Boratkar
Publisher & Managing Editor

COVER 20

Innovation Takes Centre Stage in Paediatric healthcare

Children represent approximately one-third of the world's population, with over 580 million in the East Asia and Pacific region alone (Source: UNICEF). Historically underrepresented in healthcare care delivery and innovation, the landscape is evolving as governments and healthcare organisations in the region strive to address paediatric healthcare needs. Paediatric healthcare spans recommended immunisations before adulthood to developmental health, mental health, neonatal care and rare diseases, among others. Let's deep dive into the innovations enhancing children's well being in the region.

Hepatitis

Obesity

Speaking With

Investments

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REGULARS

TIME TO SHAPE UP OR...

Dr Milind Kokje
Chief Editor
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The Food and Drug Administration (FDA) of the Philippines has issued a second order recalling the chemotherapy drug Trexasaph after more of its batches were found to be contaminated with bacteria that could cause fatal infections. As per the FDA database, the medicine is produced by the Indian company Bruck Pharma Pvt Ltd and imported by Nelpa Lifesciences Inc.

Following a report of adverse reaction to the medicine in a child, a sample was tested and was found positive for Pseudomonas aeruginosa. The FDA issued the first warning not to use the drug and recalled it in March and then again in May. Methotrexate, a chemotherapy agent and immune system suppressant, is used in the treatment of cancers.

P. aeruginosa is commonly contracted by patients who are hospitalised for a longer period. It can cause bloodstream infections, which can lead to death. It can spread in many ways including through water, soil, food and contaminated medical devices, as well as person to person.

About two years back, after an inspection of Intas Pharma, the US FDA stopped imports of its life-saving cancer drugs calling them adulterated. The shortage of that drug which was created as a result of stopping the import was made by a similar drug produced by the Chinese company Quila Pharmaceuticals. The US had to turn to China despite its policy to reduce its reliance on China, since a shortage of life-saving drugs can be a threatening situation.

Despite the image of Indian medicines getting tarnished due to such incidents, fortunately, the export of drugs has not yet been severely hit. It increased in 2023-24 by 9.67 per cent to little less than $3 billion over the previous year. This rise arrested to some extent the dip in overall exports of the country which was 3 per cent.

India has better opportunities as the US looks at it as a trustworthy alternative to China when it comes to medicines and their ingredients. India already provides 60,000 generic brands from 60 therapeutic categories. It is rightly called the pharmacy of the world being the third largest in volume and 13th largest by value.

But when issues related to quality surface, the image of the entire sector gets affected. Particularly if they are linked to deaths or cases of severe adverse reactions among the patients. Sadly, the negative comments do not restrict to only a particular company which is allegedly faulted but against the regulator also.

An argument is put forward by some that regulators in foreign countries purposely malign the names of Indian companies to throw them out of competition. Even assuming that there could be some truth in such arguments, one needs to understand that when the medicines are linked to deaths and severe adverse reactions, it becomes a serious issue. Particularly when it comes to the US it does not need to have any specific grudge against Indian companies for any specific purpose. Because, if that is the case then they have to turn to China for supplies which the US is against and going by developments in the last few months (commented on in previous issues of this magazine) the distance between the US and China is widening, particularly pharma and biotechnology is being used as a turf for this conflict. Naturally, India stands a good chance to make more inroads and several media reports have indicated that.

But the US (and other countries too) would not compromise on quality. Banning a drug is an extreme step, but the US FDA has been regularly issuing warning letters to production facilities here. Hence, lack of good manufacturing practices (GMPs), poor record keeping and failure to meet global standards remains a major challenge for several Indian pharma companies. Continuation of the same will regretfully be a lost opportunity for Indian companies when pharma producers abroad have China plus one policy and are looking for alternatives or additional to Chinese suppliers. BS

Abu Dhabi strengthens position as global pharma and life sciences distribution hub

The Department of Health – Abu Dhabi (DoH), the regulator of the healthcare sector in the Emirate, and Abu Dhabi Investment Office (ADIO), Etihad Airways and AD Ports Group have signed a Memorandum of Understanding (MoU) to strengthen Abu Dhabi's position as a global pharmaceutical and life sciences distribution hub, leveraging its strategic location, lucrative investment opportunities and advanced logistics capabilities. In line with the Abu Dhabi Economic Vision 2030, the MoU is a pivotal step in Abu Dhabi's ongoing efforts to become a leading healthcare destination in the global healthcare landscape. The strategic partnership aims to create attractive value propositions for pharmaceutical, biotechnology, and medical technology companies to establish their operations in Abu Dhabi. By capitalising on DoH's world-class regulatory framework, ADIO's attractive investment platform, Etihad Cargo's expertise in air freight, and AD Port's robust logistics infrastructure, the collaboration is set to position Abu Dhabi as a global healthcare and life-science distribution hub.

South Korea, Estonia to collaborate in healthcare through use of AI

The Ministry of SMEs and Startups, in Korea, held director-general-level discussions with the Estonian Ministry of Social Affairs in Tallinn, Estonia's capital, recently. The talks took place to discuss Estonia's genomic information and medical data. Moreover, there were discussions about support measures for Korean AI healthcare startups looking to collaborate with Health Founders, a health tech-focused accelerator, and universities and companies in Estonia. Health Founders, the first health tech-specific accelerator in the Baltic Sea region, identifies and supports startups in the health tech sector by integrating them with Estonia's health information system. Also, a Memorandum of Understanding (MoU) has been signed between Heo Jang-hyeon, Head of Gangwon Technopark, the dedicated agency for Gangwon's Global Innovation Special Zone for AI healthcare, and Andrus Kurvits, Director of Tartu Science Park, a regional innovation agency in Estonia. This MoU aims to provide empirical support and foster talent development for AI healthcare companies.

SS Innovations' Mantra surgical robotic system receives approval for use in Indonesia

Indian firm SS Innovations International, Inc. (SSII), a developer of innovative surgical robotic technologies dedicated to making world-class robotic surgery affordable and accessible to a global population, has announced that its SSi Mantra Surgical Robotic System has received regulatory approval from the Indonesian Ministry of Health for clinical use in the Republic of Indonesia. With more than 279 million people, Indonesia is the world's fourth-most-populous country. However, robotic surgery has been slow to reach the island nation. Indonesia's Bunda

Hospital in Jakarta acquired its first robotic surgical system in 2012 and has only completed about 700 surgeries in the past 12 years. Last month, SS Innovations announced that it had completed 100 robotic cardiac surgery cases in just over a year, utilising the SSi Mantra Surgical Robotic System. It is the first surgical robotic system made in India, and one of the only systems in the world designed to be cost-effective with broad-spectrum surgical applications. The SSi Mantra is clinically validated in more than 70 different types of surgical procedures. SS Innovations has commenced the regulatory approval process in the United States and the European Union and anticipates receiving US FDA approval to market and CE Mark approval in 2025.

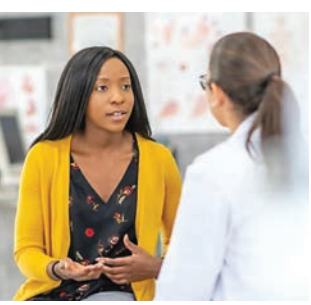
Singapore launches child & maternal health, well-being strategy and action plan report

The interagency Child and Maternal Health & Well-being (CAMH) Taskforce in Singapore has completed its Strategy and Action Plan and published its report. The CAMH Strategy and Action Plan set out three thrusts and nine recommendations, which have been translated into 48 initiatives, to drive better health outcomes for children and their families, and maximise the development potential of the young. 28 of these initiatives have already been implemented, with the remainder to be progressively implemented over the next two years. The CAMH Taskforce

was convened in January 2021 to explore ways to strengthen holistic support for the health and well-being of children from birth to 18 years old, and their families. Led by Minister for Social and Family Development and Second Minister for Health, Masagos Zulkifli, and supported by representatives from over 20 agencies across the health, social and education sectors, the Taskforce is part of the government's larger efforts to address individual health needs and modifiable risk factors beyond the health domain. The Taskforce has conducted a comprehensive review of evidence-based research with experts, and consulted families and frontline officers from the health, social and education domains to identify gaps and discuss ways to enhance support for children and their families.

Australia injects $160M in tailored women's health package

The Australian government is investing more than $160 million in a tailored women's health package to tackle gender bias in the health system, upskill medical professionals and improve sexual and reproductive care. The 2024-25 Budget delivers $5.2 million for scholarships and to cover travel costs so that healthcare professionals – including doctors, nurses and midwives – can do training in the insertion and removal of Long Acting Reversible Contraception; $1.1 million to develop an online contraception decision-making tool for women and health practitioners; and $5.5 million to fund the Australian Institute of Health and Welfare to develop a national sexual and reproductive health dataset. It will identify changing women's health care needs across all stages of their lives, explore equity in care, and identify groups needing additional support.



India to set up mental health assistance helpline for armed forces

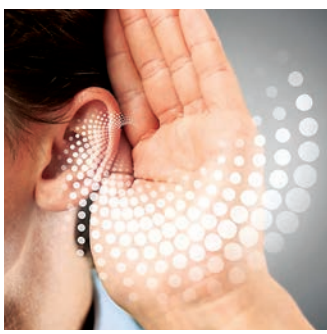
A Memorandum of Understanding (MoU) has been signed between the Ministry of Health and Family Welfare (MoHFW), Government of India, and the Ministry of Defence (MoD) to facilitate collaboration between the two ministries in operating a special cell of Tele MANAS, the National Telemental Health Helpline of MoHFW, as a pilot project for a period of two years at the Armed Forces Medical College in Pune. Recognising the unique stressors faced by the Indian military, the need for tele-mental health services in the Armed Forces has become evident. The operational environment, cultural challenges, and specific stressors related to regional conflicts necessitate a specialised approach to mental healthcare in Armed Forces. With the signing of the MoU, the mental health and well-being of Armed Forces personnel and their families will be addressed and the Armed Forces beneficiaries will have direct access to specialised care, ensuring that their unique mental health needs are addressed promptly and effectively. Tele MANAS is the digital extension of the District Mental Health Programme (DMHP), offering comprehensive, integrated, and inclusive 24/7 tele-mental health services.

Thailand to invest $1.54B in biochemicals, data centres and hospital

The Thailand Board of Investment (BOI) has approved the investment promotion applications of eight large projects worth a combined 56.95 billion baht ($1.54 billion), including a bio-ethylene plant project by the local joint venture of Brazil's Braskem, as well as data centres, power plants, & a major new hospital. The Board has approved two large data centre projects, aiming to support the economy's digital transformation, & the fast-increasing demand for cloud computing, IoT & AI- A multinational company headquartered in the United States received approval for a 7.19 billion baht investment in a data centre in Samut Prakan province; & True Internet Data Center Co. received approval for a 3.35 billion baht investment to expand one of the company's four existing data centres, which is located at the True IDC East Bangna Campus, also in Samut Prakan province. Bumrungrad International Hospital Phuket Co. received approval for a 4.96 billion baht investment to build a 212-bed hospital & Advanced Diagnostic Centre.

Shionogi signs €400M deal with French firm Cilcare to address hearing loss

Japan-based Shionogi & Co. has entered into an option agreement with French firm Cilcare DEV SAS to acquire the exclusive license for the development, manufacturing and commercialisation of CIL001 and/or CIL003, the hearing loss treatment drug candidates worldwide. In conjunction with the signing of the agreement, Shionogi will make an upfront payment of Euros (€) 15 million to Cilcare. If Shionogi exercises its option for both compounds and development and commercialisation proceeds successfully, the total of the option payments and development, regulatory, and sales milestones may reach approximately Euros 400 million, plus royalties on net sales. Cilcare has been developing CIL001, a novel candidate drug for hearing loss treatment with auditory nerve protective effects. Currently, preparatory activities are underway to collect auditory data in patients with type 2 diabetes or mild cognitive impairment. From the fiscal year 2025, Phase 2a studies are planned to evaluate the safety and efficacy of CIL001 in patients with type 2 diabetes who have cochlear synaptopathy. Additionally, preclinical studies for CIL003 are currently underway. Shionogi will decide whether to exercise the option right based on the results of the Phase 2a studies of CIL001 and preclinical study data of CIL003, both to be conducted by Cilcare.



AbbVie inks deal worth $1.56B with China's FutureGen to develop IBD therapy

US-based firm AbbVie and FutureGen Biopharmaceutical (Beijing) have announced a license agreement to develop FG-M701, a next generation TL1A antibody for the treatment of inflammatory bowel disease (IBD) currently in preclinical development. FG-M701 is a fully human monoclonal antibody targeting TL1A, a clinically validated target in IBD. FG-M701 is uniquely engineered with potential best-in-class functional characteristics compared to first-generation TL1A antibodies with the goal to drive greater efficacy and less frequent dosing as a therapy for IBD. Under the terms of the agreement, AbbVie will receive an exclusive global license to develop, manufacture and commercialise FG-M701. FutureGen will receive $150 million in upfront and near-term milestone payments and will be eligible to receive up to an additional $1.56 billion in clinical development, regulatory and commercial milestones, as well as tiered royalties up to low-double digits on net sales.

Singapore contributes S$24M to the WHO's inaugural investment round

At the World Health Organization's (WHO) Strategic Roundtable on 'All for Health, Health for All: the WHO Investment Case' held in Geneva, Switzerland recently, Minister for Health Ong Ye Kung announced Singapore's contribution of S$24 million to the WHO's newly launched 2025/28 Investment Round. The contribution will support the WHO's 14th General Programme of Work over the next four years from 2025 to 2028. This is the first time that WHO has made a targeted, forward-looking call with the aim of securing predictable and sustainable funding for its work. Singapore is the first in Asia and one of the first WHO member states to announce its pledge. Singapore will prioritise its contribution specifically on improving protection from health emergencies. This means that the contribution will go towards building domestic capacities, especially amongst developing countries, to prepare for, prevent, detect, and respond to health emergencies.

Kotak Alt invests Rs 1445 Cr for acquisition of API business of Viatris by Matrix Pharma

Kotak Alternate Asset Managers (Kotak Alt), a part of India's Kotak Mahindra Group, has announced an investment of Rs 1445 crore for acquisition of API business of Viatris by Matrix Pharma. The acquisition has been consummated by the Kotak Strategic Situations Fund II. Post this acquisition, Matrix will be the 2nd largest Indian active pharmaceutical ingredients (API) player with global leadership in antiretroviral (ARV) APIs. Matrix will gain access to strong R&D capabilities, including 185+ scientists and 600+ DMF filings. With regulatory approvals for the US and EU, it will be able to leverage its long-standing relationships with global pharma majors. Kotak Alt will enable Matrix to consolidate its leadership in the API business by strengthening its third-party sales and will selectively evaluate inorganic opportunities in the pharma contract development and manufacturing organization (CDMO) space.

UQ secures $32M global partnership to create homegrown lifesaving vaccines

Queensland will be a major international hub for vaccine discovery and development with a $32 million partnership secured between The University of Queensland (UQ), Australia and US-based Emory University, with support from the Queensland Government, to establish the Queensland Emory Vaccine Centre (QEVC) at UQ. QEVC will bring together UQ and Emory researchers, along with industry partners including global pharmaceutical company Sanofi and homegrown biotech company Vaxxas, to accelerate the development of vaccines and their delivery to help address the world's critical health challenges. The new partnership extends a longstanding collaboration in drug discovery between Emory University and UQ through UniQuest's Queensland Emory Drug Discovery Initiative (QEDDI) and the Queensland Emory Development (QED) Alliance together with QIMR Berghofer.

Olympus to set up R&D Offshore Development Center (ODC) in India

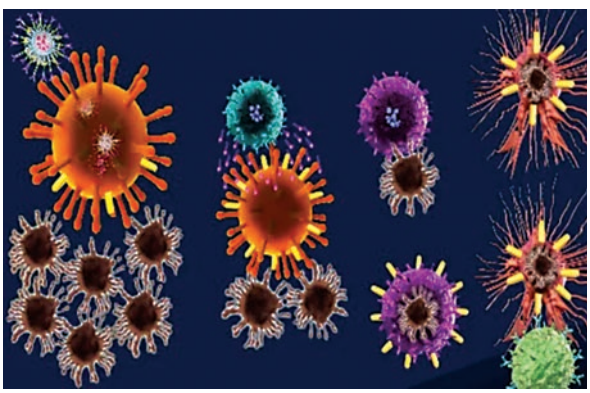
Olympus Corporation, a Japan-headquartered medtech company, has announced its strategic initiative to establish an R&D Offshore Development Center (ODC) in Hyderabad, India. This decision comes as a result of a strategic agreement with global technology company HCLTech, aimed at diversifying Olympus' innovation generation activities. Concurrent with the creation of the ODC, Olympus will also prepare for the establishment of Olympus' in-house R&D centre in the coming years. This centre would be in addition to the company's current R&D centres in Japan, the United States and Europe. The company plans to further establish its presence in India by collaborating with AIG Hospitals, Hyderabad for joint research projects. By partnering with one of India's premier healthcare institutions, Olympus aims to leverage clinical expertise and insights to drive the development of innovative medical solutions that address the evolving needs of patients worldwide.

Dontia Alliance launches first advanced dental implant strategies CoE in Malaysia

Dontia Alliance (DA) has opened its first Advanced Implant Strategies Centre of Excellence or CoE (AIS Centre) in Penang, Malaysia. This launch marks the first step in DA's vision to establish a vast and robust AIS Centre network that will contribute to its growing dental ecosystem in Asia. The launch is in collaboration with SmileBay Dental Sdn. Bhd., a leading dental group in Penang with eight clinics across Malaysia. DA has announced that SmileBay Signature Advanced Implant Centre as the first AIS Centre. SmileBay AIC, equipped with a laboratory and training facility in addition to its clinical practice, is SmileBay's largest full-service implant centre. In the next two years, four more AIS Centres will be launched in Singapore, Hong Kong (SAR), Vietnam and the Philippines.

EnGeneIC, Singapore Institute of Advanced Medicine forge partnership to revolutionise cancer treatment in Asia

EnGeneIC, an Australia-based clinical-stage biopharmaceutical company pioneering the development of a First-in-Class targeted nanocell for cancer therapy, has announced strategic partnerships with Singapore Institute of Advanced Medicine Holdings (SAM) and Singapore Medical Incorporation (SMI). The partnerships will bring significant new funding to allow EnGeneIC to immediately progress its clinical trial programmes in Australia and the US. Further, the agreements aim to accelerate the clinical development, manufacture and commercialisation of EnGeneIC's proprietary technology, EnGeneIC Dream Vector (EDV) for cancer treatment across Asia. The commercial deal will provide exclusive rights to SAM for sales of EDV therapeutics in Asia and net profits will be shared between the two companies with EnGeneIC receiving a majority. In addition, EnGeneIC and SAM will collaborate on the development of EDV-based theranostics. Theranostics combine therapeutic and diagnostic capabilities to improve cancer treatment outcomes. By integrating imaging and treatment into a single platform, EDV-based theranostics have the potential to provide precise, personalised care, enabling early detection and targeted therapy.



Canon eyes strengthening industrial and medical business in India

Highlighting India's crucial role in its global growth strategy, Japanese company Canon has announced its outlined plans for strengthening its core business segments of imaging, printing, and surveillance, along with growing presence in the Semiconductor, Flat Panel Display business and the medical industry. With respect to healthcare, Canon has a comprehensive portfolio of advanced medical products and solutions from diagnostic imaging systems and healthcare IT solutions. With India as a key market, Canon further focuses on bolstering the rapidly growing medical business. The brand has established a strong footprint in the digital imaging industry, as an end-to-end solutions provider, having diversified into new markets, broadening its product range and asserting its leadership across customer segments. Canon Medical Systems India is a subsidiary of Canon Medical Systems Corporation in Japan. Canon Medical Systems has a comprehensive portfolio of advanced medical imaging from diagnostic and interventional imaging systems to healthcare IT solutions for the wider healthcare enterprise.

Novartis partners with Abu Dhabi to advance genomics research in oncology

The Department of Health – Abu Dhabi (DoH), the regulator of the healthcare sector in the Emirate, has signed a Memorandum of Understanding (MoU) with Novartis Middle East FZE, a global pharmaceutical company. Under the terms of the MoU, the entities will work together to advance solutions in multiple therapeutic areas. The two priority focus areas include advancing clinical genomics research for real-world evidence (RWE) and generating and disseminating evidence to support the understanding of radioligand therapy (RLT) for cancer patients. This collaboration will utilise Abu Dhabi's genomics expertise as well as its future-forward, agile regulatory framework research hub to collaborate on future clinical research and the generation of RWE. This will include the exploration of innovative solutions and genomics research in oncology, cardiovascular disease, and neuroscience.

Novotech joins hands with Hong Kong-Shenzhen Innovation and Technology Park

Novotech, Australia-headquartered clinical Contract Research Organization (CRO) that partners with biotech companies to accelerate the development of advanced and novel therapeutics at every phase, has signed a Memorandum of Understanding (MoU) with Hong Kong-Shenzhen Innovation and Technology Park Limited (HSITPL). The MoU aims to enhance clinical development assistance for biotech companies and other community companies within the new approximately 87-hectare Hong Kong-Shenzhen Innovation and Technology Park. Novotech was among 14 international companies invited out of some 60 partners from nine economies to collaborate with HSITPL. As part of the collaboration, Novotech intends to provide consultation services to the Park's community companies and leverage its expertise to expedite clinical trials development for biotech companies at the Park.

FootSecure in India forays into prescription footwear manufacturing

FootSecure, a healthcare startup specialising in podiatric medicine and wound care, has recently launched its state-of-the-art custom footwear manufacturing unit in Bengaluru, India, with the support of the Karnataka Institute of Endocrinology & Research. Set up with an initial investment of Rs 30 lakh, FootSecure's prescription footwear manufacturing facility offers carefully designed footwear based on the pathology and biomechanics of the foot, ensuring stability, injury prevention and comfort. Currently, FootSecure offers six models, with four options for women and two for men, starting from Rs 2000 onwards. The advanced customisations offered are also comprehensive and include the outer sole, midsole, insole, and uppers, most of which are particularly beneficial for patients with aches and pain in the foot, diabetes, arthritis, congenital foot disorders, post-accident foot deformities and post-surgical foot anomalies. The manufacturing facility has the capacity to produce up to 300 pairs of custom offloading footwear per day. By 2025, the company aims to establish India's first dedicated podiatry hospital and launch a brand of specialised therapeutic footwear designed by medical experts from India and Australia.

5i Ventures acquires major stake in Hello Health Group

Hello Health Group (HHG), the leading digital health and wellness platform in Asia, has announced the successful closing of the Singapore-based 5i Ventures (5iV) acquisition of a major stake in HHG. Following the transaction, 5iV will be the new leading investor and is dedicated to supporting the next phase of Singapore-based startup HHG's outstanding growth. This strategic investment marks a significant milestone in HHG's journey to further expand its position as the foremost digital health and wellness ecosystem across Asia. With this new partnership, HHG is poised to enhance its digital health and wellness solutions, further empowering millions of people across Asia to make better-informed decisions, and enabling them to live healthier and happier lives. The acquisition by 5iV was supported by Aument Capital Partners, the Singapore-based multi-family office for exceptional entrepreneurs.

Noul participates in malaria project initiated by US CDC

On-device AI healthcare startup in South Korea, Noul has announced that it will jointly participate in a malaria diagnosis project initiated by US Centers for Disease Control and Prevention (CDC) with the Kenya Medical Research Institute (KEMRI). The project will involve 2,000 patients who are tested for malaria at four health facilities located in malaria endemic areas of Kisumu and Siaya in western Kenya. The work will be conducted from July to December 2024. The project will compare and evaluate Noul's digital microscopy-based malaria diagnostic solution with rapid diagnostic tests and local microscopy to field-validate the effectiveness of Noul's product as a malaria diagnostic solution. Through the project with the US CDC and KEMRI, Noul plans to establish its product miLab MAL as the best-performing product to solve the global malaria diagnostic problem and prepare a bridgehead for entering the US market based on secured references.

Ryght partners with University of Adelaide for AI & biotech research

Ryght, a leading enterprise generative AI (GenAI) technology company improving clinical research in the US, has announced a new strategic partnership with the University of Adelaide, South Australia. This collaboration will provide the University of Adelaide with the Ryght AI platform to enable and accelerate the adoption of artificial intelligence (AI) use cases across grant and industry-funded local, state, and federal government initiatives - all from an Adelaide hub. The partnership will help establish South Australia as a leader in the Australian AI and biotech industries. It will foster collaborative research, development, and commercialisation initiatives between the two parties, while providing Ryght with highly qualified AI research experts who are uniquely embedded in the clinical and biomedicine fields to give it an advantage in the competitive global need for AI talent. The partnership with Ryght will provide a locally managed, sovereign, secure, and industry-tuned AI software platform to accelerate groundbreaking AI, research, and innovation.

GRIT and Quangang forge partnership to accelerate localisation of Interleukin-2

China-based startup Shanghai Grit Biotechnology Co. and Shandong Quangang Pharmaceutical Co. have announced the establishment of a formal strategic partnership to leverage both parties' R&D capabilities in innovative T-cell therapy. The objective is to jointly develop a globally standardised Interleukin-2 (IL-2) for solid tumour patients receiving T-cell therapy, aiming to localise the global standard IL-2 with accessible prices for Chinese patients. The focus of the collaboration will be on expanding the indications of Quanqi (125SER) Interleukin-2 (I) products for solid tumours. Quanqi (125SER), as a domestically marketed human Interleukin-2, is primarily used in the treatment of solid tumours such as renal cell carcinoma, melanoma, breast cancer, bladder cancer, liver cancer, colorectal cancer, lymphoma, and lung cancer, etc. Both parties will collaborate to develop a domestically produced substitute to the globally recognised immune-regulating cytokine IL-2 in T-cell therapy, addressing the significant unmet medical needs for Chinese cancer patients.

Mirxes partners with Thermo Fisher & National University Hospital in Singapore

To increase patient access to affordable, advanced genomic testing for cancer in Singapore, Thermo Fisher Scientific Inc., the National University Hospital, Singapore (NUH), and Mirxes, a Singapore-headquartered RNA technology startup, have signed a Memorandum of Understanding (MoU) agreement. The agreement formalises the commitment to collaborate, develop and clinically validate advanced, next-generation sequencing (NGS) genomic testing solutions and cancer research tailored specifically to address the needs of the Southeast Asian population. Over the last 10 years, Mirxes has partnered NUH and other local research and clinical institutions to develop and commercialise novel RNA based cancer early detection solutions, such as GASTROClear, on Thermo Fisher's PCR platforms.

WHO and Italian National Institute of Health sign MoU to improve care for healthy ageing

The World Health Organization (WHO) and the Dementia Observatory (Osservatorio Demenze) have signed a three-year Memorandum of Understanding (MoU) to formalise a close collaboration and exchange aimed at improving care for healthy ageing. The Dementia Observatory is part of the National Center for Disease Prevention and Health Promotion (Centro Nazionale per la Prevenzione delle Malattie e la Promozione della Salute) of the Italian National Institute of Health (Istituto Superiore della Sanità). The Dementia Observatory located in Rome, Italy coordinates and supports the national and international public health response to dementia and corresponding efforts for prevention and health promotion through an integrated, evidence-based approach and life-course perspective.

The MoU outlines three specific areas of collaboration- development of long-term care standards to enhance the design and organisation of the continuum of care for older persons, with a particular focus on those living with cognitive disturbances; exploration and summarisation of available scientific literature on emerging issues related to healthy ageing to prioritise and guide interventions; and development of materials to address sociocultural diversities in the care approach to older persons.

WHO releases report on state of development of antibacterials

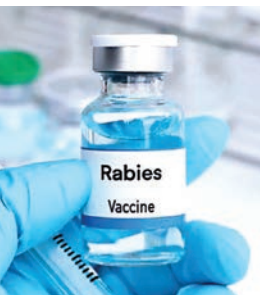
The World Health Organization (WHO) has released its latest report on antibacterial agents, including antibiotics, in clinical and preclinical development worldwide. Although the number of antibacterial agents in the clinical pipeline increased from 80 in 2021 to 97 in 2023, there is a pressing need for new, innovative agents for serious infections and to replace those becoming ineffective due to widespread use. First released in 2017, this annual report evaluates whether the current research and development (R&D) pipeline properly addresses infections caused by the drug-resistant bacteria most threatening to human health, as detailed in the 2024 WHO bacterial priority pathogen list (BPPL). Both documents aim to steer antibacterial R&D to better counter the ever-growing threat of antimicrobial resistance (AMR). Not only are there too few antibacterials in the pipeline, given how long is needed for R&D and the likelihood of failure, there is also not enough innovation. Of the 32 antibiotics under development to address BPPL infections, only 12 can be considered innovative.

FIND and WHO sign new MoU to speed up innovation and access to quality diagnostics

FIND and the World Health Organization (WHO) have signed a new Memorandum of Understanding (MoU) that lays the foundation for accelerating innovation and achieving equitable access to quality diagnostics for people globally. One year on from the historic resolution to strengthen diagnostics, and with FIND as co-lead of the Access to COVID-19 Tools (ACT) Accelerator diagnostics pillar, this new agreement marks a step change in a strengthened partnership between WHO and FIND to speed up both innovation and access to diagnostics, supporting countries to implement the World Health Assembly (WHA) Resolution on diagnostics. The new agreement establishes FIND as the key strategic partner for diagnostics, working with WHO and others to address a number of priority areas including antimicrobial resistance, infectious diseases like HIV, malaria and tuberculosis, and noncommunicable diseases like hypertension, heart disease, cervical cancer and diabetes.

Gavi to boost access to rabies vaccines in over 50 countries

Gavi, the Vaccine Alliance, in collaboration with partners, has announced support for human rabies vaccines for post exposure prophylaxis (PEP) as part of routine immunisation. Eligible countries are receiving guidance on how to access these vaccines under Gavi's co-financing policy. The first round of applications will be accepted by mid- July 2024. 95 per cent of human rabies deaths occur in Africa and Asia, most often in marginalised communities that lack access to care. This development complements ongoing global efforts of the Zero by 30 campaign, led by United Against Rabies Forum including the Food and Agriculture Organization (FAO), the World Health Organization (WHO), and the World Organisation for Animal Health (WOAH, formerly (OIE), with the goal of eliminating all dog-mediated human rabies deaths by 2030. In more than 150 countries where dog rabies remains a serious public health problem, stocks of human rabies vaccines in public health systems are often extremely limited, especially in marginalised communities.



Bavarian Nordic and CEPI partner to advance Mpox vaccination in Africa

Bavarian Nordic A/S and the Coalition for Epidemic Preparedness Innovations (CEPI) have announced a partnership to advance the development of Bavarian Nordic's mpox vaccine in children in Africa. CEPI has awarded $6.5 million to support a Phase 2 clinical study evaluating the immunogenicity and safety of the MVA-BN non-replicating vaccine in children from 2 years to less than 12 years of age compared to adults aged 18-50 years of age for the prevention of smallpox, mpox and related orthopoxvirus infections. Subject to regulatory approvals, the study plans to enrol a total of approximately 460 healthy individuals in endemic regions without previous mpox infection or poxvirus vaccination, who will receive two doses of the MVA-BN vaccine. Bavarian Nordic will be the sponsor of the trial which will be conducted in one or more African countries with planned initiation later in 2024. The new trial follows the publication of a continental plan by Africa CDC and African Ministries of Health to strengthen mpox preparedness and response efforts, as well as the World Health Organization's (WHO) framework for enhancing prevention and control of mpox.

Oxford University designs computer simulations to guide future vaccine trials

University of Oxford scientists are launching new computer simulations that will model how we can strengthen the world's response to some of the viruses most likely to cause the next pandemic. Their work, known as the 'PREpare using Simulated Trial Optimisation (PRESTO)' research project, will generate important insights for vaccine developers and public health officials on what vaccine clinical trial designs could help stop the spread of an emerging outbreak. With up to $2.4 million funding from Norway-based Coalition for Epidemic Preparedness Innovations (CEPI), researchers at the University of Oxford's Pandemic Sciences Institute will simulate real-life scenarios of deadly disease outbreaks in order to model how possible vaccine clinical trials could run and what outcomes they could produce. The infectious threats that will be tested are Nipah, Chikungunya, Lassa, Rift Valley fever, Ebola and related viruses, Coronaviruses and a new or as-yet-identified 'Disease X'.

Data from existing research will be fed into the computer model alongside evidence from previous outbreaks to create hypothetical scenarios looking at how a selected virus could spread, who it could impact and its potential severity.

Africa CDC, IVI, and KDCA join forces to forge partnerships for vaccine access

The Africa Centres for Disease Control and Prevention (Africa CDC), International Vaccine Institute (IVI), and Korea Disease Control and Prevention Agency (KDCA) have collaborated to foster partnerships with a shared aim of enhancing vaccine access and health security in Africa. With its headquarters in Korea, a new Africa Regional Office based in Rwanda, the Country and Advancing Vaccine End-to-end Capabilities in Africa (AVEC) Project Office in Kenya, and a long history of working closely with and among government agencies, research groups, academic institutions, and commercial entities in Africa, IVI is helping facilitate and build Korean-African health partnerships to advance vaccine access in Africa. On the other hand, the Korea Disease Control and Prevention Agency (KDCA) has formulated the National Pandemic Preparedness and Response Plan to ensure the prompt availability of vital medical countermeasures, including vaccines and therapeutics, within 100 to 200 days to prepare for future pandemics effectively.

PAHO, World Bank, and IDB join forces to strengthen health financing in the Caribbean

Under the umbrella of the Alliance for Primary Health Care (A4PHC), the Pan American Health Organization (PAHO), the World Bank, and the Inter-American Development Bank (IDB) are joining forces to explore avenues for strengthening health financing in the Caribbean. Currently, public health spending in the Caribbean is low (3.6 per cent of GDP) and out-of-pocket expenses are high (nearly 31 per cent of current health spending). This places a significant burden on households and frequently leads to catastrophic health expenditure and impoverishment. The organisations have highlighted the urgent need for data generation, capacity building in health financing, and facilitating the exchange of experiences to advance health financing policies within the framework of universal health and strong primary healthcare based resilient health systems in the Caribbean.

US releases H5N1 influenza research agenda

The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), has released its plan for advancing H5N1 influenza basic research and translating those findings into strategies and interventions that can benefit people. The research agenda focuses on four key objectives: increasing understanding of the biology of H5N1 viruses and the factors that influence their ability to transmit and cause disease; developing and evaluating prevention strategies, such as vaccines; advancing existing and novel treatments, including antivirals and monoclonal antibodies; and supporting strategies for detecting H5N1 virus. Since 2003, H5N1 influenza viruses have circulated in 23 countries, primarily affecting wild birds and poultry resulting in nearly 900 reported human cases, primarily among people who have had close contact with infected birds. In the past few years, however, a highly pathogenic avian influenza virus called HPAI H5N1 has spread to infect more than 50 animal species. The NIAID H5N1 research agenda builds on the institute's long standing influenza research efforts. It addresses the current outbreak in US dairy cows including potential human-to-human transmission of H5N1 influenza viruses. NIAID will leverage both its domestic and international research infrastructures to achieve the plan's objectives.

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Innovation Takes Centre Stage in Paediatric healthcare

Children represent approximately one-third of the world's population, with over 580 million in the East Asia and Pacific region alone (Source: UNICEF). Historically underrepresented in healthcare care delivery and innovation, the landscape is evolving as governments and healthcare organisations in the region strive to address paediatric healthcare needs. Paediatric healthcare spans recommended immunisations before adulthood to developmental health, mental health, neonatal care and rare diseases, among others. Let's deep dive into the innovations enhancing children's well being in the region.

Innovations in paediatric healthcare are rapidly advancing in the Asia Pacific region, driven by new technologies and collaborative efforts to improve children's well-being. From cutting-edge medical devices improving preterm births, to technology addressing mental healthcare and advanced genetic screening, Asia Pacific is leaving no stone unturned in its efforts to enhance paediatric care.

Newborn genetic screening is advancing significantly in the region. Traditionally focused on detecting a limited number of rare diseases with early onset and established treatments, such programmes are now integrating genomic sequencing to enhance early detection and intervention.

A pioneering study by Chinese firm BGI Genomics highlights the potential of gene panels as a primary screening tool, benefitting approximately one out of every 500 newborns. This approach is part of broader efforts across the APAC region, where studies like the Epi-Genomic Newborn Screening (EpiGNs) programme in Victoria, Australia, aim to identify conditions linked to intellectual disability, autism, severe obesity, and seizures through genomic analysis as part of routine heel prick tests.

Another study in Australia, the Baby Beyond project, funded by the government, plans to sequence the genomes of 1,000 newborns to screen for around 500 treatable childhood-onset disorders. This initiative builds upon earlier efforts and underscores the potential of integrating genomic data into electronic health records (EHRs) for ongoing healthcare management and research.

Meanwhile, in Singapore, the BRIDGES team conducted a study involving 196 children enrolled in the Singapore Undiagnosed Diseases Research Endeavour for Kids (SUREKids) study. Through genomic sequencing, they successfully diagnosed 37.8 per cent of children who had previously undergone genetic tests without diagnosis or whose symptoms did not match known genetic disorders. These findings, with diagnostic yields ranging from 25 per cent to 40 per cent, represent the higher end of global standards, highlighting the effectiveness of such programmes.

Professor Patrick Tan, the then Executive Director of the Genome Institute of Singapore said, "Genetics is a useful tool to gain insight into the underlying causes of childhood disorders, and explore possible treatment strategies. The BRIDGES programme illustrates the potential of multi-institutional collaboration working closely to solve problems of medical importance."

In India, where congenital and hereditary genetic diseases pose a significant health burden, the Department of Biotechnology (DBT) has launched the UMMID Initiative. Aimed at prioritising prevention over cure, this initiative targets urban areas where congenital malformations and genetic disorders rank as the third leading cause of newborn mortality. Given India's large population and high birth rate, coupled with prevalent consanguineous marriages, genetic disorders are pervasive. UMMID's

objectives include establishing NIDAN Kendras in government hospitals to offer comprehensive genetic counselling, prenatal testing, diagnosis, and multidisciplinary care, particularly in high-patient influx areas. The initiative also focuses on training clinicians in Human Genetics and implementing screening programmes for pregnant women and newborns in aspirational districts.

Prioritising mental health

There has been a notable increase in efforts to address paediatric mental health. It's encouraging to see both companies and governments taking steps to tackle the crisis, supported by studies showing a rise in children diagnosed with mental health conditions. Singapore is actively partnering with global researchers to uncover the root causes of this trend. Further research is crucial to grasp the growing prevalence of youth mental health issues in Singapore, possibly influenced by factors like extensive social media engagement and the necessity for more opportunities for unstructured play and independence.

In 2020, the Singapore Children's Society identified mental health concerns among children and young persons (CYP) as pivotal challenges to their well-being. In response, it launched the Oasis for Minds Services (OMS). Its objective is to offer a seamless continuum of care from mental health promotion and accessible early intervention to recovery-focused services. This initiative aims to empower beneficiaries to thrive positively and foster a sense of safety and inclusivity within the community. Singapore also unveiled a comprehensive mental health and well-being strategy designed for both children and adults.

COVID-19 has further underscored the need to strengthen mental health and psychosocial support (MHPSS) systems across East Asia and the Pacific, where access to such services has historically been limited. This crisis has disproportionately impacted children, adolescents, and caregivers, exacerbating conditions like depression and anxiety. Responding to these needs, UNICEF has developed a comprehensive approach that integrates MHPSS into various sectors beyond healthcare alone. This initiative aims to support children throughout their lives with a holistic and agile framework. Four countries were engaged in the process, Thailand, Malaysia, Papua New Guinea and the Philippines, and the research resulted in the development of a regional MHPSS framework. The purpose of the regional framework is to define mental health issues that are a high priority for the region and provide

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- David Coleman,
the then Assistant Minister to the Prime Minister for Mental Health and Suicide Prevention, Government of Australia

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"Paediatric health care arena is often overlooked as an opportunity for innovation. By directly collaborating with the world-class children's hospitals in the KidsX network, companies will be able to validate product and market fit in paediatrics more quickly, saving valuable time and resources and bringing much-needed digital health tools to patient families faster than ever before."

- Lara Khouri,
Executive Vice President and Chief Strategy & Transformation Officer, Children's Hospital Los Angeles

Climate change and children's health

The urgency of the climate crisis and its effects on child health are undeniable. According to the latest annual report of the Lancet Countdown on health and climate change, 2023 saw the highest global temperatures in over 100,000 years. Infants younger than 1 year, who are particularly vulnerable to extreme heat, were exposed to 8·4 days of heatwave annually in 2013–22 compared with 4·0 days in 1986–2005. Children are at increased risk of dehydration, malnutrition, life-threatening infections (eg, dengue, malaria, vibriosis), among many other adverse health effects, with lifelong consequences on their physical and mental wellbeing and human capital.

A recent study led by Australian researchers has highlighted the alarming impact of climate change on children's health. The findings reveal increased rates of preterm births, higher incidences of respiratory diseases, hospitalisations, and mortality linked to extreme weather events. Dr Lewis Weeda from The University of Western Australia and the Wal-yan Respiratory Research Centre at Telethon Kids Institute, along with Corey Bradshaw, Professor of Global Ecology at Flinders University, underscored a 60 per cent rise in the risk of preterm births due to exposure to extreme temperatures.

Countries must urgently heed these warnings and commit to climate actions that prioritise public health.

detailed guidance to support implementation, with a focus on describing sectoral roles and recommendations to strengthen a multi-sectoral mental health system. The report also identifies key recommendations to operationalise the framework and highlights the gaps and challenges which need to be addressed, some of which include identified gaps in programmes for marginalised and vulnerable children and adolescents and a limited availability of community based, adolescent friendly multidisciplinary care for mental health conditions.

Meanwhile, Australia has taken significant steps, including a $30 million investment to improve children's mental health and wellbeing, alongside launching the world's first children's mental health and wellbeing strategy. This strategy provides a comprehensive framework to support the mental health of children aged 0-12 and their families, aiming for an integrated system of care and support.

The then Assistant Minister to the Prime Minister for Mental Health and Suicide Prevention, government of Australia David Coleman, said, "Half of all adult mental health challenges emerge before the age of 14, yet few children below the age of 12 receive professional support. We need to acknowledge this and do everything we can to change it," while launching the National Children's Mental Health and Wellbeing Strategy on October 12, 2021.

Startups are actively addressing paediatric mental health challenges. One such initiative is Singaporean tech startup Neeuro, collaborating with the Institute of Mental Health to unveil their home-based attention training programme. Named Cogo, this digital therapeutic aims to tackle inattentiveness in children aged 6-12 years through a 24-session guided game. The programme utilises Neeuro's Brain-Computer Interface technology and is paired with the SenzeBand 2 EEG headband.

Enhancing network of care

Efforts are underway to enhance paediatric care through innovation, research, and strategic investments in infrastructure and training.

In Singapore, KK Women's and Children's Hospital (KKH) and National University Hospital (NUH) have initiated PaedsENGAGE (ENGagement and GP Empowerment), a pioneering programme in collaboration with general practitioners (GPs). This initiative aims to expand the role of GPs in the community by providing specialised training. GPs will gain the necessary skills to manage paediatric medical conditions effectively, including determining if further observation or intervention at Children's Emergency is necessary.

Meanwhile, Australia's CareTrack Kids study represents a significant national effort to assess healthcare standards for children. This comprehensive study focuses on 17 common childhood conditions and evaluates adherence to clinical practice guidelines by GPs and paediatricians. It also investigates adverse events within the healthcare system concerning children, aiming to identify and rectify safety issues. The outcomes of this research are pivotal for improving the efficiency, safety, and effectiveness of paediatric healthcare delivery across Australia.

In Adelaide, Australia, a global expert in artificial intelligence (AI) ethics has been recruited to optimise clinical, operational, and managerial aspects of paediatric healthcare. This strategic move underscores Australia's commitment to leveraging technology to enhance healthcare

outcomes for children.

Furthermore, the Australian government's substantial investment of $38.4 million (A$57.6 million) in the 2024-25 budget is aimed at expanding paediatric health services both in hospitals and within the community. This initiative is set to bolster Australia's healthcare infrastructure and ensure comprehensive care for children.

In South Korea, the government has earmarked $987 million (1.3 trillion won) over five years to enhance paediatric care and reduce hospitalisation costs for children under two. This initiative aims to improve access to healthcare services for children, particularly during off-hours, reinforcing the commitment to comprehensive paediatric healthcare.

China too is taking ambitious steps to strengthen its children's health services. National Health Commission official Li Dachuan announced plans to establish two national and five regional children's medical centres. These centres will support 67 key clinical specialties related to paediatric healthcare, underscoring China's dedication to enhancing medical resources for children nationwide.

Tech to the rescue

Companies are harnessing technology to address diverse paediatric challenges, from enhancing immunisation and assisting with breathing to improving care for preterm babies. Accelerators and grant programmes play pivotal roles in catalysing these innovations. Children's Hospital Los Angeles spearheads a digital health accelerator, linking over 30 hospitals in the U.S., U.K., and Australia with tech firms focused on enhancing paediatric care. This KidsX Accelerator programme, spanning 13 weeks, partners with early-stage digital health companies to validate products for paediatric patients, potentially expediting their adoption into clinical practice.

“Paediatric health care arena is often overlooked as an opportunity for innovation,” says Lara Khouri, Executive Vice President and Chief Strategy and Transformation Officer at Children’s Hospital Los Angeles. “By directly collaborating with the world-class children’s hospitals in the KidsX network, companies will be able to validate product and market fit in paediatrics more quickly, saving valuable time and resources and bringing much-needed digital health tools to patient families faster than ever before.”

Additionally, the UNICEF Venture Fund seeks to invest in open-source frontier technologies that promise radical improvements in children’s health, nutrition, and mental well-being. Offering up to $100,000 in equity-free funding, this initiative targets early-stage technology startups leveraging cutting-edge solutions like AI, machine learning, and blockchain to enhance children's lives.

Some promising startups utilising technology to enhance children’s lives are:

- In Australia, Navi Medical Technologies is developing the Neonav ECG Tip Location System, a breakthrough device designated by the US FDA. This innovation enables real-time monitoring of catheter placement during procedures, enhancing the safety and efficacy of critical care for newborns and paediatric patients. Another notable Australian startup, ResusRight, has secured significant funding to develop a medical device for safely resuscitating babies who struggle to breathe after birth. Founded by biomedical engineering students and clinicians from Westmead Hospital, ResusRight aims to reduce neonatal mortality rates and prevent disabilities caused by birth complications. Their Juno Training Monitor provides real-time feedback to clinicians during neonatal resuscitation, improving training outcomes and patient care
- South Korea and the USA startup Neofect has introduced the RAPAEL platform, a gamified rehabilitation solution for children with neurological and musculoskeletal disorders like cerebral palsy and stroke. FDA-cleared and CE-marked, RAPAEL utilises wearable devices to monitor and guide therapeutic exercises, enhancing treatment outcomes and enabling remote patient monitoring
- Meanwhile, started in Singapore and now headquartered in the USA, Child Health Imprints (CHIL) utilises IoT and AI to predict diseases in neonatal intensive care units (NICU), addressing challenges such as premature births and medical errors. Their innovative approach aims to integrate data from multiple devices and improve clinical outcomes in NICUs globally.

Moreover, in the Philippines, the Real-Time Vaccination Monitoring and Analysis (RT-VaMA) tool leverages digital technology to track vaccine coverage daily. This initiative ensures equitable vaccine distribution, particularly to remote areas, thereby enhancing immunisation campaigns and reducing health disparities.

They say it takes a village to raise a child. In healthcare, this village provides crucial components: access to the best available treatments, advancements in technology that enhance care, and improvements in diagnostic capabilities. BS

Ayesha Siddiqui

Eliminating Silent Killer Through Swift Actions

Hepatitis continues to wreak havoc globally, with the latest World Health Organization (WHO) report sounding alarms on viral hepatitis infections claiming 3,500 lives each day. The WHO estimates from 2022 reveal that 254 million people live with hepatitis B and 50 million with hepatitis C. The Asia Pacific (APAC) region is at the epicentre of this crisis, hosting the top 7 high-burden countries. Let's discuss the progress of the region towards achieving the 2030 targets for hepatitis elimination and identify what actions are needed to achieve these goals.

According to the WHO 2024 Global Hepatitis Report, viral hepatitis is on the rise and remains the second leading infectious cause of death globally, claiming 1.3 million lives annually, equivalent to tuberculosis. Ten countries account for nearly two-thirds of the global burden of viral hepatitis B and C: China, India, Indonesia, Nigeria, Pakistan, Ethiopia, Bangladesh, Vietnam, The Philippines and the Russian Federation.

The APAC region is disproportionately affected, with 70 per cent of viral hepatitis deaths occurring here. Failure to act swiftly could lead to substantial economic losses, with projected costs of $558 billion for hepatitis B and $62 billion for hepatitis C due to illness and premature mortality, according to the Coalition for Global Hepatitis Elimination report.

WHO has set a goal to eliminate viral hepatitis by 2030, aiming for a 90 per cent reduction in incidence and a 65 per cent reduction in mortality from hepatitis B and C.

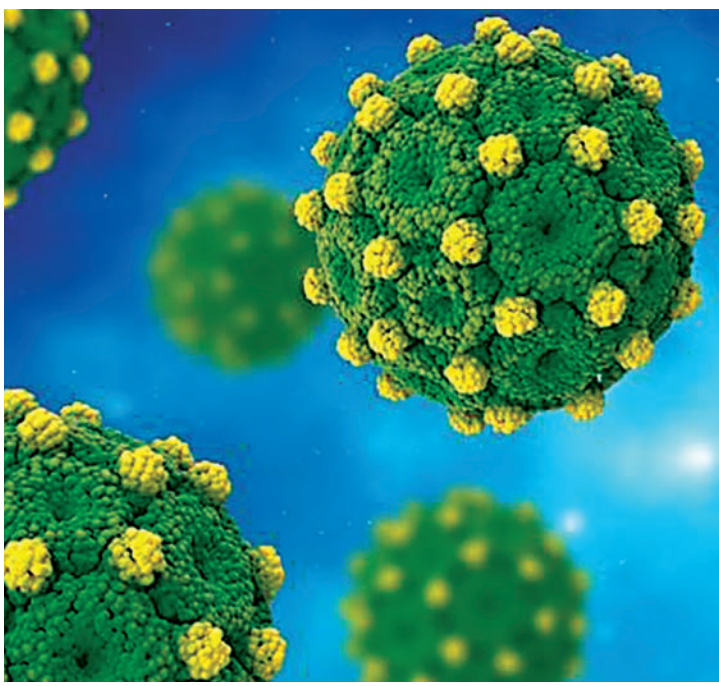
Progress so far

Most of the countries in the region have a national hepatitis elimination programme but progress remains somewhat unsatisfactory.

"Viral hepatitis has a devastating impact on South-East Asia and the Western Pacific regions, where an estimated 158 million people live with chronic hepatitis B and 16 million with chronic hepatitis C. Access to treatment for hepatitis B and C remains a challenge in many Asian countries due to cost and healthcare infrastructure limitations. Furthermore, vertical transmission (from mother to child) of hepatitis B is a major concern in the region. Such a heavy prevalence has a profound disruptive effect on society in the region. On top of causing a tragic loss of life, viral hepatitis poses a huge societal and financial burden and drives inequality," said Benedetta Nirta, Deputy Director and Fundraising Manager at The Hepatitis Fund, Geneva.

However, several countries have shown active and systemic efforts to reach hepatitis elimination. Australia is spearheading regional efforts by focusing its national hepatitis strategy on raising awareness, enhancing access to testing and treatment, and integrating hepatitis B responses into harm reduction programmes.

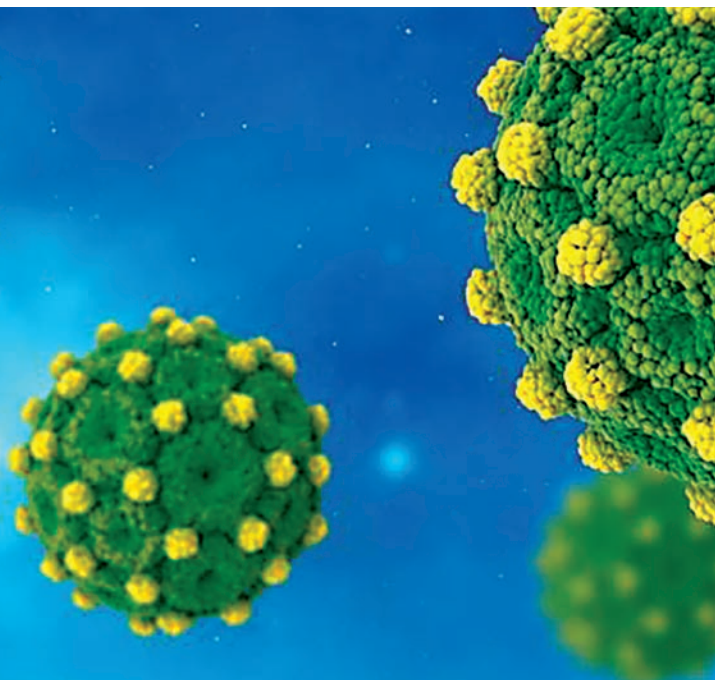
"Hepatitis C cure implementation access is variable throughout the region, with the Australian government providing access DAAs (direct-acting antivirals) to all people with hepatitis C, and which is being supported by the Eliminate hepatitis C Australia Partnership (EC Australia) is a four-year partnership project formed in 2018 to bring together



researchers, implementation scientists, government, health services and community organisations to ensure the whole of Australia sustains high numbers of people accessing hepatitis C treatment to meet our elimination goals," said Dr Jack Wallace, Senior Research Office, Viral Hepatitis Elimination Group, Adjunct Lecturer, Center for Social Research in Health, UNSW, Burnet Institute. His research focus for the past 15 years has been on investigating the lived experience of people with hepatitis B and established Hepatitis Australia.

China has launched the Hepatitis C Elimination Action by 2030 as part of its 'Healthy China 2030' plan. The National Action Plan (2021–2030) targets health education, prevention, testing, treatment, and capacity building with 15 specific goals. Strategies include strengthening health education, enhancing prevention efforts, expanding treatment access, improving testing capabilities, and implementing supportive insurance policies. China has also updated HBV treatment guidelines and adopted a triple elimination strategy for mother-to-child transmission of HIV, syphilis, and HBV.

India launched the National Viral Hepatitis Control Program (NVHCP) in 2018 to eliminate Hepatitis C by 2030 and reduce morbidity and mortality from Hepatitis A, B, C, and E. The program provides free diagnostics and treatment for hepatitis B and C. It focuses on screening pregnant women for hepatitis B in areas with less than 80 per cent institutional delivery rates, ensuring access to birth dose hepatitis B vaccination and hepatitis B immunoglobulin as needed. Additionally, Indian Immunologicals Ltd, introduced India's first indigenous Hepatitis A vaccine, Havisure, in January this year crucial for preventing this highly contagious infection transmitted through contaminated food or water.



Newer treatments in development

There is currently no cure for hepatitis B, but efforts are underway to develop treatments. As of October 2023, there are 40 candidates in clinical development for hepatitis B treatments.

Promising candidates include Bepirovirsen developed by Ionis Pharmaceuticals and GSK, entering phase 3 clinical trials and the other one is Barinthus Biotherapeutics' VTP-300, which has shown positive data, in early trials. In the Asia-Pacific region, Brii Biosciences has entered agreements with VBI Vaccines, Inc. to expand and secure future clinical and commercial supplies of BRII-179, a late-stage asset in its hepatitis B functional cure portfolio.

Source: Hepatitis B Foundation

The government of Vietnam has shown commitment to forming a robust national response to bring down new infections and explore new ways to increase case detection, treatment, and cure to eliminate viral hepatitis by 2030. In Vietnam, an ongoing project co-funded by The Hepatitis Fund and the City of Geneva (Switzerland), has played a crucial role in advancing hepatitis elimination efforts. The project, implemented by PATH and Nghe An CDC, focuses on the triple elimination of vertical transmission—from mother to child—of HIV, hepatitis and syphilis in Nghe An province, Vietnam. The preliminary results in the second year of the project implementation are incredibly promising and have led to the approval of a provincial action plan for triple elimination. HepLINK, another project in Vietnam, fully funded by The Hepatitis Fund and implemented by PATH, engaged populations at risk of viral hepatitis in prevention, awareness raising, case detection and treatment, improved viral hepatitis outcomes and provided evidence for scaling and financing interventions that are integral to the elimination of hepatitis C and B. The Vietnam Viral Hepatitis Alliance (V-VHA) launched the HEAT program in Vietnam with the Coalition for Global Hepatitis Elimination and CDC's Division of Viral Hepatitis Laboratory. They're assessing hepatitis D epidemiology in Ho Chi Minh City and expanding hepatitis B and C testing and treatment nationwide. The initiative aims to scale up testing, implement

"Viral hepatitis has a devastating impact on South-East Asia and the Western Pacific regions, where an estimated 158 million people live with chronic hepatitis B and 16 million with chronic hepatitis C. Access to treatment for hepatitis B and C remains a challenge in many Asian countries due to cost and healthcare infrastructure limitations. Furthermore, vertical transmission (from mother to child) of hepatitis B is a major concern in the region."

- Benedetta Nirta,
Deputy Director and Fundraising Manager at The Hepatitis Fund, Geneva

"The critical step in addressing hepatitis elimination is to establish and strengthen care networks so that health systems can reach and support patients in need. We need a coordinated effort to elevate disease awareness, make testing easily accessible, and immediately link those diagnosed to care while at the same time simplifying treatment."

- Dustin Haines,
Vice President and General Manager Asia, Middle East, and Turkey, Gilead, Hong Kong

"Hepatitis B is highly stigmatised, and in many countries, people with hepatitis B face discrimination. So, to scale-up screening in a way that respects human rights and can be effective, we need governments to protect people who have hepatitis B from discrimination – and we need to improve awareness and normalise discussion around hepatitis B to remove stigma."

- Chari A. Cohen,
President, Hepatitis B Foundation, United States

effective care models, and foster a sustainable public-private partnership to eliminate viral hepatitis in Vietnam by 2030.

Benedetta highlights efforts made by other Asian countries, "Taiwan has made significant strides in tackling hepatitis C and is on track to achieve elimination by 2025. Other countries, like Indonesia and the Philippines, have seen stronger engagement and interest from policymakers in the last couple of years. Indonesia is providing free testing and treatment, while the Philippines is enhancing public education, improving screening protocols, and offering free clinical treatment. Thailand is also making similar efforts."

Ending the silent killer

We have the tools such as efficacious treatments and diagnostics tests to the medical to combat viral hepatitis. Despite this, the elimination of the disease remains an elusive goal. To achieve the WHO public health goal of eliminating viral hepatitis by 2030, we need robust public health policies, increased awareness and access to care.

"The critical next step to addressing hepatitis elimination is to establish and strengthen care networks so health systems can reach and support patients in need. To do so requires eliminating barriers to education, testing, and treatment – we need a coordinated effort to elevate disease awareness, make testing easily accessible, and immediately link those diagnosed to care while at the same time simplifying treatment," said Dustin Haines, Vice President and General Manager Asia, Middle East, and Turkey, Gilead, Hong Kong.

In 2021, Gilead Sciences launched the biennial ALL4LIVER Grant to empower local communities in the fight against viral hepatitis. In 2023, 71 organisations received the Grant, including two non-profit organisations based in India: Chennai Liver Foundation and FIND.

Vertical transmission (from mother to child) of hepatitis B is a major concern in the region. It is crucial to increase coverage of hepatitis B vaccination, particularly at birth, to prevent mother-to-child transmission.

"For prevention, all babies born are recommended to receive the birth dose of hepatitis B vaccine and complete the vaccine series – and 80 per cent of babies complete this recommendation in Western Pacific. To eliminate hepatitis B, this needs to be improved. Additionally, it is recommended that all pregnant women are screened and provided treatment if needed during pregnancy to prevent mother-to-child transmission," said Chari A. Cohen,

President, Hepatitis B Foundation, the United States.

One of the major roadblocks is that the majority of people with hepatitis are unaware of their condition. Only one in eight persons with hepatitis B is diagnosed, and only one in 30 receive treatment to suppress their infections. Similarly, only one in five persons with hepatitis C is diagnosed, with one in ten receiving treatment to cure their infections, says the Coalition for Global Hepatitis Elimination.

"In terms of diagnosis, only one-quarter of people in the Western Pacific are diagnosed. We need large-scale efforts and funding to screen people so that everyone with hepatitis B has the opportunity for care and treatment to prevent liver cancer. However, there is a lack of funding for screening in many areas. Additionally, hepatitis B is highly stigmatised, and in many countries, people with hepatitis B face discrimination. So, to scale-up screening in a way that respects human rights and can be effective, we need governments to protect people who have hepatitis B from discrimination – and we need to improve awareness and normalise discussion around hepatitis B to remove stigma," said Chari.

Dr Wallace adds, " Many people within the region are tested for hepatitis B through non-health services such as workplaces, educational settings and when seeking work visas. This testing implies that the social impact of a hepatitis B diagnosis essentially affects people's social and familial lives and their willingness to access health services for their hepatitis B infection. Within many countries in this region, a hepatitis B diagnosis has significant social implications with stigma, discrimination affecting employment and education."

Efforts are underway to enhance education and awareness regarding hepatitis B, combat stigma and discrimination, and increase funding and prioritisation through grassroots advocacy. These initiatives are mainly spearheaded by small nonprofit organisations, community-based groups, academic researchers, and other partners. Comprehensive public education campaigns are essential to raise awareness about hepatitis prevention, transmission, and available treatment options.

"Community engagement and multisectoral partnerships are critical components of hepatitis eradication efforts. The APAC Liver Disease Alliance, of which The Hepatitis Fund is a member, plays a crucial role by providing a neutral platform for policy discussions and advocacy campaigns. This platform allows various stakeholders, including governments, non-governmental organisations (NGOs), academia, and healthcare organisations, to collaborate and maximise the impact of their work, ultimately implementing effective strategies to eliminate hepatitis and other liver diseases," said Benedetta.

> "Hepatitis C cure implementation access is variable throughout the region, with the Australian government providing access DAAs (direct-acting antivirals) to all people with hepatitis C, and which is being supported by the Eliminate Hepatitis C Australia Partnership to ensure the whole of Australia sustains high numbers of people accessing hepatitis C treatment to meet our elimination goals."
>
> **- Dr Jack Wallace,**
> Senior Research Office, Viral Hepatitis Elimination Group, Adjunct Lecturer, Center for Social Research in Health, UNSW, Burnet Institute, Australia

Despite the availability of affordable generic viral hepatitis medicines, many countries struggle to procure them at reduced prices. There is a critical need to expand access to affordable and effective diagnostic and treatment options, especially in rural and underserved areas.

"In terms of treatment, hepatitis B is treated with very effective antiviral therapy that suppresses the virus and can prevent liver damage and liver cancer in most people. There are many treatment access barriers, including cost. Many people cannot afford or access treatment, which is recommended for years – if not lifelong at this point. Treatment access needs to be improved. Finally, there is no cure yet for hepatitis B. While we have effective vaccines to prevent infection, and effective treatment to help people stay healthy if they have hepatitis B, we are still seeing new infections, and much illness and death. People with hepatitis B need better treatment options, and ideally, a cure or functional cure for hepatitis B – this would look like a finite course of treatment that would significantly reduce the risk of liver cancer even after treatment ends and would eliminate the risk of viral transmission," added Chari.

We possess powerful tools for preventing, diagnosing, and treating hepatitis; the challenge lies in implementing them at scale. Many barriers can be overcome with improved policies, targeted interventions, and concerted efforts from all stakeholders. Achieving the elimination goal by 2030 remains feasible if swift actions are taken now. BS

Ayesha Siddiqui

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Pharma's Obsession With Obesity On Rise

Obesity is a rapidly growing global health issue. According to the World Obesity Federation, approximately one billion people worldwide will be affected by obesity by 2030. Obesity has become big pharma's latest obsession, with significant interest and investment in this space. Both big pharma and small startups are jumping into the race, investing billions in combating obesity. Let's delve deeper into what's driving the appetite for obesity drugs.

Novo Nordisk gained approval for semaglutide, branded as Wegovy, for chronic weight management in 2021. Eli Lilly followed in 2023 with tirzepatide, marketed as Zepbound. These drugs were an instant hit, to the extent that the companies struggled to keep up with the demand. The blazing success of weight loss drugs like Wegovy and Zepbound has fueled intense interest in new obesity treatments. There are a total of 124 drugs in development for obesity: 61 in phase 1, 47 in phase 2, 7 in phase 3, and 8 already on the market, according to IQVIA.

While Eli Lilly and Novo Nordisk lead the market, other major players such as Amgen, Roche, AstraZeneca, and Boehringer Ingelheim have also joined the fray. Zealand Pharma and Boehringer Ingelheim have collaborated on survodutide, a drug targeting GLP-1 and glucagon, showing promising early results. It is currently undergoing phase 3 studies. Amgen's leading obesity candidate, AMG 133, has demonstrated promising results in early trials. The firm is now planning phase 3 trials.

Swiss pharmaceutical giant Roche made its foray into the weight loss sector by acquiring the American biotech Carmot for $2.7 billion. This acquisition added three clinical-stage obesity programmes to Roche's portfolio, including CT-388, an injectable GLP-1, and CT-996, an oral GLP-1.

Pfizer, despite shelving its late-stage candidate due to significant side effects, remains optimistic about advancing next-generation obesity drugs.

Obesity is described as a trillion-dollar healthcare issue, and a $100 billion dollar market opportunity for pharma companies, making it a lucrative revenue stream for big pharma, which is forever in search of blockbuster drugs.

"The size of the opportunity in terms of total addressable market is unprecedented. Obesity and type 2 diabetes is a rapidly increasing problem. It has been estimated that half of the world's population will be overweight or obese by 2035, including 70 per cent of adults in the US. In addition, the number of obesity-related comorbidities that these drugs treat is staggering. From sleep apnea, fatty liver disease, diabetes, cardiovascular disease, musculo-skeletal disorders associated with weight, etc. These chronic conditions place a huge financial burden on the healthcare system, & these drugs have proven to be extremely effective in addressing these problems. The drugs are also turning out to be used on a long-term basis, so it is not curative but requires ongoing therapy which is recurring revenue for pharma companies," said Patrick Smith, President, Certara Drug Development Solutions, at Certara. Certara revolutionises drug discovery & development with biosimulation software & services, serving over 2,400 clients.

It is worth noting that most current treatments for obesity, such as GLP-1 receptor agonists like semaglutide, were initially designed for type 2 diabetes. GLP-1 agonists, including dual and triple-agonists, are anticipated to remain the predominant mechanisms of action in obesity treatment. Nevertheless, researchers are also exploring alternative approaches for combating obesity.

"There is a wealth of obesity treatments currently in clinical trials, which indicate potential directions that pharmaceutical intervention may take in the future. Several new GLP-1 receptor agonists are under investigation, individually as well as in combination with other mechanisms, such as GIP and glucagon agonists. Developing small molecule, orally effective agents in the GLP-1 receptor agonist class is a particularly compelling avenue, as these may alleviate the need for injection. Amylin, which signals satiety and slows gastric emptying, is another hormone of interest, for which researchers are exploring the potential of analogues and receptor agonists. There is also interest in the use of tocotrienols to increase expression of adiponectin

and, as a result, aid in addressing insulin resistance. While these are only a sample of anti-obesity medications in development, the overall trend is in promoting appetite reduction and satiety," said Simon Bruce, Vice President of Internal Medicine and Drug Development Solutions, ICON, a leading CRO.

The trend is gaining momentum, especially since previous weight loss drugs had limited success.

"Historically, methods of treating obesity have been limited. Lifestyle modification – such as diet, exercise and behavioural therapy – rarely takes into account significant risk factors, including genetics, environment and other elements outside a patient's control. And lifestyle modification, alone, has been found to be insufficient in achieving lasting weight loss. Case in point: Patients who lose weight through lifestyle changes typically regain 80 per cent of weight lost within five years. Pharmacological intervention is an important option for obesity treatment. Recent developments, including the approval of GLP-1 receptor agonists, such as semaglutide, to treat obesity have sparked excitement in the field," said Jack L Martin, Senior Director, Cardiovascular Therapeutics, Drug Development Solutions, ICON.

Improved efficacy

Before the early 2010s, physicians had limited options for prescribing obesity treatments, with phentermine being one of the oldest approved in 1959. Research in the early 2000s led to the approval of three more treatments: Qsymia, Belviq, and Contrave in 2012 and 2014. While these drugs showed greater weight loss compared to placebos in trials, their effects were considered modest, leading to limited adoption. Qsymia faced safety concerns such as foetal toxicity and heart issues, while Belviq was withdrawn in 2020 due to potential cancer risks. Not only that, earlier approved drugs resulted in 2-10 per cent weight loss, but newer drugs like Wegovy and Zepbound have demonstrated substantial results, achieving up to 20 per cent weight loss.

"Obesity is a complex disease that requires long-term management. However traditional approaches to obesity are failing – 2 out of 3 people are unable to maintain weight loss. But a new generation of drugs - GLP-1RAs (Glucagen-Like Peptide 1 receptor agonists) - are giving doctors and their patients a new and clinically beneficial way to tackle obesity, achieve immediate health benefits and mitigate an obesity crisis," said a spokesperson from Novo Nordisk.

Developments in APAC region

Several companies in the APAC region have also joined the bandwagon to develop obesity drugs.

"Obesity and Type II diabetes is a rapidly increasing problem. It has been estimated that half of the world's population will be overweight or obese by 2035, including 70 per cent of adults in the US. In addition, the number of obesity-related comorbidities that these drugs treat is staggering. These drugs have proven to be extremely effective in addressing these problems."

- Patrick Smith,
President, Certara Drug Development Solutions, US

"Several new GLP-1 receptor agonists are under investigation, individually as well as in combination with other mechanisms, such as GIP and glucagon agonists. Amylin is another hormone of interest, for which researchers are exploring the potential of analogues and receptor agonists. There is also interest in the use of tocotrienols to increase expression of adiponectin and, as a result, aid in addressing insulin resistance."

- Simon Bruce,
Vice President of Internal Medicine and Drug Development Solutions, ICON, United States

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- Jack L Martin,
Senior Director, Cardiovascular Therapeutics, Drug Development Solutions, ICON, United States

Approved drugs for weight loss

No	Company	Drug	Approved In
1	VIVUS	Topiramate	2022
2	Roche, GSK	Orlistat	1999
3	Rhythm Pharmaceuticals	Imcivree (Setmelanotide)	2020
4	Novo Nordisk, University of Pennsylvania	Liraglutide	2010
5	Novo Nordisk	Semaglutide	2021
6	Hanmi Pharmaceutical	Phentermine	-
7	Eli Lilly	Zepbound (Tirzepatide)	2023
8	Currax Pharmaceuticals {Nalpropion Pharmaceuticals {Orexigen Therapeutics}}	Bupropion + Naltrexone	2014

Source: IQVIA

Japan's Shionogi is advancing S-309309, an anti-obesity drug now in Phase 2 after completing Phase 1 trials. Chinese firms are also at the forefront. China-based Innovent has a licensing agreement with Eli Lilly for the development and commercialisation of mazdutide 9 mg in China. Another Chinese firm, Sciwind Biosciences Co., Ltd., is developing obesity treatments, including injectable ecnoglutide (XW003) in Phase 3 for T2DM patients, and oral ecnoglutide (XW004) is in Phase 1. Some candidates under development in China are drawing interest from pharma giants. AstraZeneca announced its entry into weight loss last year by licensing a candidate from Chinese company Eccogene, currently undergoing early-stage clinical testing. The deal is valued at $1.825 billion.

South Korean firms too are leading in obesity drug development. Hanmi Pharmaceutical, among the pioneers, is advancing clinical trials for its homegrown anti-obesity drugs. Expected to launch by late 2026 or early 2027, Hanmi's first drug, HM11260C (efpeglenatide), has been in Phase 3 trials since January last year. The company has also received FDA approval for a Phase 1 trial of HM15275, a novel long-acting triple agonist targeting GLP-1, GIP, and glucagon receptors. Additionally, HK inno.N is competing with Hanmi Pharmaceutical to introduce South Korea's first anti-obesity drug, partnering with Chinese company Sciwind Biosciences in a Phase 3 trial in China. Other Korean companies in early stages of obesity drug development include Daewoong Pharmaceutical, Dong-A ST., and Yuhan.

Elsewhere in the region, Indian firm Sun Pharmaceuticals is developing GL0034, an experimental NCE for treating type 2 diabetes & obesity. Meanwhile, Taiwan's Caliway is currently conducting phase 3 trials for CBL-514, a small-molecule injectable aimed at reducing subcutaneous fat. Indian and Chinese pharmaceutical companies are also racing to develop biosimilars, aiming to offer more affordable alternatives to these expensive drugs which can cost over $1,000 per month. No weight-loss biosimilars have been approved in India so far, but Glenmark Pharmaceuticals launched Liferaft, a liraglutide biosimilar for treating type 2 diabetes for Rs 100 per day (approximately $1.20), 70 per cent less than existing therapies. Meanwhile, Biocon has developed a liraglutide biosimilar approved by the UK drug regulator for type 2 diabetes, though it is not yet available in the market.

China's drug administration has approved two GLP-1 drugs produced by Chinese companies. The first is a liraglutide biosimilar marketed as Liluping, made by Huadong Medicine in Hangzhou. The second is beinaglutide, marketed as Feisumei by Benemae Pharmaceutical Corporation in Shanghai.

These drugs are crucial in addressing the escalating obesity crisis, with current statistics showing that 1 in 7 adults worldwide live with obesity, a number that continues to rise among children and young people. Obesity is associated with heightened risks of diseases like type 2 diabetes, heart disease, and certain cancers. Without effective intervention, the economic costs of overweight and obesity are projected to surpass $4 trillion globally by 2035, according to The World Obesity Atlas 2023.

"Obesity is a 'gateway' disease that is linked to a large number of complications and disorders – some of which may impact life expectancy and health-related quality of life. Weight loss is associated with notable health benefits and improvement in various complications arising from obesity. However, current pharmacotherapy treatment options for weight management are limited, and we believe there is a need for additional effective treatment options that can help people living with obesity and obesity-related complications," said a spokesperson from Novo Nordisk.

As research and development of these drugs mature, they will reshape not only the treatment of obesity but also our understanding of the disease.

"Due to the complexity of obesity as a disease, and the difficulties inherent in maintaining weight loss, in many cases one single solution is not enough. Instead, it may require a blend of different approaches or medications to affect the desired outcomes for a patient. Most of our survey respondents (64 per cent) believe the focus of future obesity therapies will be combination therapies to treat obesity and comorbidities," signs off Simon. BS

Ayesha Siddiqui

"We anticipate starting sales of India's first invented antibiotic drug combination of Cefepime and Enmetazobactam by the next quarter"

Orchid Pharma, headquartered in India, has recently received Drugs Controller General of India (DCGI) approval for the manufacturing and marketing of its invented New Chemical Entity Active Pharmaceutical Ingredient (API), Enmetazobactam, and to manufacture and market Finished Dosage Form (FDF) of Cefepime and Enmetazobactam as a dry powder injectable, to improve the treatment landscape for serious infections in India such as antimicrobial resistance (AMR). To discuss more about this development, and to find out about the company's growth plans this year and beyond, BioSpectrum spoke to Manish Dhanuka, Managing Director, Orchid Pharma in detail. ***Edited excerpts;***

« **Manish Dhanuka,** Managing Director, Orchid Pharma, India

What are the major plans in store for FY 24-25? How much growth is expected?

We have recently received DCGI approval for India's first invented Antibiotic Drug Combination of Cefepime and Enmetazobactam (NCE). We look forward to expanding access to advanced and affordable treatment options for patients. For the Indian market, Orchid will partner with a third party with comprehensive hospital coverage while also utilising our own Antimicrobial Solutions (AMS) division for product distribution.

Enmetazobactam has already received approval from both the US FDA and the European Medicines Agency. These approvals are a significant step forward for Orchid Pharma, opening doors to royalties from lucrative markets. In India, we have also been granted waiver for Phase III clinical trials and we will be conducting a Phase IV post-launch.

Our initial expectations for launching in mid-2025 have now been advanced, and we anticipate starting sales by the next quarter. This accelerated timeline will enhance our revenue streams substantially.

Besides this our new capacities coming online will lead to a healthy growth for the coming year in line with the past trend of 2-3 years.

How much revenue do you expect to add up through this product?

This will depend on the price elasticity, but we should be able to capture ~3 per cent of the market in the medium term.

How much revenue was generated by the company during FY 23-24?

For the full year FY2024, we achieved sales of Rs 819 crore, a significant jump from Rs 666 crore last year. Our full-year EBITDA stood at Rs 142 crore, up from Rs 103 crore in FY2023. This growth is reflected in our strong Compound Annual Growth Rate (CAGR) of 22 per cent in sales and 30 per cent in EBITDA over the past three years. These figures highlight our continuous progress and ability to adapt to market demands.

Are you exploring new partnerships with global pharma companies?

As an enterprise, we are always on a look-out for expansion and collaborations. We do see a massive need for our innovations globally. Several such deals are under discussions but due to confidentiality cannot be shared. One such outcome was the Orchid-GARDP-Shionogi partnership to tackle the growing menace of antimicrobial resistance. Orchid has received the license to make this product for 135 LMICs (Low and Middle Income Countries).

Pharma innovation is progressing rapidly and is making strides in India, with significant advancements in drug discovery and development. However, there are still significant gaps and challenges to be addressed. Insufficient funding for research and development, limited collaboration between academia and industry, plus navigating regulations can feel like a maze. Additionally, we need to invest in better facilities and skilled workforce. By addressing these issues and challenges, India can truly become a global leader in innovative medicines.

Are you planning new investments, or facility expansions in India?

Orchid is committing close to Rs 800- Rs 1000 crore of capital investments in next 2-3 years.

How do you view the growing burden of AMR globally? What needs to be done?

Antimicrobial resistance (AMR) isn't just a scientific challenge; it's a growing threat to public health and has severe economic impact. The World Health Organization (WHO) considers AMR one of the top ten global health threats, highlighting its potential to send us back to a pre-antibiotic era. We may soon be returning to the pre-antibiotic era because antibiotics are losing their power. AMR is declared as the silent pandemic by the UN and WHO and it has contributed to almost 5 million deaths in 2019. In addition to death and disability, AMR has significant economic costs. The World Bank estimates that AMR could result in $1 trillion additional healthcare costs by 2050, and $1 trillion to $3.4 trillion gross domestic product (GDP) losses per year by 2030.

Combatting AMR requires more than just scientific advancements; it demands a shift in mindsets and behaviours. We see some steps that can support and build a future resilient to AMR:

Antimicrobial Stewardship Programmes that promote responsible antibiotic use in human and veterinary medicine is paramount. These programmes champion responsible prescribing practices, track resistance patterns, and advocate for rapid diagnostics.

Global Surveillance Networks: Establishing robust surveillance networks to monitor AMR trends across different regions is essential. This data will guide targeted interventions and inform research priorities.

Investing in Innovation: Increased investment in R&D for new antimicrobials, diagnostics, and alternative therapies is crucial. Public-private partnerships can accelerate innovation and ensure a steady stream of solutions.

Dedicated Funding for Innovation: Creating a dedicated "AMR and Innovation Fund" can incentivise continued research and development.

What are your views on pharma innovation in India? What are the gaps and challenges that need to be addressed?

Pharma innovation is progressing rapidly and is making strides in India, with significant advancements in drug discovery and development. However, there are still significant gaps and challenges to be addressed. Insufficient funding for research and development, limited collaboration between academia and industry, plus navigating regulations can feel like a maze. Additionally, we need to invest in better facilities and skilled workforce. By addressing these issues and challenges, India can truly become a global leader in innovative medicines.

What are major expectations from the government to strengthen the pharma sector in India, in terms of R&D, innovation and quality?

Orchid Pharma is committed to developing life-saving medications, that's our passion and purpose. However, it is always better and efficient to have partnerships and support especially from government functionaries, it can accelerate this mission in India.

First, increased R&D funding will empower our scientists to develop cutting-edge treatments. Second, streamlining the process for approving new drugs that will get them to patients faster. Protecting intellectual property is also essential, inventors need to be rewarded for their hard work to encourage continuous innovation. Finally, fostering stronger ties between universities and drug companies, along with creating a conducive environment for startups, will get everyone working together to create the next big breakthrough and drive growth in the Indian pharma sector. BS

Dr Manbeena Chawla
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"Adapting smart manufacturing represents great potential for pharmaceutical industry as a whole"

Rockwell Automation provides smart solutions for manufacturing processes. Marcelo Tarkieltaub, Regional Director for Southeast Asia at Rockwell Automation, discusses the company's smart solutions for the life sciences industry, challenges in implementing smart factories, and factors driving the adoption of digital technologies in the sector. ***Edited excerpts;***

« **Marcelo Tarkieltaub,** Regional Director, Rockwell Automation Southeast Asia, Singapore

What's been Rockwell Automation's role in driving smart manufacturing initiatives within the life sciences sector, particularly in the Asia Pacific (APAC) region?

We are a global leader in digital transformation, playing a pivotal role in advancing smart manufacturing. In the life sciences sector, smart manufacturing is crucial for enhancing efficiency, ensuring compliance, and improving product quality, which aligns with our mission to drive innovation and operational excellence.

The APAC region is a rapidly growing market for the life sciences sector, characterised by increasing demand for innovative healthcare solutions and stringent regulatory requirements. The pharma market in this region is expected to grow from almost $70 billion in 2022 to nearly $153 billion by 2032, with Singapore being one of the leading biomedical and pharmaceutical hubs in APAC.

Meeting the needs of complex manufacturing processes, while remaining compliant with regulations, businesses are turning to advanced manufacturing automation technologies. Automation enhances precision, efficiency, and scalability, crucial for innovative healthcare solutions. It ensures compliance with global regulatory standards, minimising human error and maintaining consistent product quality. Additionally, automation supports faster time-to-market and cost-effective production, essential for staying competitive in the rapidly growing APAC pharma market.

We offer a suite of advanced technologies and solutions that empower the life sciences industry. These include IoT-enabled devices, advanced analytics, and comprehensive automation platforms such as the FactoryTalk PharmaSuite. Developed specifically for the life sciences industry, this MES solution leverages IoT and an open-content architecture paired with an intelligent upgrade engine, to provide a robust system for growth in both batch and discrete processing. Deploying this solution results in automated data collection and the ability to review exceptions in real-time.

Pharmaceutical manufacturing has been characterised as a late adopter of digital technologies compared to other industries. What are your thoughts on this? How does the company view the potential for digital transformation within the pharmaceutical sector? Will we see more smart manufacturing in the sector moving forward?

The complexity of pharmaceutical production processes and the high stakes involved in product quality and patient safety have made manufacturers cautious about implementing new technologies. However, this is changing as companies recognise the benefits of digital transformation, such as improved efficiency, enhanced data analytics, and better compliance tracking. Emerging technologies like AI, IoT, and blockchain are now being increasingly integrated to streamline operations and ensure robust quality control.

In the 9th annual State of Smart Manufacturing Report, about 95 per cent of respondents – encompassing businesses of all sectors, including life sciences – are using or evaluating smart manufacturing technology, a jump from 84 per cent in 2023. Given that quality and compliance is of the utmost priority within the pharmaceutical

Real-time monitoring and predictive analytics can be adopted to ensure quality is always achieved, by having process or plant digital twins in place so that data can be observed and used in real-time. Utilising IoT in smart manufacturing solutions enables supply chain visibility, enhancing resilience and responsiveness should there be any supply chain disruptions in the future. Adopting automated solutions could reduce manual labour, reducing production costs and improving efficiency in the long run.

manufacturing industry, it is safe to say that adapting smart manufacturing represents great potential for the pharmaceutical industry as a whole.

We will see an increased adoption of smart manufacturing moving forward as the industry requires meeting the needs of more complex manufacturing processes to develop specialised medicine. The adoption of more technological advancements is instrumental in aiding organisations and manufacturers within the industry to regulate and manage their overall cost of production as well.

What are some of the main challenges and opportunities you foresee in serving the evolving needs of life sciences manufacturers especially in APAC, and how do you prioritise strategies to address these?

Amid the developments in complex manufacturing processes and new technologies, the pharmaceutical manufacturing industry is now looking at several challenges in the evolving needs of the manufacturers. One of them is the importance of adhering to the global level of quality control and standards set by regulatory bodies like the ASEAN Pharmaceutical Regulatory Policy. Other challenges include supply chain disruptions within the pharmaceutical sector, retaining the right talents with combined expertise in specialised areas like biopharmaceutical engineering and technological savviness, as well as maintaining cost efficiency while ensuring product quality.

Several strategies can be prioritised within the industry in addressing these challenges. Real-time monitoring and predictive analytics can be adopted to ensure quality is always achieved, by having process or plant digital twins in place so that data can be observed and used in real-time. Utilising IoT in smart manufacturing solutions enables supply chain visibility, enhancing resilience and responsiveness should there be any supply chain disruptions in the future. Adopting automated solutions could reduce manual labour, reducing production costs and improving efficiency in the long run.

Data privacy is paramount in the pharmaceutical industry. How does Rockwell Automation ensure robust data privacy measures are in place to safeguard sensitive information, particularly in the context of digital transformation initiatives within the sector?

Rockwell Automation helps provide robust data privacy by implementing comprehensive security frameworks and advanced encryption technologies. Our solutions include secure data storage, access controls, and continuous monitoring to prevent unauthorised access and data breaches. The pharmaceutical industry is vulnerable to cyberattacks, like all industries. We use the NIST Cybersecurity Framework to address five categories of effective defence: Identify, Protect, Detect, Respond and Recover.

Looking ahead, what are your key priorities and strategic initiatives in advancing smart manufacturing capabilities for life sciences clients, and how do you anticipate these initiatives evolving in the coming years?

One of Rockwell Automation's key priorities is to assist businesses in various sectors – including the life sciences industry – in their journey toward transforming their business digitally. Recently, Rockwell Automation expanded its collaboration with NVIDIA, driving the use of AI in autonomous mobile robots (AMRs) to enhance performance and efficiency. This is a continuation of Rockwell Automation's cooperation with NVIDIA in accelerating a next-generation industrial architecture. This is excellent news for the pharmaceutical manufacturing industry, as it will accelerate the adoption of smart manufacturing solutions within the industry.

As technology continues to evolve, Rockwell Automation remains committed to integrating the latest advancements into its solutions. With increased adoption of digital twins, greater use of predictive maintenance, and deeper integration of AI and IoT devices, Rockwell Automation aims to drive innovation in precision medicine and ensure seamless, secure, and efficient manufacturing processes in the life sciences sector. BS

Ayesha Siddiqui

"Collaborative efforts between countries and institutions are shaping the R&D landscape in genomic medicine in APAC"

Precision medicine treatment expenditures in Asia Pacific (APAC) are anticipated to reach $18.2 billion by 2027, up from $8.32 billion in 2022. The prospects for foreign direct investment (FDI) in the region remain resilient, with favourable environments particularly in South-East Asia countries. In an interaction with BioSpectrum Krishna Karnati, Commercial General Manager, Genomic Medicine APAC, Cytiva shares more strategic approaches and trends in the current biopharma market landscape which are driving innovation for the competitive advantage. ***Edited excerpts:***

« **Krishna Karnati,** Commercial General Manager, Genomic Medicine APAC, Cytiva, Singapore

What are the trends driving precision medicine demand in APAC?

There are several trends that are driving demand for precision medicine in APAC. The power of genomics and immunotherapies are driving progress in precision medicine. There is an increasing shift from reactively treating, to proactively preventing diseases such as hereditary forms of cancer through early detection and interventions. Furthermore, developments in health IT and adoption of electronic health records across APAC have paved the way for a more comprehensive storage of data on a patient's health history including genetic history, which can accelerate and be integrated into research and clinical settings. There's a need to address higher incidences of cancer in the region and improve quality of life. Approximately half of global cancer cases are found in APAC. mRNA has shown promise in managing cancer, especially virus-related cancers, which account for 20 per cent of cancers.

There is a surge in the trend of drug development companies investing in mRNA R&D to test this technology against various other diseases. With its cell-free production, scalability, and standardised production methods, mRNA is a high-potential technology ideal for precision medicine with precise biomarker targets. mRNA will increasingly address infectious diseases such as dengue and malaria and drive the access to vivid drugs. Beyond infectious diseases, mRNA will also address the needs in the oncology space through personalised medicine.

Other than mRNA, we observed that genomic medicines such as cell therapies have proven to be effective for patients with leukaemia and lymphoma and are expected to bring major improvements to many other cancer treatments over the next decade.

How will the biopharma market be revolutionised in the coming years by new and emerging technologies? How is Cytiva responding to it?

Cytiva is responding to evolving market dynamics by providing end-to-end technology solutions, and services, to develop platform processes across multiple modalities, increasing demand for access to contract development and manufacturing organisation (CDMO) facilities across the landscape, including Australia and Japan as companies seeking additional manufacturing capacity for their diverse range of therapeutic modalities.

In Australia, for example, Cytiva and the University of Adelaide worked together with BioCina, an Australian-based multi-product biologics CDMO, to expand its facility in Adelaide to manufacture mRNA-based vaccines and therapies.

In India, there is a growing need to install manufacturing capacities with pioneers in small molecules entering the large molecule space such as nucleic acid therapies (mRNA, siRNA), leveraging their experience in chemical synthesis.

Globally, Cytiva manufacturing technologies have enabled 5 out of 6 approved CAR-T therapies from development through to commercial production. With our FlexFactory biomanufacturing platform, we've helped Genepeutic Bio, a leader in Thailand's

life sciences sector, establish the first GMP-certified cell therapy manufacturing facility in the country so it can deliver chimeric antigen receptor-T (CAR T) cell therapies to a few hundred patients with relapsed and refractory blood cancers such as acute lymphoid leukaemia (ALL) in Thailand and Southeast Asia by 2025.

With regard to growth trajectory this year, molecule (asset) movements across genomic medicines show positive signs. Specific to cell therapies, we've observed that there are molecule additions across all clinical phases, largely under preclinical phases, followed by those in Phase 1 and Phase 2 across CAR T, natural killer (NK), chimeric antigen receptor natural killer (CAR NK), and tumour-infiltrating lymphocytes (TILs). Globally, the growth rates for nucleic acid-based therapies (mRNA, siRNA) are astronomical in Phase 1 and 2, starting with a low baseline of molecules.

Across advanced therapies in APAC, we're anticipating movements from Phase 2 to commercial stage in the coming years. This movement is driving growth in manufacturing footprint across nucleic acid therapies, viral vectors and cell therapies to a great extent, with CDMOs leading from the front, to install manufacturing capacities and with larger biopharma companies entering the foray. We're also seeing growth in the translational space, where there is a focus to launch clinical assets backed by government grants and support.

Asia is cultivating innovative startup ecosystems. What are the key enablers that can elevate the region to become successful in developing and delivering genomic medicines to the global market?

To become more successful in delivering genomic medicines to the global market, firstly startups need more support and can't do it alone. Cytiva is involved in initiatives such as 'BioChallenge' supporting biotech startup innovation, while 'Fast Trak' process development services acts as a manufacturing centre of excellence to help startups optimise scalability and resource utilisation. Fast Trak Bioprocess Training and Education not only groom the next generation of bioprocessing talent and enhance specialist knowledge; they help customers to mitigate bottlenecks in the process, or in some cases develop the complete processes for scale up or scale out.

Secondly, working closely with industry and governments can accelerate progress. Currently, we observe collaborative efforts between countries and institutions that are shaping the R&D landscape in genomic medicine in APAC - for example, the NATi program for Oligo and mRNA in Singapore and Korean National Institute of Bioprocessing Research and Training (K-NIBRT) to deliver educational programming on biopharmaceutical and cell therapy development and manufacturing.

In addition, Asian countries have been actively participating in industry associations and academic societies including ISCT (International Society for Cell & Gene Therapy) and ISSCR (International Society for Stem cell research), ISEV (International society for extracellular vesicles). Through these platforms and among the regional chapters, Asian players are actively seeking clarity on regulatory pathways and shaping R&D excellence.

Thirdly, the clinical development of mRNA-based treatments requires significant capital investment to foster ongoing innovation. Despite the economic challenges experienced across various sectors in the past year, there's a bright spot in the form of increased innovation and investment in Advanced Therapy Medicinal Products (ATMPs) within the APAC region (as indicated by the Alliance of Regenerative Medicine report).

Governments and the industry have been actively providing funding support to establish mRNA capabilities, with infectious diseases as an immediate target. For instance, Ricoh started a Biomedical Startup Fund in Japan to support mRNA drug discovery and invest in local startups in the drug research field, enhancing their support for mRNA drug development. Quite recently, ARCALIS, a partnership between Axcelead and Arcturus, received $115 million in grants from the Japanese government. This funding will be used to build a factory and buy equipment for mRNA drug production meeting Good Manufacturing Practice (cGMP) standards. This global trend is reinforced by the Coalition for Epidemic Preparedness Innovations (CEPI), which recently pledged funding of up to $3.6 million to propel Gennova Biopharmaceutical's self-amplifying thermostable mRNA vaccine platform. This funding is specifically directed towards expediting the development of vaccine candidates targeting "Disease X."

The cumulative efforts and financial support of various countries and organisations in supporting mRNA research and development is crucial not only for immediate applications targeting infectious diseases but also for creating a robust knowledge and platform base that can be leveraged to expand mRNA applications into other critical areas, including cancer therapeutics. BS

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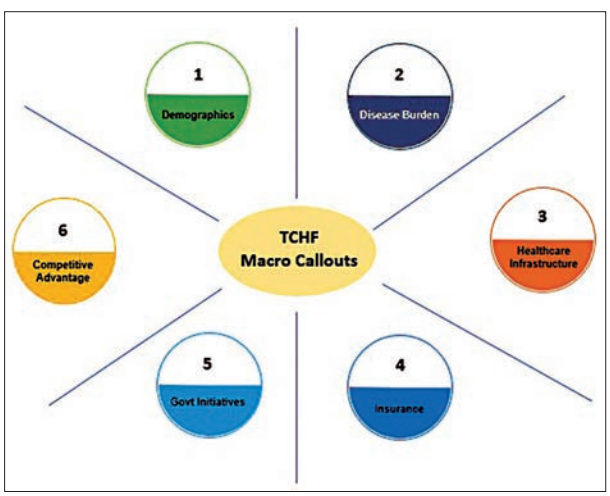
Macro Callouts for Healthcare Investing in India

India will have ~1.2 billion people in the middle-income segment with over 42 per cent of the population in urban cities, by 2030. India's healthcare and lifesciences market is estimated to reach $285 billion by 2028 implying a growth that is twice our GDP growth. These developments will lead to an estimated $30-35 billion in private capital investment getting allocated to the sector over the next 5 years.

« **Visalakshi Chandramouli,** Managing Partner, Tata Capital-Healthcare Fund

India's healthcare and life sciences sector is one of the fastest-growing healthcare and life sciences markets in the world. By 2030, India will have ~1.2 billion people in the middle-income segment with over 42 per cent of the population in urban cities. While on the one hand, the sector today stands at a threshold of significant supply-demand mismatch, on the other hand there are signs of improving affordability and availability of talent pool. This makes the sector a compelling investment opportunity for both private and public market players. As we see today, India's healthcare and lifesciences market is estimated to reach $285 billion by 2028 implying a growth that is twice our GDP growth.

This growth trajectory for the sector is underpinned by several favourable macro factors namely 1) Demographics - increasing affluence among the population; 2) Disease Burden - a dual disease burden; 3) Insurance Penetration - improving insurance penetration; 4) Infrastructure: gaps in healthcare infrastructure; 5) Government Initiatives - government's focus on healthcare and 6) India's competitive advantage – low cost and availability of talent.

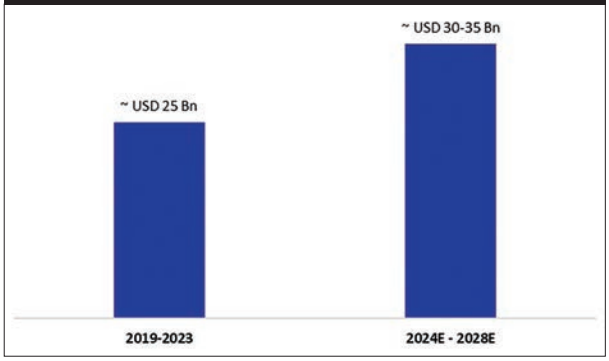


Delving deeper into macro callouts

1) Demographics: By 2030, 140 million additional households will be classified as middle-class and more than 40 per cent of the population will live in urban areas. This shift in demographics will result in 3x-4x growth in healthcare expenditure. Urbanisation and modernisation lead to significant changes in lifestyle - sedentary jobs, lack of physical activity, and unhealthy dietary habits – contributing to increased prevalence of chronic diseases. Meanwhile, India will have more than 200 million elderly (60+) population by 2036; this combined with the rising life expectancy will create an unprecedented demand for healthcare services in the country. Significant investments towards increasing hospitals and other allied services capacity will be required to address the demand.

2) Disease Burden: An estimated 11.6 per cent of the population suffers from some form of NCD and ~ 6 million people die from chronic diseases every year. Cardiovascular disease is the leading cause of death in the country annually claiming over 3 million lives. It is estimated that the prevalence of Diabetes, Cardiovascular disease and Cancer will reach 226 million in 2030 from 169 million currently. In order to tackle the growing NCD burden, concerted efforts from both the government and private sectors are required. This

5 Yr Private Capital Investment in India Healthcare



has already been demonstrated in the remarkable reduction we have achieved in communicable disease-related deaths. We believe that the country's chronic care management space has high scope for players to offer preventive/ therapeutic services.

3) Healthcare Infrastructure: India has made remarkable strides in medical infrastructure over the past decade with an estimated 1.2 million beds added, almost tripling the beds in 2013 (0.6 million beds). It is estimated that India with a current bed density of 1.3 per 1000 population needs 2.4 million additional beds to meet the WHO recommended ratio of 3 beds per 1000 population. Both the government and private enterprises are investing and increasing the bed density in Tier-II and beyond regions of the country. Given the significant demand for healthcare services and rising affordability, we expect the pace of investment in healthcare infrastructure to rise over the next five years.

4) Insurance Penetration: India's health insurance penetration has gone up from ~25 per cent in 2013 to 65 per cent in 2023 but is still low with 35 per cent of the population uninsured (~500 million people). This clearly constitutes the "Missing Middle" that needs urgent addressing. The country is also grappling with more than 50 per cent out of pocket expenditure (OOPE) in healthcare which significantly lags the global average of 18 per cent OOPE. The government has indeed taken marquee steps such as Pradhan Mantri Jan Arogya Yojana (PMJAY) to improve the insurance coverage to the underserved, meanwhile private health insurance companies have also played a pivotal role in reducing the OOPE and ease of claiming insurance through product innovation, distribution and technology.

5) Government Initiatives: Healthcare is a key focus area for the government, and public spending is estimated to reach 2.5 per cent of GDP by 2025. The government has launched its marquee four mission mode projects to improve healthcare accessibility and affordability namely PM-Ayushman Bharat Health Infrastructure Mission (PM-ABHIM), Ayushman Arogya Mandir (erstwhile AB-HWCs), PMJAY and Ayushman Bharat Digital Mission (ABDM). Recently, the government has also launched the Ayushman Bhav campaign which is a comprehensive nationwide healthcare initiative that aims to provide saturation coverage of healthcare services, reaching every village and town in the country. The government has also taken several steps such as offering Production Linked Incentive (PLI) Scheme in the Active Pharmaceutical Ingredients (API), intermediaries and Key Starting Material (KSM) production where import dependence is high. Medical Devices has also been a key area of focus for the government where several med-tech parks have been setup to boost indigenous manufacturing.

6) Competitive Advantage: India benefits from a vast skilled talent pool across physicians, nurses, science, and engineering graduates. India is renowned for its cost-effective healthcare solutions, offering medical treatments, surgeries, and pharmaceuticals at lower costs compared to many developed countries. Estimates indicate medical services in India at 80 per cent discount to the USA, this affordability factor attracts patients from around the world, approximately 2 million patients visit India each year from 78 countries for medical, wellness and IVF treatments, generating $6 billion for the industry. Additionally, India is the largest provider of generic medicines globally, occupying a 20 per cent share in global supply by volume. Indian companies have the largest share of the United States Food and Drug Administration (USFDA) Drug Master Files (DMFs) filings annually with ~ 35 per cent market share. With 670 USFDA approved plants, India has the highest number of USFDA compliant pharmaceutical plants outside of the USA. India is also one of the biggest global suppliers of low-cost vaccines with an estimated 60 per cent of global vaccines being produced in the country.

Conclusion

In summary, we estimate the outcome of the above positive macro environment will lead to an estimated $30-35 billion in private capital investment getting allocated to the sector over the next 5 years. BS

Why are strategic partnerships critical for life science innovation?

Strategic alliances between startups and large companies will be more and more important as the life science sector develops because they will spur research and expedite the release of breakthrough treatments for patients. Innovation stays at the forefront of the industry thanks to the cooperative efforts of resource-rich businesses and nimble startups, which ultimately benefit patients and improve global health outcomes.

« **Karin Koch,**
Executive Director,
University Lab Partners,
United States

Strategic partnerships between life science startups and large corporations are becoming increasingly vital for accelerating innovation and bringing new therapies to market. These collaborations provide a symbiotic relationship where startups gain access to resources, expertise, and infrastructure, while large companies tap into cutting-edge research and innovative ideas.

Benefits for startups

For early-stage life science startups, strategic partnerships with large companies can be a game-changer. These collaborations provide access to resources that would otherwise be out of reach, such as:

Expertise for Various Stages in the Commercialisation Process: Navigating the complex landscape of regulatory affairs, clinical trials, and large-scale manufacturing can be daunting for startups. Large companies typically have established regulatory teams and streamlined processes that can significantly aid startups in obtaining necessary approvals and conducting comprehensive clinical trials. Additionally, large-scale manufacturing facilities and expertise ensure that startups can scale their innovations effectively. Access to this expertise can help startups overcome regulatory hurdles, design, and execute clinical trials more efficiently, and transition from small-scale production to mass manufacturing seamlessly.

Funding and Financial Support: Securing sufficient funding is one of the most significant challenges for early-stage startups. Strategic partnerships often come with financial investments that can propel research and development efforts forward. This support can be crucial for startups, enabling them to focus on innovation without the constant pressure of financial constraints. Funding from large companies not only provides the necessary capital but also adds credibility to the startup, making it easier to attract additional investors and resources.

Building a Network of Supporters: The mentorship and advisory networks that large companies provide can be invaluable. These networks consist of seasoned professionals with years of experience in the industry. Their guidance can help startups avoid common pitfalls, refine their business strategies, and navigate the competitive landscape more effectively. Mentorship from industry veterans can also open doors to new opportunities, collaborations, and markets that would otherwise be inaccessible to startups.

By leveraging the resources and expertise of a larger partner and the surrounding innovation community, startups can accelerate their development timelines, mitigate risks, and increase their chances of success. These partnerships enable startups to focus on their core competencies - developing innovative solutions - while relying on the established processes and infrastructure of larger companies to bring these solutions to market.

Benefits for large companies

Large life science companies also stand to gain significantly from strategic partnerships with startups. These collaborations allow them to:

Access Innovative Technologies and Novel Therapeutic Approaches: Startups often work on the cutting edge of science and technology. By partnering with these agile entities, large companies can integrate groundbreaking innovations into their pipelines, enhancing their product offerings and staying ahead of industry trends.

Expand Product Pipelines and Diversify

Portfolios: The competitive nature of the life science industry necessitates a constantly evolving product portfolio. Strategic partnerships enable large companies to broaden their product lines and diversify their portfolios without incurring the full risk and cost of in-house development.

Tap into the Agility and Creativity of Entrepreneurial Teams: Startups are known for their agility, creativity, and ability to pivot quickly in response to new data or market demands. Large companies can benefit from this nimbleness, fostering a culture of innovation and adaptability within their organisations.

Outsource High-Risk, Early-Stage Research and Development: Early-stage research and development is inherently risky. By collaborating with startups, large companies can outsource some of this risk while still retaining access to promising new technologies. This approach allows them to allocate their resources more efficiently, focusing on later-stage development and commercialisation.

By partnering with startups, large companies can stay at the forefront of innovation while sharing the risks and costs associated with early-stage research. These partnerships create a dynamic where both parties benefit, driving the industry forward and fostering a culture of continuous improvement and innovation.

Role of Pitch Competitions

Pitch competitions provide a unique platform for startups to showcase their innovations and potentially secure strategic partnerships with large companies. These events also serve as highly efficient search and evaluation mechanisms, allowing large companies to see many promising technologies in a cohort at very early stages. These events offer several advantages for startups such as:

Exposure to Industry Leaders, Investors, and Potential Partners: Pitch competitions are attended by key players in the life science ecosystem. This exposure can lead to valuable connections, funding opportunities, and strategic partnerships. It provides startups with a rare opportunity to present their ideas to a highly relevant audience, increasing their visibility within the industry.

Opportunity to Receive Valuable Feedback and Validation: The feedback provided by judges and attendees can be incredibly insightful. It allows startups to refine their pitches, improve their business models, and address potential weaknesses in their strategies. This constructive criticism is essential for startups looking to fine-tune their offerings and increase their market readiness.

Chance to Network and Establish Connections Within the Life Science Ecosystem: Networking is a critical component of success in the life science industry. Pitch competitions facilitate connections with mentors, advisors, and potential partners, creating a supportive network that can help startups navigate the challenges of commercialisation. These connections can lead to long-term partnerships and collaborations that are crucial for sustained growth and innovation.

Potential for Securing Funding, Resources, or Partnership Agreements: Successful participation in pitch competitions can lead to tangible benefits, such as securing funding, access to resources, or formal partnership agreements. These outcomes can significantly accelerate the development and commercialisation of innovative therapies. For instance, opportunities such as the Golden Ticket competition sponsored by Allergan Aesthetics serve as a platform for early-stage startups innovating in aesthetics to incubate near their Irvine, California, headquarters. The winner receives sponsored lab space for one year with access to state-of-the-art research equipment, professional support staff, conference rooms, and unparalleled collaboration opportunities, exemplifying how pitch competitions can provide startups with the resources and support needed to advance their innovations.

As the life science industry continues to evolve, strategic partnerships between startups and large corporations will become increasingly crucial for driving innovation and bringing new therapies to patients faster. The collaborative efforts between nimble startups and resource-rich corporations ensure that innovation remains at the forefront of the industry, ultimately benefiting patients and advancing global health outcomes. BS

The Philippines- a preferred destination for medical education?

The Philippines is revolutionising medical education by providing affordable and value-for-money learning options at a fraction of the cost. With yearly tuition prices ranging from $2,000 to $6,000, it offers an economically realistic option for ambitious professionals worldwide. Furthermore, its curriculum is matched with US standards, ensuring seamless integration into foreign jobs, particularly in North America. This is supported by a strong network of residency programmes in the United States that aggressively seek the expertise of Philippine medical graduates.

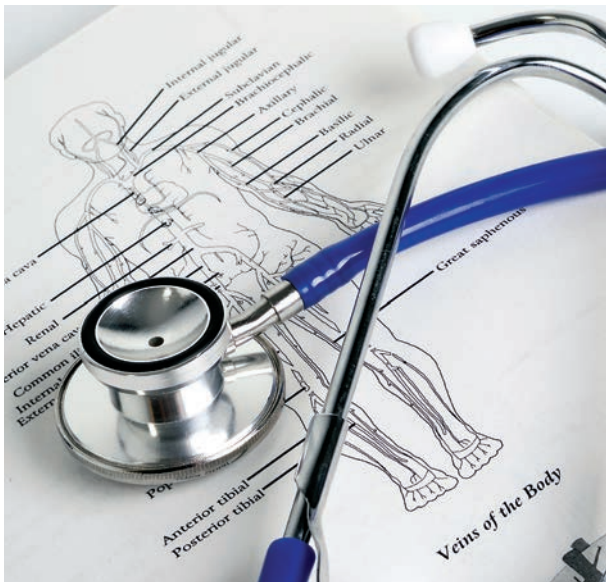
« **Kadwin Pillai,** Director, Transworld Educare and Chairman, Kings International Medical Academy, India

The global medical education system is currently grappling with several pressing challenges. Foremost among these is the critical shortage of healthcare professionals, a problem which is aggravated by the ever-growing demand for healthcare services. According to the World Health Organization (WHO), projections indicate a shortfall of over 15 million health workers by 2030, underscoring the urgent need for action. In addition to this shortage, there is intense competition for medical school seats, particularly in countries such as the US and Canada. This competition further complicates the task of educating and training an adequate number of medical professionals to meet global healthcare demands. Moreover, the high costs and limited availability of seats in medical colleges, notably in countries like India, drive many aspiring doctors to pursue education abroad. However, concerns persist regarding the quality of education and the challenges associated with passing licensing examinations upon returning home, deterring some from this option.

Furthermore, aspiring healthcare professionals increasingly seek international career opportunities, necessitating educational systems that equip them for seamless transitions and success in diverse global healthcare settings. Ensuring the quality of medical education received internationally is paramount, particularly concerning the preparedness of students to pass licensing exams such as the Foreign Medical Graduate Examination (FMGE) upon their return. Addressing these challenges requires concerted efforts from governments, educational institutions, and healthcare organisations. Collaboration is essential to maintain the accessibility, affordability, and high standards of medical education globally, thereby meeting the escalating demand for healthcare professionals and ensuring quality healthcare delivery worldwide.

New opportunities in medical education

The Philippines is revolutionising medical education by providing affordable and value-for-money learning options at a fraction of the cost. With yearly tuition prices ranging from $2,000 to $6,000, it offers an economically realistic option for ambitious professionals worldwide. Furthermore, its curriculum is matched with US standards, ensuring seamless integration into foreign jobs, particularly in North America. This is supported by a strong network of residency programmes in the United States that aggressively seek the expertise of Philippine medical graduates. Similarly, to promote global inclusion, the Philippines has an English-medium curriculum that allows students and staff members to communicate and collaborate effectively. Clinical training is a cornerstone of Philippine medical school, providing students with hands-on exposure in real-world healthcare settings early on, fostering clinical abilities and preparing them for future ambitions. Philippine medical schools are accredited by major international authorities such as Educational Commission for Foreign Medical Graduates (ECFMG), the Foundation for Advancement of International Medical Education and Research (FAIMER) and WHO, which validates the quality of education and opens openings for graduates all over the world.



Is the Philippines becoming a preferred destination for medical education?

The Philippines is rising as a top destination for medical education for several compelling reasons. Firstly, medical school in the Philippines is far more affordable, with typical yearly tuition expenses ranging from $2,000 to $6,000. This cost-effectiveness makes it an appealing alternative for budding physicians looking for a high-quality education without breaking the bank. Furthermore, Philippine medical schools provide curricula that are closely aligned with those in the United States, providing smooth transfers for students aiming to foreign jobs. This alignment is critical since it prepares students for licencing exams such as the United States Medical Licensing Examination (USMLE), allowing them to enter competitive healthcare systems such as the United States.

Furthermore, Philippine medical schools have built a strong network of globally recognised residency programmes, notably in the United States. Graduates from these schools are actively sought after by hospitals and healthcare facilities in the United States for residency programmes, demonstrating their trust in the quality of education and training delivered. Another aspect adding to the Philippines' popularity is its English-medium education system, which attracts a varied group of students from all over the world. This linguistic advantage promotes effective communication and collaboration among students and instructors, which enriches the learning environment.

Plus, Philippine medical education places a high value on clinical training, allowing students to obtain vital hands-on experience in real-world healthcare settings from an early age. This hands-on approach improves students' clinical skills while also providing them with the confidence and preparation they need for their future jobs. Furthermore, Philippine medical schools are accredited by prestigious international authorities such as FAIMER and the WHO, ensuring the quality of education and allowing graduates to seek medical jobs worldwide. Furthermore, recent regulatory reforms, such as House Bill 10145, known as "An Act Providing for a Philippine Medical Act," have paved the way for Indian students and other international students to register and practice medicine in the Philippines.

As part of the Philippine government's support for the medical education system, medical schools are accredited by major international organisations such as the FAIMER and the WHO. Also, a recent amendment to the Philippine Medical Act of 1959 has been approved by the House of Representatives, paving the way for Indian students, including those from foreign, to register and practice medicine in the Philippines.

Job opportunities and future prospects

Medical students in the Philippines and globally are greeted with exciting job prospects in the healthcare field. The WHO projects a significant shortage of healthcare professionals worldwide by 2030, indicating a pressing need for skilled medical personnel. This shortage translates into ample opportunities for medical students, not only locally but also on a global scale.

For those aspiring to practice in North America, particularly in the United States, success in the USMLE is crucial. Philippine medical schools have an impressive track record of preparing students for these exams, with pass rates often exceeding 90 per cent. Consequently, graduates from Philippine medical schools are highly sought after by prestigious hospitals and healthcare institutions in the US for their residency programmes, highlighting numerous job openings within the US healthcare system.

Likewise, the Philippines has garnered recognition for its robust medical education standards, with its medical schools accredited by esteemed international organisations like the FAIMER and the WHO. This accreditation facilitates global recognition and enables graduates to pursue medical careers worldwide, expanding the employment opportunities for Filipino medical students beyond national borders. BS

IIT Bhubaneswar collaborates with Institute of Life Sciences for technical education & research

With an objective to explore opportunities of collaboration in technical education and research, Indian Institute of Technology (IIT) Bhubaneswar has signed a Memorandum of Understanding (MoU) with Institute of Life Sciences (ILS). The MoU intends to have collaboration between the two premier institutions to bring about excellence in technical education, particularly in the fields of Biological Sciences, Molecular Biology, and Microbiology to improve the quality of academic

practices and to build research capabilities of their students and faculty members. Both institutes have agreed to carry out research projects with special emphasis on the development of vaccine for preventing tuberculosis.

Also, as per the MoU, the faculty members from IIT Bhubaneswar and ILS will be free to collaborate and train students of both institutes in their area of expertise based on mutually agreed programmes; they can jointly organise symposia, colloquium, workshops, seminars, and conferences on chosen topics and areas to train students in both the institutes; and conduct joint research projects based on specific interest of individual faculties of both the institutes.

USYD renews partnership with University of Glasgow

The University of Glasgow, UK and the University of Sydney (USYD), Australia have strengthened their ongoing relationship by signing a new Memorandum of Understanding (MoU) in Glasgow to renew and reaffirm their collaborations across research and education. Under the agreement, the two institutions will explore how they can continue to cooperate to address pressing issues in Australia, Scotland, and across the globe. The renewed MoU reflects the strength of academic exchange and research collaborations across the breadth of disciplines at the two universities. One of the strongest collaborations has brought together the Charles Perkins Centre and the College of Medical, Veterinary and Life Sciences at Glasgow to work on projects that could revolutionise the treatment of conditions like heart disease and stroke, focusing on new interventions to prevent the formation of blood clots or the progression of cancer.

Peking University & Boehringer Ingelheim establish joint lab of human medicine in China

The Peking University Health Science Center (PKUHSC) and Boehringer Ingelheim have signed a memorandum of cooperation for setting up the Joint Laboratory of Human Medicine in China. Both have a long history of collaboration. Since signing a memorandum of cooperation in teaching and scientific research in 2014, PKU doctoral students in epidemiology have been offered internship opportunities at Boehringer Ingelheim's headquarters and China office each year. In terms of scientific research, the two parties have collaborated on research in skin diseases and infectious diseases. Marking ten years of cooperation, they have now established a joint laboratory. This new lab will deepen their existing collaboration across more disease areas, promote the integration of production, education, research and benefit patients in China and globally.
The joint laboratory operates under a director responsibility system guided by an academic committee. Professor Zhan Siyan has been appointed as the director of the joint lab, and Professor Li Liming will serve as the director of the academic committee.

Qihan Biotech names Yingyong Xu as Chief Medical Officer

China's Hangzhou Qihan Biotech Co. has announced the appointment of Yingyong Xu as the Chief Medical Officer. Yingyong Xu brings over two decades of specialised expertise in clinical treatment and innovative drug development in haematology and oncology. He has participated in the development of new drugs for chronic myeloid leukaemia, lymphoma, myeloma, myelodysplastic syndrome, lung cancer, pancreatic cancer, and more. Before joining Qihan Biotech, Xu served as Vice President of Clinical at Zai lab, where he led product development initiatives, focusing on hematologic malignancies and lung cancer for over four years. Prior to Zai lab, he worked at Bristol Myers Squibb and Celgene and concentrated his efforts on clinical product development in hematologic malignancies and pancreatic cancer. Before transitioning to the pharmaceutical industry in 2011, Xu was a paediatric haematologist-oncologist specialising in allogeneic hematopoietic stem cell transplantation.

Organon India appoints Vivek Soares as new Country Lead for India & South Asia

Organon India has announced the appointment of Vivek Soares as its new Country Lead for India and South Asia. Soares will take the reins from Anjan Sen, who will retire after 35 years in the biopharmaceutical sector, which includes 11 years with MSD and Organon. Soares brings over 20 years of experience in the biopharmaceutical industry, having held numerous leadership roles at both country and regional levels. He has successfully led diverse teams across markets, developed and executed successful strategies, to increase sales and profitability, while building future capabilities. Prior to joining Organon India, Soares served as Strategic Partnerships & Business Development Lead for Organon Thailand. He has also held positions such as Director, Fertility Business Unit in Asia Pacific, Head of Tender & Key Account in Vietnam, and Senior Marketing Manager for Women's Health covering India, Sri Lanka, and Nepal.

Australian Digital Health Agency appoints Dr Amandeep Hansra as new Chief Clinical Adviser (Medicine)

The Australian Digital Health Agency, the Australian Government's statutory agency responsible for My Health Record, Australia's digital prescriptions and health referral system, and other e-health programmes under the national digital health strategy, has announced the appointment of Dr Amandeep Hansra as its new Chief Clinical Adviser (Medicine). She is a leading expert in digital health and telehealth, with extensive and ongoing experience in clinical practice, education and governance. Dr Amandeep Hansra's unique skill set would be a great asset for the Agency and the health sector to guide its vision of a more connected health system for all Australians. She is a visionary leader who has been at the forefront of transforming healthcare delivery through digital solutions. She will take over the role from Dr Steve Hambleton, who has served as the Agency's Chief Clinical Adviser since 2016 and who will continue to work with the Agency as a Specialist Adviser as he manages other time commitments.

Lupin appoints Abdelaziz Toumi as CEO of API CDMO Subsidiary

Global pharma major Lupin has announced the appointment of Abdelaziz Toumi as the Chief Executive Officer (CEO) of its newly formed subsidiary, Lupin Manufacturing Solutions (LMS). LMS is engaged in the development, manufacture and sale of Active Pharmaceutical Ingredients (APIs) and is starting to build its Contract Development and Manufacturing Operations (CDMO) business. Abdel is a seasoned leader with a blend of scientific and commercial skills, and brings over two decades of rich experience in the biotech, pharma and CDMO sectors, spanning Europe, North America and Asia. He has held leadership positions at Bayer, Merck, Catalent, Lonza, and KBI Biopharma, where he was responsible for driving growth, innovation and operational excellence. Abdel will be based in Switzerland and will spend considerable time in India.

Prof. Liu Xiaogang wins prestigious Royal Society of Chemistry Prize

Professor Liu Xiaogang from the Department of Chemistry, National University of Singapore (NUS) has been named winner of the Royal Society of Chemistry's Centenary Prize in recognition of brilliance in research and innovation. Prof. Liu won the prize for outstanding contributions to the understanding and optical manipulation of photon conversion in nanocrystals and their applications in X-ray and light-field imaging, and for excellence in communication. He is the only winner from Asia and Singapore among this year's three recipients. The Royal Society of Chemistry's prizes have recognised excellence in the chemical sciences for more than 150 years. In medical imaging, his team has devised new and safer X-ray imaging techniques that significantly enhance diagnostic and treatment guidance. They have also developed a prototype interactive mouthguard embedded with pressure-sensitive optical nanomaterials.

Prof. Park Yeong-min of Sejong University steps in as KDDF's 2nd CEO

Prof. Park Yeong-min of the Department of Integrative Biological Sciences and Industry at Sejong University in Korea has been appointed the second Chief Executive Officer (CEO) of the Korea Drug Development Fund (KDDF). Prof. Park has served as the director of the Medical Science and Engineering Research Centre, the leading research centre for basic biomedical sciences at the Ministry of Science and ICT, the dean of the College of Biomedical and Health Science at Konkuk University, and the head of the Department of Medicine at the Basic Research Division of the National Research Foundation of Korea. In particular, he has been prioritising research on overcoming intractable diseases and neurodegenerative diseases, which are rapidly increasing in line with the ageing population and is recognised as a leader with expertise and knowledge.

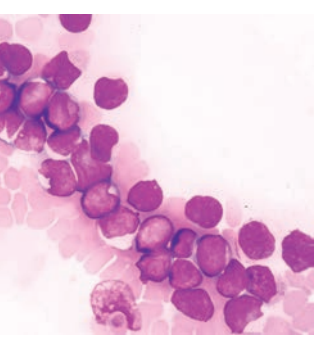
New blood test by Australian scientists tracks brain recovery after concussion

A blood test can accurately detect the ongoing effects of sport-related concussion and help determine when it's safe to return to the field, Australia's Monash University-led research has found. Researchers measured two brain-specific proteins in the blood of 81 Victorian Amateur Football Association (VAFA) players who experienced concussion and compared them with 56 players who did not. By tracking levels of the blood biomarkers over time, they monitored how long it took the players' brains

to recover, otherwise known as 'neurobiological recovery', to help determine when it may be safe to return to play without elevated injury risk. Until now, there have been no well-established tools for tracking neurobiological recovery after sport-related concussion. This cohort study delved into the dynamics of two brain cell proteins, glial fibrillary acidic protein (GFAP) and neurofilament light (NfL), which are released into the blood following brain trauma. While the team's previous research demonstrated diagnostic potential of these blood biomarkers, this study aimed to reveal how their levels changed over time in concussed players.

Breakthrough research in New Zealand offers hope for treating aggressive leukaemia

Researchers at University of Auckland in New Zealand are working on an innovative way to treat an aggressive blood cancer, called acute myeloid leukaemia. It is the most common type of acute leukaemia in adults in New Zealand, affecting around 150 people per year, but current treatments haven't changed much since the 1970s. Acute myeloid leukaemia affects the blood and bone marrow, which is where blood cells are made. It makes the body produce an excessive number of abnormal white blood cells, which interferes with the production of healthy blood cells. Scientists have found that a small group of cells, called leukaemia stem cells, are a big part of the problem. The current treatments do not specifically target the stem cells but all cells indiscriminately, and that's why they are very toxic and frequently do not lead to cure. A specific inhibitor was found to get rid of leukaemia stem cells in a mouse model of leukaemia, while protecting the healthy stem cells. This means there might be a new way to treat acute myeloid leukaemia that could be more effective and have fewer side effects.



Hong Kong develops 3D-printable bioactive material to treat large-to-massive tendon injuries

A research team led by Professor Elmer Ker, Assistant Professor in the School of Biomedical Sciences at The Chinese University of Hong Kong (CUHK)'s Faculty of Medicine (CU Medicine), who is also a member of the CUHK's Institute for Tissue Engineering and Regenerative Medicine, has developed a 3D-printable bioactive material for the repair of severe tears of the shoulder tendons, also known as the rotator cuff. This newly developed material provides adequate mechanical support to sustain normal shoulder movement and with the inclusion of bioactive molecules such as growth factors, is able to enhance tissue regeneration. The fact that it can be 3D-printed not only facilitates economical on-demand fabrication but can also allow the material to be personalised for treating irregular, patient-specific tendon tear shapes. Thus, there is a high potential to apply this invention as a new treatment option in repairing rotator cuff injuries including large-to-massive tears.

Korea announces breakthrough in using bispecific antibodies for solid tumours

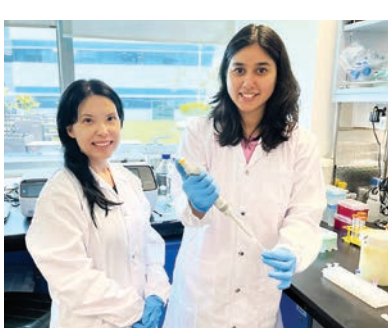
Researchers from the Department of Life Sciences at Pohang University of Science and Technology (POSTECH), in collaboration with Kangwon National University, South Korea have revealed a groundbreaking method to significantly enhance the efficacy of bispecific antibody therapies in treating solid tumours. Bispecific antibodies, which can simultaneously bind to two different antigens, are currently under active investigation in cancer therapy research. Bispecific T cell engagers can engage both T cells and tumour cells at the same time, prompting T cells to effectively attack the tumours. Over the past two years, the US FDA has approved 7 bispecific T cell engagers, establishing this approach as a leading strategy in the antitumor immunotherapy market.

IIT-M & NASA lay focus on multidrug-resistant pathogens on international space station

Researchers at the Indian Institute of Technology Madras (IIT-M) and NASA's Jet Propulsion Laboratory (JPL) are studying multi-drug resistant pathogens on the International Space Station (ISS), which could have key applications for astronauts' health as well on earth. The researchers conducted a comprehensive study to understand the genomic, functional, and metabolic enhancements observed in multidrug-resistant pathogens with a particular focus on Enterobacter bugandensis, a prevalent nosocomial pathogen found on surfaces within the ISS. Astronauts operating in altered immune conditions with limited access to traditional medical facilities face unique health challenges during space missions. Understanding the microbial landscape aboard the ISS is paramount for assessing the impact of these microorganisms on astronaut well-being. The current study emphasises the critical need to investigate the pathogenic potential of microorganisms in space environments to safeguard astronaut health and mitigate the risks associated with opportunistic pathogens.

Singapore-Japan team finds common virus that triggers growth of nasopharyngeal cancer

Scientists from Nanyang Technological University, Singapore (NTU Singapore) and Chiba University in Japan have shown how the Epstein-Barr virus (EBV) alters specific genes, making nasopharyngeal cancer tumours (NPC) grow faster. The Epstein-Barr virus, also known as human herpesvirus 4, is one of the most common human viruses, causing infectious mononucleosis, also known as mono or glandular fever, and other illnesses. The



researchers found that EBV tricks human cells into turning on specific genes that promote cancerous growth. Studying cells from patients with NPC, scientists observed how the virus acts as it infects nasopharynx cells to 'switch on' genes that trigger the rapid multiplication of NPC cells. This new study provides additional insight into the link between EBV and NPC. Although previous research has associated the two diseases, researchers have not convincingly demonstrated a definitive interaction between the virus and disease until now.

NSG BioLabs, Eppendorf partner to support biotech companies in Singapore

NSG BioLabs, Singapore's largest provider of biotech co-working laboratory and office space, has announced a new partnership with Eppendorf, a leading international life science company that develops, manufactures, and distributes instruments, consumables, and services for use in laboratories around the world, to support biotech startups by providing needed resources such as product and applications expertise and its networks to advance startup research and development (R&D). Since 2019, NSG BioLabs has been assisting innovators in creating impactful solutions in the health, biomedical, agrifood, and industrial biotechnology sectors, working in areas such as precision medicine, nucleic acids, AI-enabled drug discovery, synthetic biology and other impactful areas. With the largest co-working biotech laboratory and office footprint in Singapore, coupled with extensive networks with local and international partners, suppliers, and industry experts, NSG BioLabs has helped over 40 companies as residents. The company's residents include several multi-billion-dollar multinationals as well as many promising startups that have achieved key milestones.

Shimadzu acquires all shares of Zef Scientific Inc.

Japan-headquartered firm Shimadzu has acquired all shares of Zef Scientific Inc., through its US subsidiary Shimadzu Scientific Instruments, Inc. (SSI). ZefSci, now a subsidiary of SSI, provides maintenance and repair services on liquid chromatographs (LC) and liquid chromatograph mass spectrometers (LC-MS). With the acquisition of ZefSci, Shimadzu will expand its after-sales services and strengthen its structure in North America. For analytical equipment, after-sales service such as replacement of consumable parts and repairs is essential. In recent years, with the tightening of quality control in the pharmaceutical industry, there has been an increasing demand for a single-source after-sales service of analytical equipment regardless of the manufacturer (multi-vendor services, MVS). The Group plans to increase sales in North America from 51 billion yen in fiscal 2022 to more than 70 billion yen in fiscal 2025 by providing total solutions to customers through product and technology development that meets cutting-edge needs and high-quality after-sales services.

Qiagen launches advanced QIAstat-Dx respiratory panel in Malaysia

Qiagen has introduced an improved version of its QIAstat-Dx Respiratory SARS-CoV-2 Panel in Malaysia, following approval by the Medical Device Authority (MDA). This new version, which holds a CE-IVD mark, increases its detection capability from 22 to 23 pathogens and is compatible with the QIAstat-Dx Rise system, a high-capacity variant of the QIAstat-Dx automated syndromic system. This upgraded panel is a multiplexed nucleic acid real-time PCR test designed for the qualitative detection of common pathogens presenting with influenza-like symptoms. It now can detect and differentiate among 23 viral and bacterial targets, including Chlamydophila pneumoniae. QIAstat-Dx solutions and syndromic tests are available in over 100 countries globally. The systems have been installed in various hospitals, including those under the Malaysian Ministry of Health, with the first installation in 2019.

Sartorius opens new CoE for bioanalytics in US

Germany-headquartered life science group Sartorius has opened its new Center of Excellence (CoE) for bioanalytics in Ann Arbor, Michigan, US two years after breaking ground in the Tech Loop at Research Park. Sartorius has invested around $100 million in the state-of-the-art facility, consolidating existing sites and functions in Ann Arbor. The number of employees at the site is expected to double over time. The 130,000-square-foot facility houses a modern manufacturing and services area, biology labs,

a warehouse, office and training spaces, as well as a Customer Interaction Center (CIC). Sartorius will develop and manufacture a range of bioanalytical instruments at this site, including the associated reagents, consumables and software solutions. In addition, the company will provide particle validation services and produce microcarriers used in cell culture processes. The CoE was built with a focus on sustainability and is seeking a Leadership in Energy and Environmental Design (LEED) gold certification, to be administered by the US Green Building Council. Sustainable features include green electric energy supply from 200 kilowatt solar panels, 30 electric vehicle charging stations, and Research Park's first storm runoff pond.

HKBU and Agilent (China) establish joint lab to promote research on new pollutants and toxicology

The Hong Kong Baptist University (HKBU) State Key Laboratory of Environmental and Biological Analysis (SKLEBA) and Agilent Technologies (China) have jointly established the "SKLEBA (HKBU) - Agilent Joint Laboratory". With its research focus on environmental new pollutants analysis and toxicology, the Joint Laboratory will provide scientific support to authorities in formulating public health policies, making contributions to Hong Kong, the Greater Bay Area and the Nation. The SKLEBA at HKBU is dedicated to cutting-edge research on persistent organic pollutants, while Agilent Technologies has state-of-the-art instruments and extensive expertise in engineering with robust technical support. The establishment of the Joint Laboratory will create a more advanced research and analysis platform, further empowering HKBU to broaden its capabilities in scientific research.

Thermo Fisher introduces Heracell incubators to support future of fully automated labs

To support the future implementation of workflow automation in cell therapy production, Thermo Fisher Scientific has introduced the Thermo Scientific Heracell VIOS 250i AxD CO2 Incubators. These first-of-their-kind CO2 incubators are designed for integration into automated and modular laboratories. The VIOS family of incubators are known for optimal cell growth conditions and minimal contamination risk. Now adding the innovation of patent-pending automated door control, the Heracell VIOS AxD CO2 incubator opens automatically when integrated into a centralised lab automation platform, allowing vessel loading and unloading through robotic control and supporting continuous cell therapy production processes. The Heracell VIOS 250i AxD CO2 incubators are the most advanced incubators in the VIOS portfolio. Owing to its excellent cell culturing conditions that help ensure critical quality attributes of cells, Heracell VIOS 250i AxD CO2 incubators support the emerging automated cell therapy production processes on a large scale, culminating in an advancement that helps improve human health by supporting the cell manufacturing process within cell and gene therapies.

Safeguarding Public Health Against Counterfeit Drugs

On June 20, the World Health Organization (WHO) issued a medical product alert on falsified semaglutides, medicines used for treatment of type 2 diabetes and obesity in some countries. The alert addresses three falsified batches of product of semaglutide (under the brand Ozempic, product from Novo Nordisk), which were detected in Brazil and the United Kingdom of Great Britain and Northern Ireland in October 2023, and the United States of America in December 2023. The WHO pointed out that its Global Surveillance and Monitoring System (GSMS) has been observing increased reports on falsified semaglutide products in all geographical regions since 2022. This is the first official notice issued by WHO after confirmation of some of the reports.

Three weeks before this alert from the global health agency, Novo Nordisk, in a statement on May 30 said that it is filing nine new lawsuits and seeking to add claims to two existing lawsuits against several medical spas, weight loss clinics, pharmacies, and other companies in the US. These actions aim to protect US patients and consumers from deceptive marketing by these entities as well as potentially harmful and improperly compounded drugs claiming to contain semaglutide.

As of March 31, 2024, the FDA Adverse Event Reporting System (FAERS) data includes 442 cases of adverse events associated with compounded drugs claiming to contain semaglutide. Of those cases, 319 were classified as "serious" adverse events, 99 reported hospitalisation, and seven involved death. With these new lawsuits, Novo Nordisk has filed 21 legal actions against entities that have engaged in deceptive, unfair, unlawful, and dangerous practices regarding the marketing and sales of alleged semaglutide products. The latest round of legal actions is based on alarming new evidence collected by Novo Nordisk on the practices and products being sold by these entities.

The company noted that among the prior 12 lawsuits brought forward by it, courts thus far have already entered five final judgments, permanently barring the defendants in those matters from engaging in deceptive, misleading, and unlawful marketing practices related to the sales of compounded semaglutide drugs. The other lawsuits are still in active litigation. The US FDA noted that it has found illegally marketed semaglutide online and is investigating reports of counterfeit Ozempic being marketed in the US. But has taken no action against anyone so far.

The Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom had issued warning notes to the public on October 26 last year not to buy pre-filled pens claiming to contain Ozempic (semaglutide) or Saxenda (liraglutide), but to consult a healthcare professional qualified to prescribe medicines and first obtain a prescription. The MHRA noted that it has seized 369 potentially fake Ozempic pens since January 2023. The MHRA has received reports of a very small number of people who have been hospitalised after using potentially fake pens.

Novo Nordisk, whose products are available in falsified form in different countries, noted that it is committed to supporting the active fight against counterfeit of its products and other illegal activity in the market. It intends to do so by proactively applying relevant security features on its products, based on an informed risk assessment and regulatory requirements; having a quality management system that investigates occurrences of counterfeited products; cooperating with regulators and other stakeholders to investigate counterfeit products and develop new anti-counterfeit measures and cooperating internationally with scientific and trade organisations as well as regulatory bodies to develop legislation to counteract counterfeit products.

It may be noted that according to Pharmaceutical Security Institute (PSI), a not for profit membership organisation with 40 pharma players that collects information and coordinates investigations into counterfeit products within the pharma industry worldwide, observed that the top three regions that are more frequently linked to pharma crime incidents (total 6,615 incidents recorded in calendar year (CY) 2022; increase of 10 per cent over CY 2021) are North America (3029), Asia Pacific (1738), Latin America (934) where the government operations are quite transparent and their activities are known to the media and public.

To protect the public health, the need of the hour is sharing information on the counterfeiting of pharmaceuticals and initiating enforcement actions through the appropriate authorities. BS

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