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Drugs Controller General of India

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TWIN TROUBLES



GROWTH, GIMMICKS, AND GAPS



AGING BODY, AGELESS PASSION



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A Tale of Promise and Pitfalls

Dear Readers,

s we step into the November issue of Double Helical, our commitment to spotlighting innovations, trailblazers, and transformative strides in healthcare remains steadfast. This edition takes stock of India's growing stature as a global healthcare leader, fuelled by visionary individuals, robust pharmaceutical frameworks, and collective action against the challenges we face.

In this issue, we are privileged to feature interviews with two luminaries of India's healthcare ecosystem, whose journeys embody resilience, leadership, and a vision for a healthier future: Dr Vinay Aggarwal, former National President of the Indian Medical Association (IMA), and Dr Rajeev Raghuvanshi, Drugs Controller General of India (DCGI). These two exclusive interviews offer invaluable insights from stalwarts of the medical fraternity.

In a freewheeling interaction with Double Helical, Dr Vinay Aggarwal reflects on his remarkable journey. From humble beginnings to pioneering initiatives such as the "Aao Gaon Chalen" project, his career epitomises the transformative potential of integrating a sense of service, compassion, innovation, and infrastructure in healthcare. His initiatives to tackle issues like violence against doctors and improve rural healthcare access are truly inspiring. His work, recognised through prestigious accolades such as the Dr B C Roy Award, underscores the importance of individual endeavours in uplifting healthcare of the nation.

On the pharmaceutical front, Dr Rajeev Raghuvanshi outlines the meticulous efforts behind India's ascent as the world's largest supplier of generic drugs and vaccines. From stringent quality checks to aligning Indian standards with global benchmarks, his leadership exemplifies how regulatory initiatives can safeguard public health while fostering industry growth. Dr Raghuvanshi's commitment to upholding quality standards and fostering transparency highlights the strides India has made—and the challenges it must overcome like maintaining the critical balance of maintaining safety while addressing the dynamic demands of the pharmaceutical landscape—to solidify its position as a trusted global pharmacy.

However, India's pharmaceutical sector, while celebrated for its contributions, is not without its share of criticism. Dr Amitav Banerjee's special story, "Drug Regulation: Corruption, Contamination, and Crisis," exposes the alarming prevalence of substandard drugs, their devastating impact, and the urgent need for stricter oversight. This article serves as a wake-up call for all stakeholders to prioritise safety and accountability over profits.

Thus, the pharmaceutical industry's journey is a tale of contrasts. On one hand, we have remarkable achievements in drug development and regulation, thanks to the pioneering work

of Dr Raghuvanshi. On the other, we face troubling lapses, as highlighted in Dr Amitav Banerjee's investigative piece. The tragic consequences of substandard medicines—both at home and abroad—expose critical gaps in oversight and enforcement.

This issue also delves into pressing challenges that India must address to achieve its ambition of becoming a Vishwa Guru in healthcare. Antimicrobial Resistance (AMR) threatens to upend decades of medical progress. Dr Suneela Garg and Dr Arvind Garg's article, "AMR: Race Against Resistance," highlights the urgent need for collective action to combat this existential threat. With projections of 10 million annual deaths by 2050 due to AMR, the article calls for urgent, collaborative action to mitigate this silent pandemic.

Healthcare delivery in India continues to grapple with dual challenges: rising costs and suboptimal outcomes. Dr Vijay Agarwal's analysis in "Twin Troubles" sheds light on the systemic issues that plague our healthcare institutions and calls for structural reforms and bold measures. As private hospitals wrestle with accusations of profiteering, the delicate balance between affordability and quality of care remains elusive.

This issue also features a compelling analysis of the Vitamins, Minerals, and Health Supplements (VMHS) sector, an industry rife with opportunities and obstacles. While personalised health solutions are reshaping consumer engagement, affordability and trust remain barriers to widespread adoption. Regulatory scrutiny, particularly on certain supplements flagged for potential harm, underscores the need for stringent quality standards. As the market evolves, proactive collaboration between manufacturers and regulatory bodies can rebuild consumer confidence, ensuring safety and efficacy.

The November edition of Double Helical encapsulates the complexities of Indian healthcare—its triumphs, trials, and transformative potential. While challenges abound, the strides India has made in healthcare cannot be overlooked. This issue encapsulates the ethos of Double Helical—to celebrate progress while holding a mirror to the gaps that remain. From the resilience of leaders like Dr Aggarwal to the regulatory excellence led by Dr Raghuvanshi, these stories inspire hope and determination.

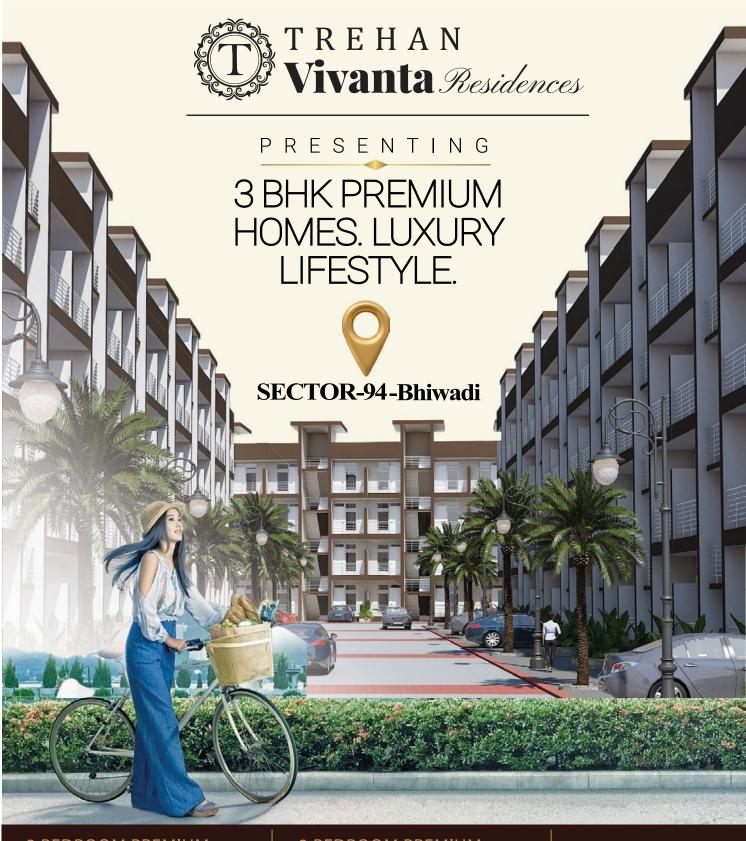
This issue is packed with a variety of interesting and thought-provoking pieces. Happy reading!

Happy reading!

Thanks and regards

Alkaly

Amresh K Tiwary, Editor-in-Chief



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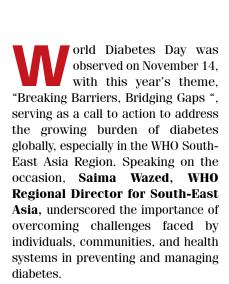
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World Diabetes Day: Saima Wazed Highlights Need for Collective Action



"Diabetes affects nearly 246 million people in the WHO South-East Asia Region, with more than 60 per cent unaware of their status. Untreated and uncontrolled diabetes can lead to severe complications like heart attacks, strokes, and kidney failure, placing an immense emotional and financial burden on individuals and healthcare systems," Wazed noted.

She commended the region's progress, highlighting that over 23 million people have been placed on protocol-based management by mid-2024, as countries work towards the SEAHEARTS target of standard treatment for 100 million individuals by 2025. However, Wazed stressed the urgent need to enhance primary

healthcare readiness by equipping systems with essential medicines, diagnostics, and trained personnel.

As part of her address, she advocated for integrating diabetes care into primary healthcare systems, implementing the WHO HEARTS D package, and aligning diabetes services with infectious disease programmes like tuberculosis for mutual benefit.

Wazed urged governments, healthcare providers, and communities to work together, stating, "Let us ensure equitable, affordable, and high-quality diabetes care for all, leaving no one behind.



Apollo hosts symposium on Integrative Medicine

he Apollo Group of Hospitals, New Delhi, recently organised a symposium on the Integration of "Multi-Disciplinary Medicine for Future Healthcare" at the auditorium of Indraprastha Apollo Hospital, New Delhi. This symposium provided a unique platform to discuss the critical importance of effective, integrated, and multidisciplinary healthcare tailored to the needs of diverse populations and communities. Experts from various medical specialties, including Ayurveda, gathered to examine the rapidly evolving landscape of innovative approaches to managing both prevalent and complex diseases.

Panel discussions explored topics such as cancer, diabetes, hypertension, coronary heart disease, and chronic liver and kidney diseases. The emphasis was placed on precision and personalised care, preventive strategies, public engagement, and educational outreach, fostering a holistic approach to advancing health and well-being.

On this occasion, Lt Gen Prof Bipin Puri, DMS, Apollo Hospital, New Delhi, inaugurated the symposium and delivered a remarkable address on the importance of Integrative Medicine (IM). Dr (Prof) Arun Agarwal, Medical Advisor (Innovation and Clinical Research), Apollo Group of Hospitals, introduced the concept and scope of IM.

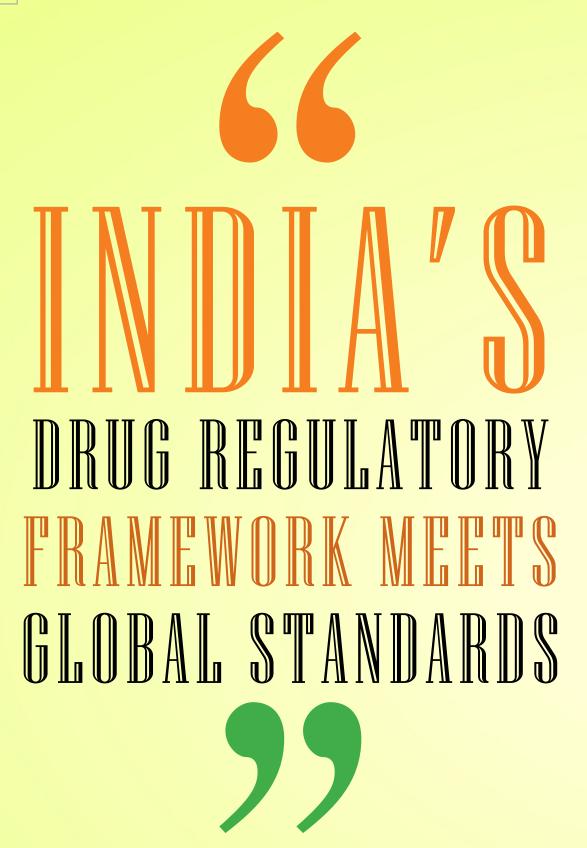
According to Dr Agarwal, IM is a medical approach that combines conventional and complementary therapies to treat the whole person, considering a patient's physical, emotional, mental, and spiritual needs. This approach uses a combination of therapies, including conventional methods like drugs and surgery, alongside complementary therapies such as acupuncture and yoga. It employs an evidence-based approach to improve health and wellness, recognising that physical, mental, emotional, and spiritual needs are interconnected and impact overall well-being.

IM adopts a healing-oriented approach that encompasses all aspects of a patient's lifestyle. It underscores the therapeutic partnership between practitioner and patient, is informed by evidence, and employs all appropriate therapies. This approach involves collaboration among nurses, doctors, and various specialists, covering diagnosis, treatment, disease prevention, and medical research. It aims to promote and maintain health and well-being comprehensively.

Several experts participated in the symposium, including Dr Anupam Sibbal, Group Medical Director, Apollo Group of Hospitals; Dr Preetha Reddy; P Shivkumar; Ravi Vasudevan, CEO, Apollo Ayurvaid; Dr Dharini Krishnan; Dr N K Ganguly; Dr Bhavna Prashar, IGIB, New Delhi; and Sreeith Edamana, COO, Apollo Ayurvaid. They shared their insights and perspectives, enriching the discussions with their expertise.

Apollo's recent healthcare events have focused on multidisciplinary healthcare approaches, artificial intelligence in patient safety, and technological advancements, often held alongside large conferences like the International Patient Safety Conference (IPSC) or the Transforming Healthcare with IT (THIT) conference.





INTERVIEW BY AMRESH KUMAR TIWARY





The Drugs Controller General of India (DCGI) leads the Central Drugs Standard Control Organisation (CDSCO), the Drug Regulatory Authority under the Ministry of Health & Family Welfare (MoHFW), Government of India. Tasked with ensuring the safety, efficacy, and quality of medicinal products, the CDSCO oversees drug approvals, clinical trials, and coordination with state drug control organisations under the Drugs and Cosmetics Act, 1940.

In an exclusive conversation with **Double Helical**, Dr Rajeev Raghuvanshi, the DCGI, delves into the strides made in enhancing the quality of Indian medicines, the collaborative role of regulatory bodies, and initiatives aimed at aligning Indian pharmaceutical standards with global benchmarks.



EXCERPTS FROM THE INTERVIEW:

HOW DO YOU ENSURE THE QUALITY AND SAFETY OF INDIAN MEDICINES?

At CDSCO, quality and safety are at the core of our regulatory framework. We rigorously review clinical trial applications for new drugs, investigational new drugs, and imported drugs. Standards for manufacturing, sale, import, and distribution are established under the Drugs and Cosmetics Act, 1940 and monitored stringently.

We conduct monthly testing of 2,000 to 3,000 drug samples from the market. Medicines failing any quality parameter are flagged and listed on our official website. This ensures transparency and accountability. Furthermore, we adhere to the quality standards outlined in the Indian Pharmacopoeia (IP), which is regularly updated to meet international norms.

India's contribution as the world's largest supplier of generic drugs and vaccines reflects our adherence to these standards. Over 50 per cent of the global vaccine demand is met by India, underscoring the robustness of our regulatory mechanisms. However, maintaining such high standards requires continuous collaboration between the CDSCO and state-level regulatory agencies, along with periodic training and capacity-building efforts.

Q: COULD YOU EXPLAIN THE STRUCTURE OF INDIA'S DRUG REGULATORY SYSTEM?

India's drug regulatory framework operates through a dual structure: the CDSCO and 36 state-level regulatory agencies.

The CDSCO primarily handles new drug approvals, clinical trials, and the regulation of imported medicines. Meanwhile, state authorities oversee the licensing for manufacturing, sale, and distribution of drugs. A critical role of these state bodies is conducting regular inspections to prevent the production and distribution of spurious or adulterated drugs. This two-tiered system ensures checks and balances across the pharmaceutical supply chain.





A critical role of the state bodies is conducting regular inspections to prevent the production and distribution of spurious or adulterated drugs. This two-tiered system ensures checks and balances across the pharmaceutical supply chain.





Additionally, efforts are underway to enhance collaboration between central and state agencies to strengthen the monitoring of drug quality and compliance with regulatory norms.

THE INTERNATIONAL CONFERENCE OF DRUG REGULATORY **AUTHORITIES** (ICDRA) WAS SUCCESSFULLY HELD UNDER YOUR LEADERSHIP. WHAT WERE THE KEY OUTCOMES?

The recent ICDRA, themed "Smart Regulation: Delivering Quality Assured Medical Products for All," was a milestone event. It brought together regulatory authorities from most of the World Health Organization (WHO) member states, fostering collaboration and building international consensus on key regulatory priorities.

The conference provided a unique platform to exchange best practices, promote regulatory reliance, and harmonise practices across nations. Union Health and Family Welfare Minister, Shri J P Nadda who inaugurated the event, highlighted the importance of such events in ensuring the timely availability of safe, effective, and affordable medical products.

One of the significant outcomes was the emphasis on capacity building and trust among regulatory authorities to enable regulatory convergence. This is essential for ensuring quality healthcare worldwide, especially in today's dynamic and innovation-driven pharmaceutical sector.

WITH INDIA BEING A GLOBAL LEADER IN PHARMACEUTICALS, WHAT ARE YOUR PRIORITIES FOR THE FUTURE?

Our primary focus is on ensuring that Indian pharmaceuticals meet global standards consistently. This includes capacity building among regulators and manufacturers, promoting innovation in dosage form design, and enhancing audit processes.

We also aim to strengthen pharmacovigilance, foster research and development, and streamline clinical trial approvals. By integrating advanced technologies and fostering collaboration at both domestic and international levels, we can maintain India's position as a trusted global supplier while addressing emerging challenges in the pharmaceutical sector.

India's pharmaceutical industry stands at a pivotal moment. The initiatives we are undertaking today will ensure a safer, more efficient, and globally competitive future for Indian healthcare





WHAT WAS THE ROLE OF THE DGCI DURING COVID-19?

During the Covid-19 pandemic, MoHFW, the Directorate General of Health Services (DGHS) and the regulatory ecosystem, including the DCGI, faced the enormous challenge of ensuring the timely availability of safe and effective medicines to patients amidst global disruptions. The healthcare system encountered significant difficulties in maintaining a consistent supply of Covid-19-related drugs, which necessitated innovative measures to address the crisis.

The Indian Pharmacopoeia Commission (IPC), a critical partner in this effort, introduced an important general chapter titled 'Approach to Alternative Microbiological Methods'. This guidance document provided stakeholders with the framework to adopt alternatives to traditional microbiological methods, enabling faster batch releases of critical Covid-19 medicines while maintaining quality standards.

YOU MENTIONED PHARMACOPOEIA. COULD YOU ELABORATE?

A pharmacopoeia is an authoritative compendium of drug quality standards, providing detailed information about medicines' quality specifications including their identification, limits of quality parameters, method of analysis etc. Typically revised every four years, it serves as a legally enforceable document to ensure the quality of medicines.

The IP is the official standard for medicines sold in India. Its ninth edition, published in 2022, became effective from December 1, 2022, and has been lauded globally as one of the most comprehensive editions to date. This edition introduced 92 new monographs, encompassing 60 chemical monographs, 21 monographs on vitamins, minerals, amino acids, and fatty acids, among others. Furthermore, it added 12 new general chapters, including critical updates on dosage uniformity and clarification of key methodologies such as IP General Chapter 2.5.4(i).

The 2022 edition reflects India's commitment to aligning with global standards while addressing unique domestic pharmaceutical challenges. It has been widely appreciated





for its detailed guidelines, which bolster the safety, efficacy, and quality of medicines in the Indian market.

Additionally, the IPC introduced a general requirement for 'Phytopharmaceuticals', providing much-needed operational clarity for defining this unique class of drugs in the context of modern pharmacology.

Further advancements included a new general chapter on 'Elemental Impurities,' designed to guide stakeholders on the detection and management of such impurities in pharmaceutical products. While this chapter was not immediately made mandatory for individual monographs, it served as an alternative to traditional heavy metal tests under the provisions of the IP General Notices. The IPC aims to progressively integrate these standards, making them mandatory in future editions of the IP. Another significant addition was the general chapter on 'Nitrosamine Impurities,' offering critical guidance for detecting and addressing these impurities in marketed pharmaceutical products, thereby enhancing drug safety.

THE INDIAN PHARMACEUTICAL MARKET HAS FACED CRITICISM FOR QUALITY ISSUES RECENTLY. HOW IS THIS BEING ADDRESSED?

The regulatory framework in India is robust, and stringent measures are undertaken to address instances of non-compliance. When manufacturers fail to meet the quality and regulatory parameters established by the CDSCO, immediate corrective actions are implemented.

These actions include recalling substandard drugs from the market, conducting comprehensive mapping of the supply chain to trace affected products, and initiating show-cause notices to manufacturers. Depending on the severity of noncompliance, regulatory authorities may also recommend further punitive measures. Such proactive interventions aim to uphold public trust in the pharmaceutical system while ensuring patient safety. The commitment to enforcing quality standards underscores the regulators' dedication to maintaining the integrity of the Indian pharmaceutical industry, even amidst challenges.



From Research to Industry Leadership

Dr Rajeev Singh Raghuvanshi's illustrious career reflects a seamless blend of academic excellence, innovative research, and impactful leadership in the pharmaceutical industry. A graduate of the prestigious IIT-BHU, Varanasi, he earned his bachelor's and master's degrees before pursuing a PhD at the National Institute of Immunology, New Delhi. His doctoral research focused on the development of Extended Release Vaccine Formulations, an innovative approach aimed at reducing the number of injections required for immunisation—a significant step toward improving vaccine compliance and accessibility.

After completing his PhD, Dr Raghuvanshi served at the National Institute of Immunology for seven years, contributing to cutting-edge research. He then transitioned to the private sector, joining Ranbaxy Laboratories Ltd., one of India's leading multinational pharmaceutical companies. Over the course of twelve years at Ranbaxy, he played a significant role in the development, registration, and launch of Novel Drug Delivery Systems (NDDS), generics, and branded generics across multiple global markets. His tenure at Ranbaxy not only underscored his technical expertise

but also showcased his ability to navigate the regulatory landscapes of various countries, enabling successful market entries.

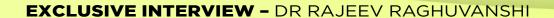
Building on this success, Dr Raghuvanshi moved to Dr Reddy's Laboratories Ltd., Hyderabad, where he spent the next eleven years in diverse roles. For the first eight years, he led the Chemistry, Manufacturing, and Controls (CMC) teams in the development of 505(b) (2) NDA products for the US market. Under his leadership, the company achieved first-cycle approvals for six products by the USFDA, an exceptional feat in the highly competitive pharmaceutical sector. These accomplishments required not only scientific rigor but also strategic coordination with regulatory agencies such as the USFDA, with whom he had multiple face-to-face interactions. Additionally, he engaged with regulatory bodies from countries like the UK, South Korea, Sweden, and Romania, further solidifying his global credentials.

The latter part of his tenure at Dr Reddy's Laboratories marked a shift in focus, as he spearheaded the establishment of an R&D team dedicated to emerging markets, including India, China, and Russia.



This role demanded an acute understanding of the unique pharmaceutical landscapes of these regions and involved innovation in product differentiation, regulatory registrations, and successful launches. His efforts ensured that the company maintained a competitive edge in markets characterised by distinct regulatory and consumer dynamics.

Dr Raghuvanshi's contributions extend far beyond corporate achievements. He has been instrumental in the development of more than 200 pharmaceutical products, many of which are currently being marketed in India, the US, Europe, and other emerging economies. His ingenuity is further reflected in his intellectual property







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Dr Raghuvanshi's vision, expertise, and leadership continue to shape the pharmaceutical landscape, both in India and globally, reinforcing his status as a transformative figure in the sector.

portfolio, which includes 19 granted US patents and over 250 published patents across PCTs and Indian filings. In addition to his contributions to product development, he has coauthored six book chapters and published more than 60 articles in peer-reviewed journals, thereby enriching the scientific literature in his field.

A passionate advocate for leadership development, Dr Raghuvanshi has mentored numerous professionals who now hold senior positions in leading pharmaceutical companies worldwide. His commitment to knowledge sharing is evident in his role as a visiting faculty member at esteemed institutions such as NIPER-Hyderabad and IIT-BHU, as well as his engagements at NIPER-Mohali, where

he has taught and inspired future industry leaders. He is also a sought-after speaker at international and national conferences, where his insights on pharmaceutical innovation and regulatory science have earned widespread acclaim.

For his outstanding contributions to the pharmaceutical industry, Dr Raghuvanshi has been recognised with numerous accolades, including the prestigious Dr Reddy's Excellence Award, which he received twice.

After a very successful career with corporate pharma, he decided to do something completely different which is socially more impactful. Of many possibilities, he chose to work with the Government of India and joined the MoHFW as Secretary-cum-Scientific

Director of Indian Pharmacopoeia Commission on 16 February 2021. In a short stint of two years, he changed the face of IPC and bought multiple long lasting changes impacting quality standards for medicines being sold in India. Cultural shift to more open and receptive organisation scaling up the Impurity Standards inventory, harmonisation of quality specification with ICH and other global standards, increasing user base for IP and IPRS, PDG membership for IP, international recognitions and scaling up of Pharmacovigilance Materiovigilance program of India are some of them. Dr Raghuvanshi's vision, expertise, and leadership continue to shape the pharmaceutical landscape, both in India and globally, reinforcing his status as a transformative figure in the sector.





CORRUPTION, CONTAMINATION, AND CRISS

Potential erosion of trust confronts India's pharmaceutical industry as substandard medicines continue to thrive and claim lives. From Gambia to Uzbekistan, several countries have suffered the consequences of systemic failures in both oversight and enforcement within India's drug regulatory framework, leading to the preventable deaths of innocent victims, often children, who are more vulnerable.

BY DR AMITAV BANERJEE

ith great privilege comes greater

responsibility, particularly the responsibility of ensuring quality control and safety. Unfortunately, India has outdated regulations—or no regulations at all—in some critical areas. Even the old regulations are applied with kid gloves by drug regulators, inspectors, and the judiciary, who tend to condone manufacturers of substandard drugs.

In the race for fast growth in the pharmaceutical industry, quality and safety are being sacrificed, often at the cost of innocent human lives. Recent amendments to the Drugs and Cosmetics Act of 1940, such as the Jan Vishwas Bill, instead of making drug regulations stricter, have introduced provisions whereby a manufacturer of substandard drugs can be let off by paying a monetary fine instead of facing imprisonment. The present narrative describes the tragedies that have resulted from lax drug regulations in our country.

Recent cases of such tragedies have occurred in foreign lands due to drugs imported from India, tarnishing the image of the country known as the "pharmacy of the world." Cases of substandard drugs lead to inquiries that are long and protracted, followed by court cases that are even longer and never-ending, with manufacturers of substandard drugs often continuing business as usual, while justice is denied to the victims.

A CHEQUERED PAST AND LESSONS NOT LEARNED

Over the years, drug regulation in India has gone from bad to worse. In 1986, after the deaths of 14 patients due to the consumption of glycerine contaminated with diethylene glycol (DEG) poisoning at the prestigious J J Hospital in Bombay (now Mumbai), the Chief Minister of Maharashtra appointed Justice Bakhtavar Lentin, a sitting judge of the Bombay High Court, to head a commission of inquiry into the tragedy.

The Lentin Committee produced an inquiry report spanning 300 pages, which indicted the Joint Commissioner of the Food and Drug Administration (FDA) in Maharashtra and did not even spare the State's Health Minister from accountability for the tragedy. The report's findings received wide coverage in the media, leading, albeit temporarily, to censure and suspension for many involved. The State's Health Minister had to resign, and senior officials of the State FDA, including the influential Joint Commissioner, were suspended. Several senior doctors at J J Hospital also faced suspension.

The Lentin Report summed up the problems of drug regulation in India. The executive summary is scathing, stating:

"These pages describe and illustrate the ugly faces of the human mind and human nature, projecting errors of judgment, misuse of ministerial power and authority, apathy towards human life, corruption, and quid pro quo between unscrupulous license holders, analytical laboratories, elements in the



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The recent Jan Vishwas Bill, which seeks to decriminalise certain drug offences, has raised alarms among public health experts. Critics argue that it sends the wrong message, potentially offering leniency to pharmaceutical companies that produce substandard medicines, at the expense of patient safety.







Dr Amitav Banerjee

The Lentin Report held the staff of J J Hospital accountable for poor communication and lack of swift action in withdrawing the stock of glycerine contaminated with DEG, Justice Lentin observed, "The success of any system must ultimately depend on the integrity and efficiency of those manning it, and if these attributes are found at the top, they must percolate downwards. It is here that the system has utterly failed, resulting in the kind of tragedy that struck J J Hospital."

The Lentin Commission also exposed the loopholes in the drug procurement systems of public hospitals, which allow for corruption at a huge public cost. It was revealed that the FDA granted a license to Alpana Pharma, which supplied the contaminated drug illegally, without ensuring that basic standards of quality were met. Ramanlal Karwa and his brothers, the owners of Alpana Pharma, enjoyed special status in the corridors of power. Even after their company was found responsible for supplying the killer product, the Karwa brothers, instead of facing imprisonment, continued to supply medicines to public hospitals under a different company name. Hospital administrators, on their part, went out of their way to place orders with them, exceeding the ceiling set by the industries department in their rate contract. Money was allegedly deposited in the private bank accounts of the committee members placing the orders.

industries department controlling the awarding of rate contracts, manufacturers, traders, merchants, suppliers, the FDA, and persons holding ministerial rank. None of this will be palatable to the affected quarters. But that cannot be helped."

The Lentin Report was tabled around 1986. Did the detailed inquiry and its recommendations bring about the needed change, or did it get confined to the pages of history? Unfortunately, unfolding events suggest the latter.

The 14 deaths at J J Hospital in 1986 may be just the tip of the iceberg. According to court documents, 150 patients in other hospitals across Maharashtra were also affected or disabled by the same batch of glycerine contaminated with DEG.

DEFAULTING FIRMS CONTINUE BUSINESS AS USUAL, GREASING THE PALMS OF REGULATORS



THE CASE DRAGS ON FOR FOUR DECADES IN THE COURTS WITH NO JUSTICE IN SIGHT

Though two charge sheets were filed in the case in 1990, the J J Hospital tragedy illustrates the difficulties that victims of adulterated drugs face in seeking justice. Nearly four decades on, the case continues to be heard at a metropolitan magistrate's court in Mumbai, but charges have still not been framed against the 24 people accused. Since the hearings began in 1991, two of the accused have died, while one is absconding. Most of the other accused are now between 70 to 90 years of age.

The Lentin Report, which pinpointed lapses at all levels leading to the tragedy, should have been sufficient evidence to convict those responsible, provided we had a strong and efficient system of justice. Unfortunately, the reality is different. Even after almost four decades, the case languishes in the courts. No amount of rules and regulations can compensate for the lack of accountability by the courts in convicting offenders within a reasonable timeframe. Justice delayed is justice denied.

The greater fallout of such a laissez-faire attitude is that it fails to convey a sense of urgency to the pharmaceutical industry to set its house in order. Only quick and harsh punishments for acts of commission and omission that put human lives at stake can act as a deterrent.

LESSONS FROM MILITARY LEADERSHIP DURING WORLD WAR II

Drawing a lesson from the Second World War, Field Marshal William Joseph Slim, in his memoirs titled Defeat into Victory, narrates:

"Good doctors are of no use without good discipline. More than half the battle against disease is not fought by doctors but by regimental officers. It is they who ensure that the daily dose of mepacrine (an anti-malarial tablet used in World War II) is taken... If mepacrine was not taken, I sacked the commander. I only had to sack three before the rest got my message. Slowly, but with increasing rapidity, as all of us—commanders, doctors, regimental officers, staff officers, and NCOs—united in the drive against sickness, results began to appear. On the chart that hung on my wall, the curves of admissions to hospitals and malaria in forward units sank lower and lower until, in 1945, the sickness rate for the whole 14th Army was one per thousand per day."

Crises like wars—and perhaps the one surrounding spurious drugs circulating in the market—bring out both the worst and the best in humans. We should strive to identify the best. Military leaders like Field Marshal Slim had the capacity to turn defeat into victory. Lessons from such military leadership, if adopted by our stakeholders—including doctors, drug inspectors, regulators, and the judiciary—can bring about the required reforms. Of course, all involved must have

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Despite India's reputation as a global pharmaceutical powerhouse, a series of recent tragedies involving contaminated drugs, including the deaths of children in several countries, highlight systemic issues within the industry. Substandard medicines continue to slip through the cracks, exacerbating an already fragile public health framework.



the courage to stand up to political interference.

HISTORY REPEATS ITSELF ON FOREIGN SOIL

Fast forward to recent times. In October 2022, the WHO issued a global alert on four cough syrups made in India, following the death of 69 children due to acute kidney failure in Gambia. Laboratory tests revealed that the cough syrups were contaminated with two highly toxic chemicals, diethylene glycol (DEG) and ethylene glycol, which are industrial solvents.

Before we could recover from the news of this tragic event, within a span of a couple of months, a similar tragedy occurred in Uzbekistan, where 19 children died after taking cough syrup manufactured in India. Once again, the deaths were linked to contamination of the cough syrups with DEG.

These tragedies are entirely preventable with proper checks and balances.

The first instance of large-scale DEG poisoning occurred in



1937 in the USA. Sulpha drugs had recently been invented, and a manufacturer wanted to make a liquid preparation of the antibiotic for children. They ended up using DEG as a solvent, unaware of its poisonous nature. After the drug entered the American market, a total of 105 patients—including 34 children—died. The chief chemist of the manufacturing plant committed suicide.

After this tragedy, drug regulations in the US became more stringent with a focus on safety. The US has never witnessed a single case of DEG poisoning since then. Alas, the same cannot be said for India and other developing countries, including those that import drugs from India.

DEVELOPING COUNTRIES ARE FACING THESE TRAGEDIES REPEATEDLY, AN INDICATION OF LAX DRUG REGULATION.

DEG poisoning has remained a recurrent phenomenon in the developing world. DEG poisoning killed 7 children in South Africa in 1969; 47 children died of DEG toxicity in Nigeria in 1990, and 84 again in 2018; 236 children died in Bangladesh between 1990–92; 29 people died in Argentina in 1992; 88 children died in Haiti in 1996; and 365 people died in Panama in 2007.

India's report card on DEG poisoning is equally dismal. It has had five major DEG poisoning events. The first occurred in Madras (now Chennai) in 1972, killing 15 children. The second in Mumbai in 1986 was at the famous J J Hospital, killing 14 patients. The third in Bihar in 1988 killed 11 patients. The fourth in Gurgaon in 1998 saw 33 children die after consuming cough syrup contaminated with DEG. The most recent victims were 12 children from Ramnagar, Jammu, as recently as 2019.

These tragedies were entirely preventable through the strict implementation of safety measures by pharmaceutical companies, combined with an overhaul of drug regulations.

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The tragic history of substandard drugs in India spans decades, from the 1972 poisoning in Madras to the most recent cases in Jammu. This ongoing crisis is a result of inadequate enforcement of safety measures and a deeply ingrained culture of corruption that prioritises profit over patient protection.

However, Indian pharma companies often fail to test either the raw materials or the final product before releasing it to the market, violating the Good Manufacturing Practices (GMP) laid out in Indian law, which mandates testing of both raw materials before they are used in production and the final drug sample before mass distribution.

DRUG REGULATORY SYSTEM IN INDIA IS UNWIELDY AND TOOTHLESS.

The drug regulatory system in India consists of the Central Drugs Standard Control Organisation (CDSCO) and 36 statelevel regulatory agencies. The CDSCO deals with new drugs, clinical trials, and imported medicines. The state authorities issue licenses for the manufacture, sale, and distribution of drugs. An important role of the state authorities is to carry out periodic inspections. This is supposed to prevent the manufacture and distribution of spurious or adulterated drugs. Since Independence, the buck has been passed to and fro between the central and state agencies, with ill-defined roles and a lack of accountability in implementing regulations. Inter-state jurisdictional ambiguities also give rise to many loose ends. Ill-defined hierarchies between the CDSCO and state drug authorities lead to a lack of accountability. This results in poor regulations and a lack of uniformity in drug quality across India.

Adding to the problem is the lax and lenient implementation of the letter of the law. Manufacturing drugs that are not of standard quality (NSQ) is a serious offence, punishable by imprisonment and hefty fines. But often, as documented in The Truth Pill, judges impose a fine of a few thousand rupees and a sentence of "simple imprisonment till the rising of the court."

JAN VISHWAS BILL: AN AMENDMENT TO THE DRUGS AND COSMETICS ACT, 1940 SENDS THE WRONG SIGNAL.

The Lok Sabha on 29 July 2023 and the Rajya Sabha on 2 August passed the Jan Vishwas (Amendment of Provisions) Bill. It essentially decriminalises 183 provisions in 42 laws, ostensibly to promote 'ease of doing business' in the country.

An amendment to the Drugs and Cosmetics Act, 1940, proposed in the Jan Vishwas Bill, introduces a provision for 'compounding' some offences, i.e., paying a fine instead of facing imprisonment. The bill amends Section 27 (d) of the Drugs and Cosmetics Act, 1940, allowing for the 'compounding' of offences that can be settled, where the complainant can agree to withdraw the charges.

On the surface, it aligns with the catchphrase 'minimum government, maximum governance,' supposedly making India a preferred country for the pharmaceutical industry. Whether this will compromise the safety and health of the people is a concern. In the race to become the pharmacy of the world, will quality suffer? Whatever the case, it certainly sends the wrong signal of leniency to the pharmaceutical industry.







India's regulatory structure, comprising the Central Drugs Standard Control **Organisation (CDSCO) and state** authorities, is marred by jurisdictional confusion, corruption, and a lack of coordination. These failures allow unsafe drugs to enter the market and contribute to recurring public health disasters across the globe.

Dinesh Thakur, author of The Truth Pill, which created quite a flutter, tweeted, "The Lok Sabha passed the Jan Vishwas Bill 2023 with little debate. This bill fulfils a longstanding wishlist of the industry that if you suffer bodily harm from substandard medicine, no one will be held punitively accountable."

A Member of Parliament expressed concerns: "When we buy a medicine, we assume the government has verified that it will work and it won't harm us. But the proposed amendment will now reduce punishments for medicines that are not of standard quality. It benefits big business but harms all of us. Very dangerous."

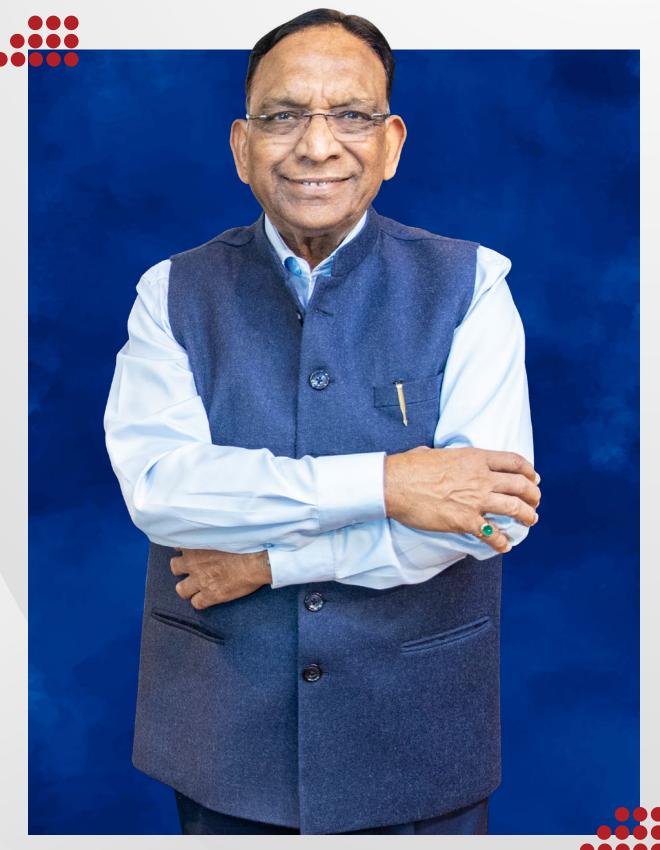
THE PATH TO REFORM

Democratising regulations, empowering citizens with information and the right to participate, and increasing accountability in public procurement are the keys to reform. Patient protection needs to be streamlined: while thorough testing and clinical trials are necessary to ensure drug safety, companies must be penalised for any lapses in the quality of drugs they supply.

This calls for an urgent re-strategising of the Indian pharma regulatory framework to focus on the quality of drugs, bringing patient safety back to the forefront of the discussion. There must be greater consultation among patients, families, civil society, doctors, parliamentarians, and policymakers because human lives are at stake.

(The author is a renowned epidemiologist and currently serves as Professor Emeritus at a Medical College in Pune, India. Having served as an epidemiologist in the armed forces for over two decades, he was recently ranked in Stanford University's list of the world's top 2% scientists.)









FACE 2 FACE Onteraction WITH MEDICAL LEGEND

DR VINAY AGGARWAL





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Dr Vinay Aggarwal,

former National President of Indian Medical the (IMA) Association and currently the Chairman of Pushpanjali Medical Centre, is a visionary thinker with an enduring aspiration to reform India's medical system. His mission involves integrating research and innovation into the healthcare landscape, aiming for transformative changes at the national level and aspiring to extend these efforts globally through collaborations with the World Medical Association.

With exceptional leadership qualities and the resolve to challenge conventional boundaries, Dr Aggarwal has been recognised with numerous prestigious awards. including the esteemed Dr B C Roy Award for his contributions to medical field. He envisions a comprehensive framework where quality, expertise and infrastructure are seamlessly integrated under the aegis of the IMA, positioning Indian healthcare as a global exemplar.

In an exclusive interview with Amresh K Tiwary, Dr Aggarwal candidly reflects on his journey, his landmark initiatives during his tenure at the IMA, and his unyielding commitment to addressing pressing healthcare challenges, such as violence against doctors and ensuring patient safety.



EXCERPTS FROM THE INTERVIEW:

YOUR JOURNEY IN HEALTHCARE IS TRULY INSPIRING. PLEASE SHARE WITH US THE PIVOTAL MOMENTS THAT SHAPED YOUR CAREER.

I come from a humble, middle-class background. After completing my schooling, I had the privilege of being selected for admission to two of India's premier medical institutions—All India Institute of Medical Sciences (AIIMS) and Maulana Azad Medical College (MAMC). However, due to financial constraints, I chose MAMC to pursue my MBBS.

Even during my medical education, financial struggles were a constant challenge. To make ends meet, I sold dissection boxes to afford books and pay my hostel fees. These hardships taught me resilience and shaped my determination to succeed. Significantly, I built strong connections with my seniors and professors during this time, which later proved invaluable in fostering a robust network within the medical fraternity.

After earning my MBBS degree, I joined an Employees' State Insurance Scheme of India (ESI) Hospital as a medical officer. However, I soon realised that my aspirations extended beyond the role of a practitioner—I wanted to make a broader impact. This led me to establish a family clinic in Krishna Nagar, Delhi in 1980 and then Pushpanjali Medical Centre in Anand Vihar, Delhi in 1989.

Building on this success, we went on to establish Pushpanjali Crosslay







Multispecialty Hospital in Vaishali, Ghaziabad, which later became Max Super Speciality Hospital. These experiences underscored my belief in creating institutions that not only deliver excellent healthcare but also embody compassion and community service.

DURING YOUR TENURE AS THE IMA PRESIDENT, YOU LED A PROJECT TO IMPROVE HEALTHCARE IN RURAL VILLAGES. CAN YOU SHARE SOME SUCCESS STORIES FROM THIS PROJECT AND THE CHALLENGES YOU FACED IN IMPLEMENTING IT?

Indeed, every new initiative comes with its share of challenges, but it is through overcoming these hurdles that meaningful change is achieved. One of the projects closest to my heart is "Aao Gaon Chalen", which was initiated to improve healthcare access in rural areas. This initiative was introduced during the historic 191st Central Working Committee Meeting of the IMA, held from 6th to 8th June 2004 in Bangkok.

The project was formally launched on 8th August 2004 in Lakhvad, a village in Mehsana District, Gujarat. From there, it expanded significantly, with IMA state branches adopting villages across the country. Local branches identified villages based on need assessments, community requirements, and opportunities for inter-sectoral coordination, ensuring that the interventions had a wide-reaching impact.

The core goal of "Aao Gaon Chalen" was to bring about a holistic improvement

in rural health by leveraging existing infrastructure and fostering partnerships among the IMA, public healthcare delivery systems, and the local community. The initiative, supported by UNICEF and some of the National Health Programmes, involved training medical professionals through ten workshops conducted in places such as Haryana, Punjab, Chennai, Ahmedabad, Trivandrum, Kanpur, Guwahati, Kolkata, Hyderabad, and Nagpur in 2004.

The results of this initiative have been transformative. Over 1,040 villages have been adopted by various IMA state and local branches to date, and the project has benefitted more than two million people. Monthly activity reports from several branches are still being compiled, but the impact of this initiative is clear. It represents a shining example of public-private partnership, aligning the efforts of the



IMA with the Ministry of Health & Family Welfare to enhance rural healthcare delivery systems.

WHAT WAS THE GOAL OF THE PROJECT, AND HOW WAS IT IMPLEMENTED?

The overarching goal was to improve the health scenario in rural villages by promoting inter-sectoral coordination and optimising the use of existing resources. By actively involving the IMA, public healthcare systems, and community stakeholders, the project sought to foster a sustainable model of rural healthcare development.

Workshops conducted as part of the initiative trained healthcare professionals in rural health management, while the adoption of villages allowed for targeted interventions tailored to local needs. Activities included health camps, awareness campaigns, and capacity-building programmes for local healthcare providers.

Through "Aao Gaon Chalen," the IMA demonstrated that with a concerted effort, even the most underserved communities could gain access to quality healthcare. This initiative continues to inspire similar efforts to address the healthcare needs of the country.

IS IT TRUE THAT DURING YOUR TENURE AS IMA PRESIDENT, THE "SAVE THE GIRL CHILD" INITIATIVE GAINED SIGNIFICANT RECOGNITION?

Yes, the "Save the Girl Child" programme has been one of IMA's flagship initiatives, and it holds a special place in my heart. This initiative, which defines "girl child" as a female up to the age of 18, is aimed at providing comprehensive support to girls, particularly from underprivileged





backgrounds.

One of the key features of this programme is the provision of financial assistance. For instance, individuals can contribute by depositing a fixed amount of ₹1.5 lakh in a bank, with the accrued interest being credited to the girl's account until she turns 18. Upon reaching adulthood, the donor can reclaim the principal amount.

Other aspects of the initiative include organising skill development programmes to empower girls with income-generating skills, supporting free heart surgeries for girls whose families cannot afford treatment, and adopting schools to provide health



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To make ends meet, I sold dissection boxes to afford books and pay my hostel fees. These hardships taught me resilience and shaped my determination to succeed.

lectures and health check-ups. Additionally, the initiative addresses nutritional deficiencies by distributing iron and folic acid supplements in schools and raises awareness about child sexual abuse and the legal protections available.

The programme also encourages doctors to waive consultancy fees for the birth of a girl child and provides assistance to girls requiring critical medical treatment. Through campaigns like "950", the initiative aims to address the gender imbalance by raising the child sex ratio to 950 girls for every 1,000 boys.

The "Save the Girl Child" initiative is more than a healthcare programme; it









is a societal movement advocating for the dignity, safety, and rights of every girl child in India.

Q: MENTAL HEALTH IS OFTEN A
NEGLECTED AREA IN INDIAN
HEALTHCARE. HOW CAN
HEALTHCARE PROVIDERS AND
POLICYMAKERS BETTER
ADDRESS MENTAL HEALTH
ISSUES ACROSS DIFFERENT
DEMOGRAPHICS?

A: Mental health is an integral yet severely neglected aspect of healthcare in India. Globally, mental health challenges have reached alarming proportions, with over 726,000 people dying by suicide annually. This accounts for 73 per cent of global suicides predominantly occurring in low- and middle-income countries. Suicide remains the third leading cause of death among individuals aged 15–29, an age group

that represents the backbone of any nation's workforce and future. The global suicide rate among men is also more than double that of women, emphasising the need for genderspecific approaches to mental health.

In India, the situation is quite grim. The National Crime Records Bureau (NCRB) data, released in August 2022, highlighted an alarming surge in suicides. In 2021, the country recorded 164,033 suicides, marking a 7.2% increase from the previous year. This figure rose to 171,000 in subsequent years, the highest ever recorded. These staggering numbers underscore an urgent public health crisis, as most suicides stem from unresolved or untreated mental health issues.

Policymakers and healthcare providers must adopt a multi-pronged approach to combat this crisis:

1. AWARENESS CAMPAIGNS:

Educating the public to reduce stigma surrounding mental health disorders and promote early intervention.

2. COMMUNITY OUTREACH:

Leveraging local healthcare workers and NGOs to deliver mental health education and services, especially in rural areas.

3. WORKPLACE POLICIES:

Encouraging mental health support systems in schools, colleges, and workplaces to address the needs of students and employees.

4. HOLISTIC MEDICAL EDUCATION:

Reforming curricula to focus on mental health, ensuring future healthcare professionals are equipped to handle such issues compassionately.

The World Health Organization (WHO) defines mental health as more than





just the absence of mental disorders. It is a state where individuals can realise their potential, cope with everyday stresses, work productively, and contribute meaningfully to their communities. Mental health must, therefore, be seen not only as the absence of illness but as an active pursuit of happiness, well-being, and balance.

Risk factors for mental health disorders are diverse and multifaceted. They include:

- **MODIFIABLE FACTORS:** Socioeconomic conditions, employment opportunities, quality of housing, and access to education.
- **NON-MODIFIABLE FACTORS**: Age, gender, ethnicity, and genetic predispositions.

It's important to note that having a

family history of mental illness does not guarantee the development of a disorder, just as the absence of such a history does not ensure immunity. Environmental, social, and lifestyle factors play an equally critical role in shaping mental health.

A collective effort, involving policymakers, healthcare providers, educators, and the public, is essential to ensure that mental health becomes a priority for the nation's overall growth and well-being.

Q: TODAY, VIOLENCE AGAINST DOCTORS HAS BECOME A CRUCIAL CONCERN, WITH INCIDENTS LIKE THOSE AT RG KAR MEDICAL COLLEGE, KOLKATA. WHAT IS YOUR TAKE?

A: The issue of violence against doctors has reached alarming levels and has persisted for over three decades. This violence often stems unrealistic expectations. dissatisfaction with healthcare outcomes, and frustrations related to the high cost of medical care. These challenges are exacerbated by the government's inadequate investment in healthcare, which currently stands at 1.1% of GDP-a meagre sum compared to the total healthcare expenditure of approximately ₹13 lakh crore.

This financial shortfall places enormous pressure on both public and private healthcare systems. Despite their diversity, ranging from corporate tertiary care hospitals to small private clinics, instances of violence are uniformly distributed, with government hospitals frequently bearing the brunt.

In the 1980s, during my family practice, I never encountered incidents of violence. However, today's scenario is starkly different, characterised by a

significant increase in both the frequency and intensity of such incidents. This shift highlights the growing trust deficit between patients and healthcare providers.

The Supreme Court has taken steps to address this issue, and organisations like the IMA are advocating for comprehensive solutions. Key measures include:

- 1. DECLARING HOSPITALS AS SAFE ZONES: Implementing strict security protocols to ensure the safety of healthcare professionals and patients alike.
- 2. ENHANCING WORKING CONDITIONS: Providing adequate staffing, resources, and support systems to reduce stress among medical personnel.
- **3. ENACTING STRINGENT LAWS:** Introducing legislation with severe penalties for those who commit violence against healthcare workers.

It is imperative to create an environment where doctors can work without fear, ensuring that healthcare delivery remains effective and compassionate. I, as IMA's Action Committee Chairman, will keep on fighting for bringing a Central law against violence against medical professionals.

Q: WHAT IS YOUR TAKE ON PATIENT SAFETY CONCERNS?

A: Patient safety is a cornerstone of quality healthcare but remains a challenge due to systemic inefficiencies. It has evolved into a distinct healthcare discipline, supported by extensive research across various fields. However, its implementation often encounters resistance due to hierarchical barriers within hospitals.



For example, quality managers, who are typically junior in the hospital hierarchy, may struggle to convince senior clinicians of the importance of safety protocols. Meanwhile, administrators, focused on financial outcomes, may overlook safety concerns altogether.

TO ADDRESS THESE CHALLENGES:

- 1. All departments and personnel must take ownership of safety protocols.
- 2. Senior medical professionals must actively lead and support safety initiatives.
- 3. Structured discussions should take place within departments to review and refine processes.

By fostering a culture of accountability and continuous improvement, healthcare institutions can significantly enhance patient safety standards.

Q: DON'T YOU THINK THERE ARE MAJOR CHALLENGES LIKE UNFAVOURABLE OUTCOMES AND COSTS IN HEALTHCARE?

A: Unquestionably, unfavourable

outcomes and high costs are two of the most pressing challenges in modern healthcare. Public perception of the medical profession is increasingly negative, fuelled by media coverage of medical errors and incidents of violence. This has contributed to a deepening trust deficit between the public and healthcare providers.

Unfavourable outcomes, which occur when healthcare interventions do not yield the expected results, are often a result of the complexities of modern medicine. According to the Joint Commission's Annual Report on Quality and Safety (2007), over half of serious adverse events in hospitals are caused by poor communication among healthcare providers, patients, and families. Other contributing factors include inadequate patient assessments, leadership failures, and insufficient documentation.

Addressing these issues requires a systematic overhaul of healthcare delivery processes. including:

- **IMPROVED COMMUNICATION:** Ensuring clarity and transparency between all stakeholders.
- STRUCTURED TRAINING

PROGRAMS: Equipping healthcare professionals with the skills needed to manage complex cases effectively.

• ROBUST DOCUMENTATION: Maintaining comprehensive records to minimise disputes and improve patient outcomes.

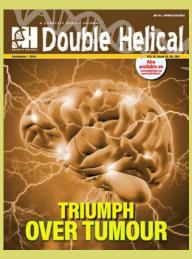
Q: IN THE PUBLIC MIND, PRIVATE HEALTHCARE IS SEEN AS "UNREASONABLY" EXPENSIVE. WHAT CAUSES THIS PERCEPTION?

A: The cost of private healthcare appears "unreasonably" high due to the complex nature of quality healthcare delivery. Factors influencing costs include hospital type (secondary vs. tertiary), location (Tier-I, II, or III cities), and specialisation (single vs. multispecialty). Efforts like government health insurance schemes often fix procedure costs based on the lowest tender quotes, which fail to meet the expectations of consumers and providers alike.

Transparency in cost structures and a balance between affordability and quality are essential to addressing this perception. Developing standardised models for costing can help bridge the gap between public expectations and provider capabilities.

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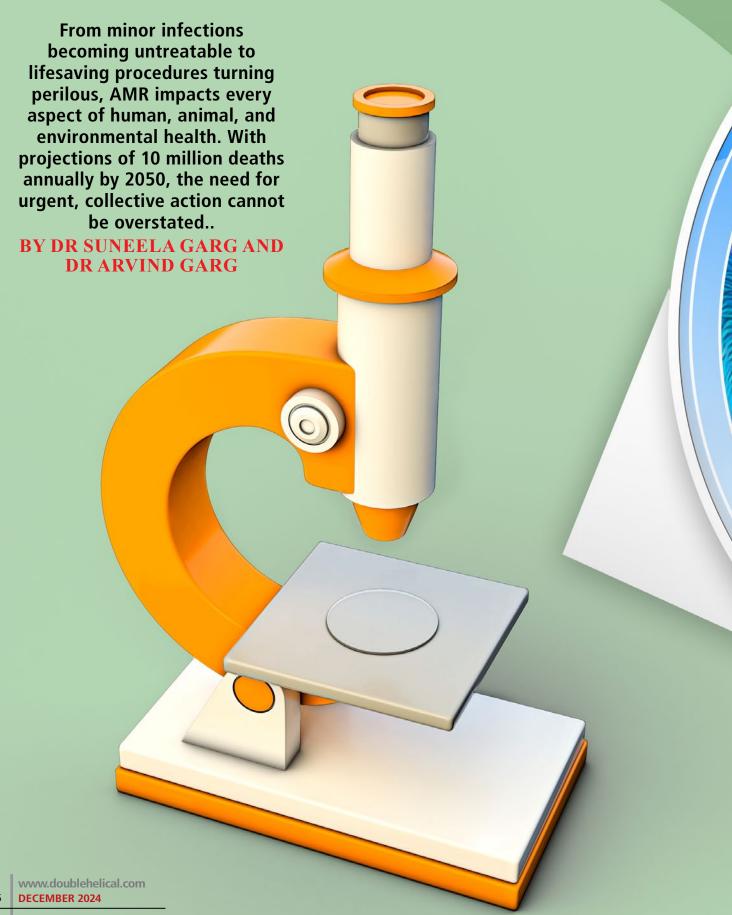
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CONCERN - AMR





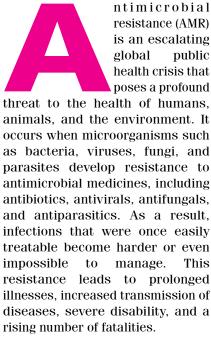


CONCERN - AMR









The misuse and overuse of antimicrobials in humans, animals, and agriculture are the primary factors driving the development and spread of drug-resistant pathogens. Addressing this crisis demands immediate and comprehensive action across all sectors of society, including healthcare, agriculture, and the environment.



Dr Arvind Garg

WORLD ANTIMICROBIAL RESISTANCE AWARENESS WEEK

The World Antimicrobial Resistance Awareness Week (WAAW) is observed annually from 18-24 November. This global initiative aims to raise awareness about AMR, educate stakeholders across the spectrum of human, animal, plant, environmental health, and advocate for measures to curb the emergence and spread of resistant pathogens. This year's theme, "Educate. Advocate. Act Now," underscores the urgency of the issue, urging the global community to take immediate action. The campaign calls for educating policymakers, healthcare providers, and the public, advocating for bold commitments, and implementing tangible, actionable strategies to combat AMR.

THE DEVASTATING IMPACT OF AMR

AMR is responsible for an alarming toll on human health. In 2019, it directly caused 1.27 million deaths worldwide and contributed to an additional 4.95 million deaths. These numbers are projected to worsen if



no significant action is taken. By 2050, AMR could lead to the deaths of 10 million people annually, surpassing the mortality rates of major diseases like cancer.

Beyond its human toll, AMR has severe economic consequences. It is estimated that the global cost of AMR could reach USD 3.4 trillion annually by 2030, pushing 28 million people into poverty. The financial burden is exacerbated by prolonged hospital stays, the need for more expensive treatments, and loss of productivity due to illness and disability.

Patients with pre-existing conditions such as cancer, diabetes, or HIV are particularly vulnerable, as







AMR's impact extends beyond health, threatening food security and global economies. By 2030, the global cost of AMR could reach \$3.4 trillion annually, driving 28 million people into poverty. Coordinated action across sectors is imperative to curb this growing crisis.

AMR compounds their susceptibility to infections. Routine medical procedures, such as caesarean sections, organ transplants, and chemotherapy, become significantly riskier due to the potential for untreatable infections. Even individuals in good health are not immune, as minor injuries or common infections could escalate into life-



CONCERN - AMR



threatening conditions.

A SILENT EPIDEMIC WITH A GLOBAL REACH

AMR knows no borders. Like the COVID-19 pandemic, it is a transnational threat requiring coordinated global action. No single country can combat AMR in isolation. Collaborative efforts are essential to track resistance patterns, identify high-burden regions, and develop targeted interventions.

Proposals for an international treaty on AMR have been put forth to establish a unified framework for addressing this crisis. A global tracking system is also being considered to monitor resistance levels and guide policy decisions. The United Nations General Assembly (UNGA) High-Level Meeting on AMR in 2024 provides a critical platform for world leaders to commit to these measures and take decisive action.

Addressing AMR Across Sectors

Efforts to combat AMR must be inclusive and multi-sectoral. The concept of One Health, which integrates human, animal, and environmental health, is central to these initiatives. Reducing the overuse and misuse of antimicrobials across all domains is crucial.

At an individual level, practical measures can significantly reduce the spread of AMR. Vaccination is one of the most effective strategies, as it prevents infections and thereby reduces the reliance on antibiotics. Good hygiene practices, such as regular handwashing with soap, are fundamental in preventing infections. Safe food handling practices—such as thoroughly cleaning hands, surfaces, and utensils during food preparationplay a key role in preventing foodborne illnesses. Antibiotics should only be used when prescribed by a healthcare professional, and the prescribed course should always



Antimicrobial resistance directly caused 1.27 million deaths worldwide in 2019 and contributed to an additional 4.95 million fatalities. Experts warn that if left unchecked, AMR could surpass cancer as a leading cause of death by 2050.

be completed to prevent resistance from developing. Sharing or using leftover antibiotics should be strictly avoided. Wounds and cuts should be cleaned properly and kept covered until fully healed to minimise the risk of infection. Additionally, managing chronic conditions such as diabetes or heart disease effectively reduces susceptibility to

infections and the subsequent need for antibiotics.

Healthcare providers are at the forefront of the fight against AMR and have a critical role in this battle. They must prescribe antibiotics judiciously, ensuring they are only used when absolutely necessary. Educating patients about the correct use of antimicrobials is essential to foster





b e t t e r understanding and compliance. Strict adherence to infection prevention protocols, including hand hygiene and the sterilisation of medical equipment, is non-negotiable. Quarantining patients with drugresistant infections can help prevent the spread of these pathogens within healthcare settings and communities.

THE IMPACT ON FOOD SECURITY

AMR also poses a significant threat to global food security. Drug-resistant infections can spread through the food chain, impacting both animal and human health while causing substantial economic losses in the agricultural sector.
Overuse of antibiotics
in livestock farming is
a major contributor to
the problem, further
complicating efforts to ensure
sustainable food production.

HUMAN STORIES BEHIND THE STATISTICS

While the numbers illustrate the magnitude of the AMR crisis, the human stories behind these statistics are equally compelling. Survivors of drug-resistant infections often endure prolonged suffering, financial hardship, and emotional trauma. Advocacy efforts by survivors and their families have helped put a human face on the AMR crisis, raising awareness and inspiring action

against this invisible but deadly threat.

TAKEAWAYS

AMR is one of the greatest challenges of our time, threatening to reverse decades of medical progress. Governments, nongovernmental organisations (NGOs), healthcare professionals, academic institutions, and civil society must unite to combat this crisis. The time for action is now. By addressing AMR with the urgency it demands, we can protect the health and well-being of current and future generations.

(The authors are Chair, Programme Advisory Committee, National Institute of Health & Family Welfare, and Director, Child Care Clinic & Head of Paediatrics, Apollo Hospital, Noida.)



TROUBLES

Healthcare delivery in India faces dual challenges: unfavourable outcomes and the rising cost of care. While systemic issues such as inadequate communication and teamwork compound unsatisfactory healthcare delivery, private hospitals face accusations of profiteering, even as they struggle to balance care and costs

BY DR VIJAY AGARWAL

ealthcare and the medical profession are increasingly finding themselves at the centre of public scrutiny. It is rare to come across a gathering where the topic of medical practice is not tinged with negative overtones. The media, too, seems to spotlight incidents almost daily that fuel the growing trust deficit between the public and

ASSESSMENT - OUTCOMES & COSTS





healthcare professionals. Reports of medical errors and cases of violence against doctors and healthcare workers dominate headlines, leaving the medical fraternity beleaguered and overwhelmed.

A closer and dispassionate examination reveals that these issues stem from challenges at multiple levels. Two concerns in particular—unfavourable outcomes and the perceived exorbitant cost of healthcare—stand out as recurring points of contention among the community and within public discourse.

UNFAVOURABLE OUTCOMES

The increasing complexity and hightech nature of healthcare delivery have made adverse events an unfortunate reality even in countries with advanced healthcare systems. The Joint Commission's Annual Report on Quality and Safety in 2007 noted that inadequate communication between healthcare providers, or between providers and patients or their families, was responsible for over half of all serious adverse events in accredited hospitals. Other significant contributors to these outcomes included insufficient assessment of patients, poor leadership, inadequate training, and incomplete of documentation—all which exacerbate disputes when adverse events occur.

Part of the problem lies in the fact that clinicians, despite their expertise, often lack training in soft skills, an essential but largely neglected component of the medical curriculum. This shortcoming becomes particularly glaring in the modern context, where healthcare delivery increasingly relies on effective teamwork rather than the isolated efforts of individual practitioners. Unfortunately, many clinicians struggle to adapt to this paradigm shift, resulting in gaps in communication and coordination.

To mitigate these issues, medical professionals must prioritise adherence to patient safety guidelines, enhance communication with patients and colleagues, and adopt more efficient, team-based work processes. The concept of patient safety has evolved into a distinct healthcare discipline, enriched by extensive interdisciplinary research. However, despite the availability of evidencebased practices, there remains a reluctance among clinicians to learn from quality managers, who are often

ASSESSMENT - OUTCOMES & COSTS



specialists in process improvement. This hesitance is partly due to hospital hierarchies, where quality managers are generally junior to senior clinicians and struggle to assert the importance of following protocols and ensuring thorough documentation.

Simultaneously, hospital administrators, preoccupied with financial performance, often downplay quality-related concerns raised by their teams. This lack of alignment between management and clinical staff hinders the successful implementation of patient safety measures. Effective quality implementation requires the active involvement of all stakeholders, with clinicians leading the charge. SOPs and guidelines must be embraced collectively by every department within a hospital. However, many institutions lack the structured and regular forums needed to foster this collective accountability.

The introduction of regular, structured meetings—often referred Operational Excellence Meetings—can serve as a critical tool in this regard. These meetings involve representatives from all departments, the quality management team, and hospital leadership, with a defined agenda to review and address quality issues. Such forums ensure that clinicians and nurses responsibility for quality initiatives, while the role of quality personnel shifts to auditing processes and presenting actionable insights.

COST OF HEALTHCARE

The second major concern revolves around the cost of healthcare, which is increasingly perceived by the public as unreasonably high. In popular discourse, these costs are often attributed to ethical lapses or malpractice within the medical profession. However, the issue is far more nuanced and complex. To determine whether healthcare costs

are truly unreasonable, it is essential to first understand the foundational aspects of delivering quality healthcare.

The cost of quality healthcare delivery involves a wide array of variables, making it difficult to arrive at a straightforward answer. Factors such as the type of hospital—whether it provides secondary or tertiary care, or whether it is a single-speciality or multi-speciality facility—play a significant role. Additionally, the location of the hospital, whether in a tier-I metropolitan city or a smaller tier-II or tier-III town, further impacts cost structures.

Efforts have been made to address this complexity. For instance, some insurance companies have developed differential packages for various procedures, taking into account factors such as hospital type and location. Government health insurance schemes have also attempted to regulate costs by fixing rates for procedures based on L1 (lowest) tender quotes from private hospitals. However, these approaches have fallen short of meeting the expectations of either consumers or healthcare providers. While patients often find these rates insufficient to cover their needs, hospitals argue that the fixed rates do not adequately account for the true cost of delivering high-quality care.

The debate around healthcare costs and unfavourable outcomes underscores the need for systemic changes. Addressing these twin challenges requires a collaborative effort that prioritises patient safety, fosters open communication, and ensures that quality care is both accessible and sustainable.

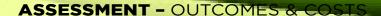
ANALYSING OPERATIONAL HEALTHCARE COSTS

The operational cost of a medical procedure encompasses numerous components, with the major cost



heads typically drawn from direct expenses such as doctors' fees, the cost of drugs, and other medical consumables. However, this is only part of the picture. A range of indirect costs significantly impacts the overall expense, including salaries for allied healthcare workers like nurses, rental lease costs for facilities, administrative expenses, utilities, legal and regulatory compliance fees, and marketing or advertising expenses for hospital services. Moreover, the capital invested in medical equipment adds another layer of cost. Such equipment is not only expensive but also has a finite lifespan, resulting in depreciation that further contributes to operational expenses. Interest on loans for plant, machinery, and working capital also forms a crucial component of healthcare costs.

Despite these substantial cost elements, the pricing of most medical procedures remains arbitrary, driven







more by market dynamics than by a thorough assessment of actual costs. Hospitals often make profits on some aspects while incurring losses on others, but public perception focuses on the profitable components, overshadowing the areas where hospitals offer services at highly economical rates. Contrary to the belief that private hospitals reap enormous profits, many of these institutions face considerable financial stress, with a slow and often insufficient Return on Investment (ROI).

There is a pressing need for hospitals to reassess and rationalise their billing and pricing models. Equally, society must allow time for such adjustments to take place, acknowledging the complexities involved. One way to demystify the cost structure of healthcare delivery is to analyse expenditures incurred in government-run hospitals, which



can provide valuable benchmarks and insights.

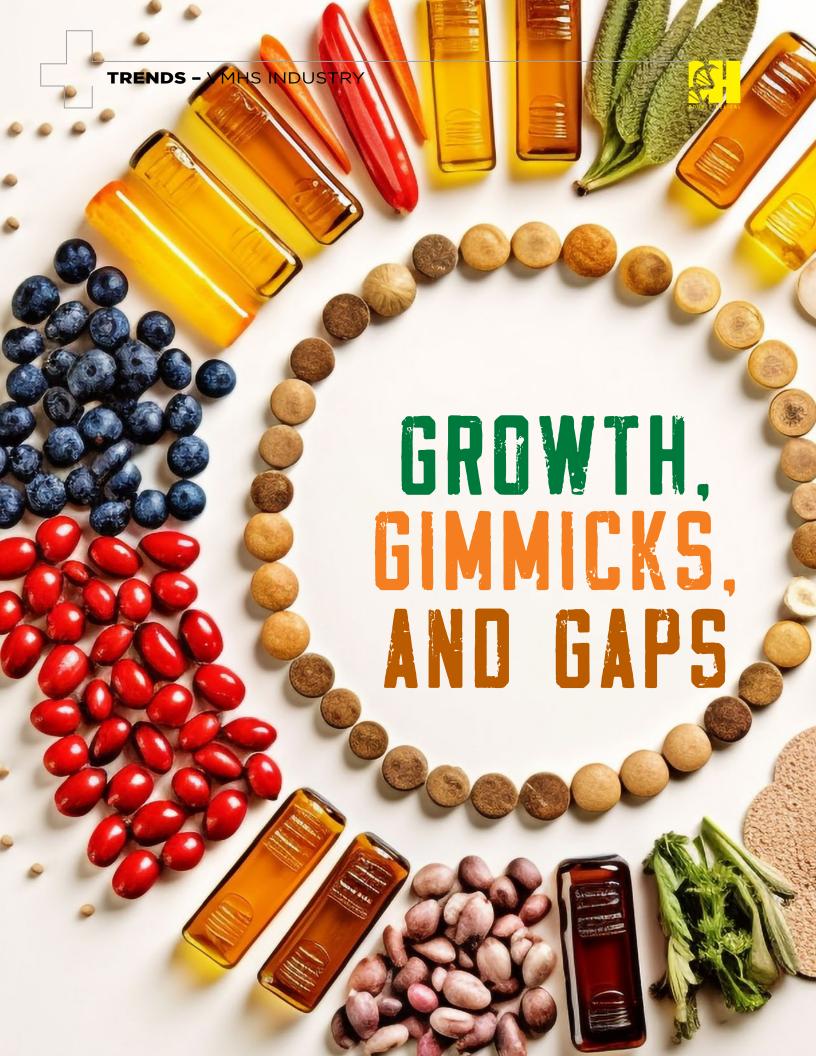
Healthcare has also become a focal point in political agendas, with an increasing number of government health insurance schemes aimed at advancing the goal of Universal Health Coverage. These cashless schemes allow patients to access secondary and tertiary care at hospitals of their choice, with the government bearing the costs. According to the World Bank, nearly 50 per cent of India's population is now covered under some form of health insurance. However, a critical challenge lies in the unilateral fixing of package rates for various medical procedures by the government, often without consulting healthcare providers.

A recent study conducted by the Government of Karnataka in collaboration with the Indian Institute of Management Bangalore (IIMB), the Association of Healthcare Providers of India (AHPI), and the Consortium of Accredited Healthcare Organisations (CAHO) revealed that these government-mandated rates are frequently unviable for tertiary care and super-speciality hospitals that adhere to quality standards. With a growing proportion of the population accessing healthcare through government or private insurance,

hospitals are increasingly compelled to accept patients at these unsustainable rates. While some degree of cross-subsidisation from cash-paying patients may temporarily offset these losses, this practice is neither a sustainable solution nor one that supports the maintenance of high-quality services.

The government and insurance companies must recognise that safe and effective healthcare comes at a definite cost, and the absence of adequate funding jeopardises not only service quality but also patient safety. Pricing for medical procedures needs to be determined on a scientific basis rather than through tendering processes or perceived affordability.

A significant contributor to the perception of healthcare being "expensive" is the lack of financial planning for medical emergencies. For most individuals, sickness is an unanticipated event, making the cost of treatment for serious ailments appear disproportionately high. Another factor influencing this perception is the existence of government-run healthcare facilities that offer "free" services. However, it is important to note that these services are not truly free; they are financed by taxpayers' money.





India's dietary supplements market faces challenges, including counterfeit products, high costs, and regulatory ambiguities. While innovation and personalised solutions are reshaping consumer engagement, the lack of affordability and trust remains a formidable hurdle for widespread adoption..

BY ABHIGYAN/ABHINAV

one are the days when primary care doctors provided all the answers to health concerns. Today, consumers increasingly rely on alternative channels for self-diagnosis and targeted health needs. This shift is partly driven by higher co-pays from insurers and incentives encouraging preventive healthcare measures.

In recent years, there has been heightened scrutiny over potential bans by the US Food and Drug Administration (FDA) on certain vitamins and supplements deemed harmful, such as specific forms of vitamin B6 and certain energy

supplements. Concurrently, clinical research trials are investigating the efficacy and long-term benefits of vitamins. Some studies suggest that large doses of certain vitamins might increase the risk of cardiac events in elderly individuals or those with heart disease.

While stricter regulations will introduce complexities for manufacturers, they also present opportunities for responsible industry players to shape the market. Proactive collaboration with regulatory bodies can establish stringent standards, enhancing consumer confidence in the safety and efficacy of Vitamins, Minerals, and Health Supplements (VMHS). This, in turn, benefits the market overall.

MARKET TRENDS AND GROWTH DRIVERS

Vitamins play a pivotal role in

TRENDS - VMHS INDUSTRY



healthcare products, including dietary supplements and pharmaceuticals, driven by a growing emphasis on preventive healthcare among healthconscious consumers. The rising prevalence of vitamin deficiencies in both developed and developing nations further fuels demand.

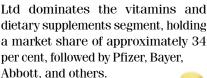
The increasing popularity of fortified food and beverages, coupled continuous with innovations and product launches, has bolstered the vitamins market in the food and beverage sector. The market is segmented by source into synthetic and natural s China to meet growing needs.

GLOBAL AND REGIONAL MARKET **DYNAMICS**

The global vitamins market, projected to reach USD 8.5 billion by 2024, is led by major players such as:

- Koninklijke DSM N.V. (Netherlands)
- BASF (Germany)
- ADM (United States)
- Lonza Group (Switzerland)
- Glanbia plc (Ireland)

In India, Amway India Enterprises Ltd dominates the vitamins and dietary supplements segment, holding a market share of approximately 34 per cent, followed by Pfizer, Bayer,





significant growth is driven by China, the largest producer, exporter, and consumer of vitamins. Factors such as rising incomes, increased purchasing power, and consumer demand for nutritional products contribute to the market's expansion. The region

> also benefits from the growing application of vitamins in the livestock feed industry, addressing the demands for high-quality dairy, meat, and egg products.

Challenges and **Opportunities**

The preference for synthetic vitamins remains strong due to the limited availability and



TRENDS - VMHS INDUSTRY







high costs of raw materials for naturally sourced vitamins. Synthetic vitamins, derived from petroleum extracts or coal tar derivatives, are cheaper to produce and widely available.

In India, the dietary supplements market has experienced a robust CAGR of 20 per cent between 2015 and 2023. Vitamins and minerals dominate this market with a 40 per cent share, followed by herbal supplements (30 per cent), proteins (25 per cent), and other categories (5 per cent). Despite their dominance, tablet and capsule formats face resistance due to their medicinal connotation. As the market

evolves, formats like gummies and jellies, offering better taste and convenience, are gaining acceptance.

Urbanisation and lifestyle changes in India, particularly among IT-BPO professionals and fitness enthusiasts, further drive the vitamins market. These consumers seek supplements to fill nutritional gaps, improve fitness, and support general health.

REGIONAL TRENDS AND CONSUMER BEHAVIOUR

Asia-Pacific witnessed tremendous growth in the vitamins market in 2018 and is projected to grow at the highest CAGR through 2024. This growth is

primarily attributed to increasing demand in China, driven by rising incomes, urbanisation, and greater health awareness. The livestock feed industry also contributes significantly to this growth, as livestock owners increasingly focus on nutrition.

The preference for synthetic vitamins continues to dominate due to their cost-efficiency and the challenges associated with sourcing natural raw materials. Most synthetic vitamins are derived from petroleum extracts or coal tar derivatives, making them an economical choice for manufacturers.

EXPANDING HORIZONS: INDIA'S

TRENDS - VMHS INDUSTRY

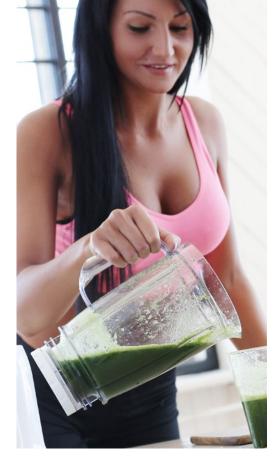


DIETARY SUPPLEMENTS MARKET

Globally, the vitamins market is led by major players such as Koninklijke DSM N.V., BASF, Lonza Group, and ADM. In India, the vitamins segment is dominated by Amway India, with competitors such as Pfizer, Abbott, and Bayer also holding significant shares. The market's competitive nature has prompted companies to innovate with new delivery formats, targeting evolving consumer preferences for health and wellness products.

The Indian dietary supplements market is experiencing exponential growth, driven by rising health consciousness, economic development, and an expanding working-class population with higher disposable incomes. Factors like endorsements by celebrities and sustained investments in R&D for product innovation are opening lucrative opportunities for industry players.

The rapid digitisation of India and increased social media usage have boosted awareness about nutrition and improved access to vital health information. Lifestyle changes are contributing to a rise in noncommunicable diseases such as diabetes, obesity, and cardiovascular conditions. These shifts have created demand for dietary





high-income consumers, with this trend expected to grow significantly.

E-commerce has emerged as a key growth driver, providing easier access to dietary supplements alongside rising per capita income. However, challenges remain, such as the lack of a clear regulatory framework. Currently, around 60 per cent of dietary supplements in India are counterfeit or unregistered, posing significant risks to consumers. Additionally, high prices

for products like protein supplements limit their affordability for lower-middle-class and rural populations.

Strategies and Innovations

To address these challenges, dietary supplement manufacturers are focusing on consumer education and quality improvement. Capsules, which are easier to swallow and offer formulation flexibility, are preferred by consumers. Emerging technologies like liquid encapsulation enhance ingredient protection and are shaping future product designs.

The market for Vitamins, Minerals, and Health Supplements (VMHS) is also evolving, with consumers increasingly taking control of their health decisions. Manufacturers have responded by ramping up education and marketing efforts and offering personalised solutions through online







tools. These strategies have created a more informed and self-reliant consumer base.

EVOLVING SALES CHANNELS

The VMHS industry is highly no fragmented, with single manufacturer dominating the market. For example, Living Essentials holds just 7 per cent of market share, and the top five branded manufacturers collectively account for less than 25 per cent. Supermarkets hypermarkets lead in sales, followed closely by online stores and specialty retailers like GNC.

Online sales have surged, driven by improved shopping experiences, better online education, and targeted marketing. Platforms like Amazon have tailored their offerings to specific demographics, such as the 50+ age group, while competitors like vitacost. com are creating niche online destinations. Live chat options on these platforms help address consumer questions, further easing the online shopping journey.

Eastern Health and Personalised Solutions

The growing interest in Eastern health and wellness products has added another dimension to the dietary supplements market. Younger consumers are particularly drawn to these offerings, and online platforms make them easily accessible. Personalised VMHS systems, such as 44

The dietary supplements industry in India caters mainly to urban, higher-income groups, leaving rural and lowerincome populations underserved. Rising health awareness and digital access promise growth, but systemic issues like high prices and counterfeit products could limit progress.

GNC's interactive vitamin guide, provide free customised wellness plans based on individual needs, creating a new standard for consumer engagement.

TAKEAWAYS

While the Indian dietary supplements market is growing rapidly, it faces several obstacles that could hinder its long-term potential. Issues such as the prevalence of counterfeit products, high costs, and a lack of clear regulatory frameworks remain pressing concerns. The industry's reliance on health-conscious, urban, higher-income consumers also limits its reach, leaving vast rural and lowerincome populations underserved.

Though innovations in technology and personalised solutions offer promise, they remain accessible primarily to a niche segment of consumers. Without addressing affordability, transparency, and quality assurance, the market's growth may remain uneven and concentrated, failing to realise its broader potential

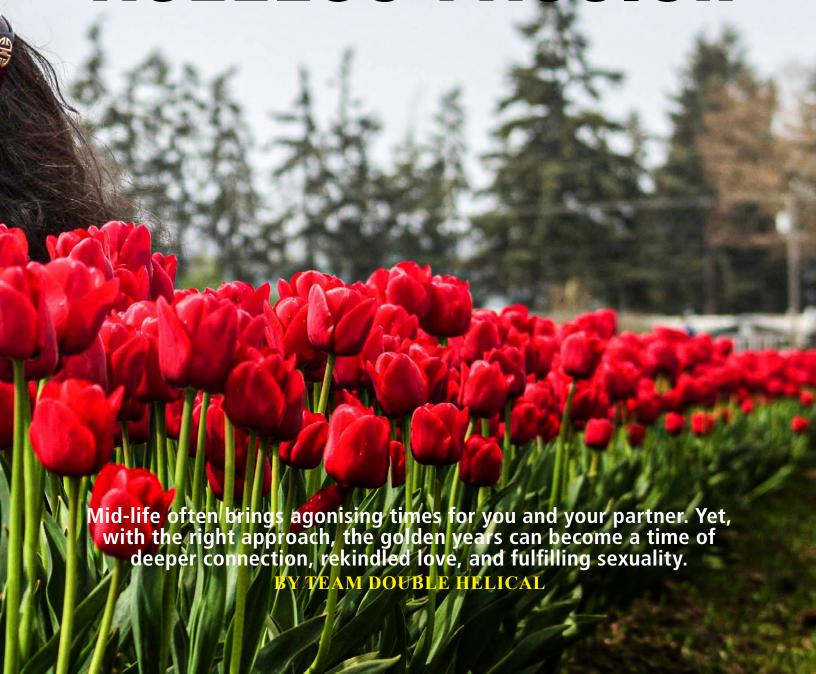
FOCUS - SEX AFTER FIFTY







AGING BODY, AGELESS PASSION



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id-life is the time of life when men often suffer f r o m problems

like premature ejaculation, erectile dysfunction, and delayed ejaculation. Women too have to face low sex drive, lack of desire, and problems with orgasms. Hundreds of men and women begin to experience the first signs of a more mature life: getting tired more easily; the surprise when a man's erection did not spring to attention when his partner kissed him; the bewilderment when an erection disappeared during intercourse or oral sex, a form of intimacy that would once have had a man groaning with pleasure; the distressing realisation that it might be time to reach for a bottle of lube because things somehow are not as juicy as they need to be for pleasurable lovemaking; the sudden realisation that your partner is actually avoiding sex with you, or even turning you down when you suggest it.

A woman might notice her clitoris and labia are not swelling up in the way that they used to during sex; she might notice that intercourse is uncomfortable because her vagina seems to be much more sensitive to thrusting and may even tear slightly during intercourse.

A man might notice that his erection doesn't stand up as high as it did, or that his ejaculation has much less force. Or he might suddenly find that he can't get another erection for several hours or even days after an ejaculation. And that can be something that shakes him to the core, especially if he has always regarded his sexuality as a crucial part of who he is.

According to a report, women are slightly better off, because there is a lot of information available which helps them prepare for the major lifechange of the menopause, as well as online support groups which help

them deal with the emotional and practical consequences of this period.

If you are a woman, and your male partner is refusing to talk about sex, how on earth would you even know what to do? You want the loving, sexual connection you once had. But every time you raise the subject of sex, he brushes you off and avoids the subject.

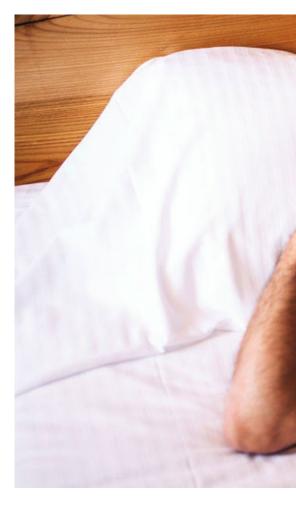
Well, there are things that you can do to show him that his sexuality is still powerful and attractive, to restore his confidence. You can tell him, through some simple actions, that you still want those blessed moments of intimacy with him. He'll respond to you with love.

If you are a man and your partner has lost interest in sex, how on earth do you ever get her to want to make love again? Or suppose your partner has gone through the menopause and now every time you try to make love, she complains intercourse is painful, or her vagina doesn't lubricate, or she always fails to have an orgasm.

Would you know what to do or say to her, not just to reassure her, but to actually turn your sex life into something that's passionate and exciting? Would you know how to help her become fully sexual once again, so you can enjoy the pleasures of intercourse, just as you always have?

The sexologists believe that most people don't know the answers to these questions. They believe the majority of people need a way to deal with middle-aged sexuality, a formula that restores intimacy and love, a set of techniques and tools that reverses the physical changes taking place (or provides a way of working around them - for both partners).

In particular, if your sex drive is dropping and your motivation to have sex is lower, it's all too easy to avoid having sex altogether. But once you start avoiding sex that becomes an established pattern. Why? Because it's much easier to avoid sex than take the



risk of losing your erection or experiencing vaginal dryness or having painful intercourse or not being able to ejaculate or reach orgasm.

If you are a woman going through the menopause, you may be very confused about hormone replacement therapy (HRT) or low sex drive. You might need to solve the problem of lack of lubrication, or the thinning of the vaginal wall that results in uncomfortable sex. You might want to know how to cope with changes in the way you feel about your body as you see it maturing.

There are probably many questions that you want to ask about how to carry on being sexual, being orgasmic. If you're feeling adventurous, you might want to know how best to explore new sexual techniques with





your partner. Or you might just want to know how to carry on as before.

As a woman, you might want to know how to support your man as he goes through changes in his sexual desire and libido, as he experiences a lessening of his staying power and his masculine strength, as he finds his erections and ejaculations changing, and as these things impact on his mood, self-image, and confidence.

As a man, you might be desperate to know how to reassure your partner that she's still attractive to you, and how much you still want sex. Or you might be struggling to understand why you don't want sex any more. All of these things are possible; all these challenges can be overcome.

If you are a man around 50, you may be scared about losing potency, or Mid-life changes can be challenging, but they also offer an opportunity to explore intimacy in new and meaningful ways. From experimenting with prolonged foreplay to addressing physical discomfort, love after fifty can be transformative.

frightened by the signs that your sexual power is lessening. You might be experiencing challenges around your role in life, about exactly how you've spent your life up till now, or how you're going to spend the years ahead of you.

You might be experiencing real discomfort at the threat of losing your sexuality, particularly if your sex drive is lower or your erections are less reliable, or your ejaculations are not as powerful. And of course, there is a lot more to the male midlife experience of sex and love than simple physical changes.

Midlife produces issues about purpose and power, about your role as a man, about how you see yourself as your sexuality evolves. Whereas you once expected instant erections as rigid as a pole, you might now need a very different kind of stimulation to become erect, just as you might need

FOCUS - SEX AFTER FIFTY



a different approach to intercourse to satisfy your partner's needs.

If you have seen your sexual capacity as an expression of your love for your partner, or as an expression of your masculinity, then you'll certainly be challenged by the changes you experience as you pass 50 years of age and enter the years beyond.

Sometimes sildenafil (Viagra) is a solution for erectile issues. Sometimes HRT is needed to overcome depression or a lack of sex drive, or to counteract the changes in your body. You might also want to know how to keep a loving relationship with your partner going, how to improve it, and how to reach a place where you enjoy better sex than ever before. Forget your preconceptions; forget what you have been told in the past. Sex is great, for both genders at 50 and far beyond.

An experienced sex therapist shares about his sexual habit after fifty from experience:

First and foremost, if you are facing some of the challenges that can come with sex after 50 years of age, don't despair! Almost every problem that affects lovers at this time in their lives can be solved.

Low sexual desire in men and

women can sometimes stop a couple having sex altogether, but there are plenty of ways to keep romance alive and your sex life on the boil. Indeed, you can have the most passionate and enjoyable sex of your life after 50. You just need to know how dealing effectively with the symptoms of the female menopause, including low sex drive, hot flashes, natural changes in your body in response to sexual stimulation, unpredictable mood swings...and the rest, including the dilemma around HRT, problems with vaginal lubrication, and painful intercourse, beating the symptoms of the male andropause - (that's the word for all the changes in a man's body around the age of 45 to 55) such as loss of sex drive and sexual desire.

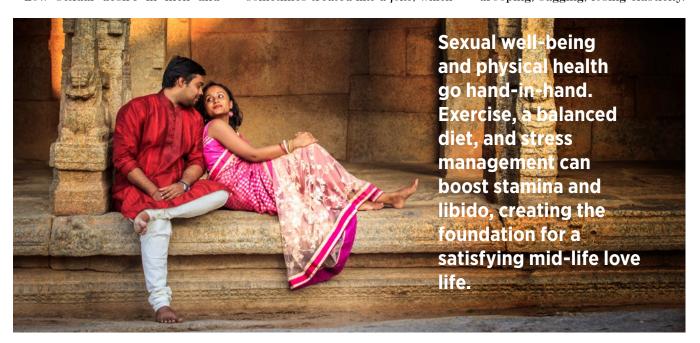
Some symptoms like changes in your body's response to sexual stimulation, especially less reliable erections and weaker ejaculations, and perhaps not even being able to get an erection, physical changes which might include penile and testicular shrinkage, aches and pains, muscle wasting, and more ... all can be dealt with very effectively if you know how.

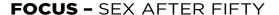
Male mid-life crisis is a stage of life sometimes treated like a joke, which in fact is anything but funny, involving as it does a lack of motivation, depression, loss of confidence, lack of purpose, feelings of hopelessness, despair, a sense of grief at aging, irritability, anger, and more.

Difficulties with sexual intercourse - whether these are caused by physical issues which make sex difficult, like vaginal dryness and loss of erection, or by relationship difficulties that stop it happening, or even a puzzling dwindling away of intercourse for no obvious reason, you can find out here how to revitalise your sex life and enjoy some of the best sex you have ever had.

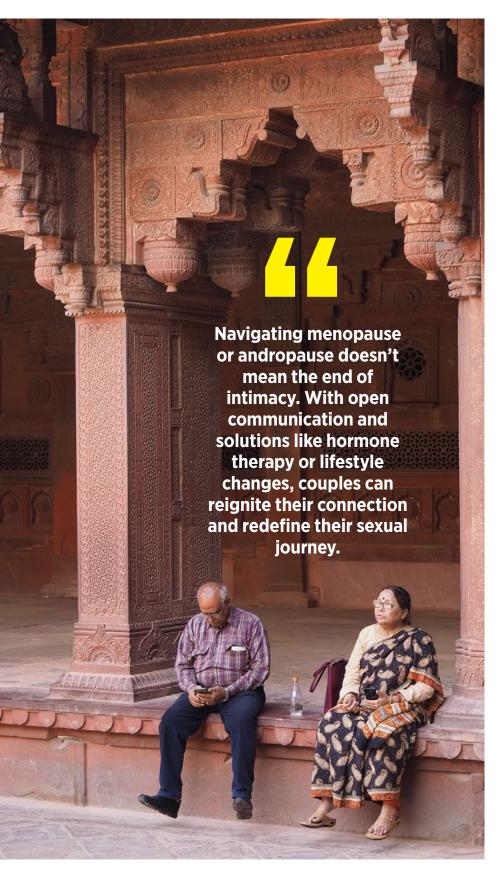
Erectile dysfunction or erection problems can range from once in a while failure to complete loss of erection, no matter what form they take, these problems can be devastating to a man's confidence. And yet, given the right treatment approach, all these issues can be resolved, your confidence restored together with your erection - and your enjoyment of sex renewed.

The common body issues of midlife are related to how do you cope with all the changes that midlife can bring drooping, sagging, losing elasticity.









Women and men want to stay on good terms with their bodies so they can enjoy sex at least as much as before...perhaps even more than before.

For women, the menopause is a crucial time, signalling the loss of fertility and the end of the possibility of getting pregnant. For some women, this heralds a new dawn of sexual freedom (no worries now about contraception) and sparks an era of new desire and passionate sex. For others, it seems like the loss of an essential part of themselves. For men, too, there can be a sense of losing the male power and vitality which has fuelled so much of their adult life. For everyone, it's a time of change. Yet in the natural order of things, women and men grow into a mature sexuality at this time of life that's just as rewarding as anything you ever experienced before.

Many couples find that when their sex drive falls, or the children leave home, there doesn't seem to be much keeping their relationship together. Yet really good sex definitely acts as the glue that keeps a couple together, no matter how old they are. It promotes affection, intimacy, bonding and mutual love. A couple can remain lovers, in every sense of that word - spiritually, physically, emotionally, and practically - with some simple, easy techniques that can transform your relationship. This is essential information if you feel that you're drifting away - possibly through a lack of sex - from your lover, partner or spouse.

Is growing into your mature sexuality more than the sum of all the things above? Yes, probably.... it's also about evolving emotionally, accepting that things aren't what they were, they are different, probably better. You should know powerful techniques to help you move to a place of psychological power, no matter how you may think about life after 50 at the moment.

The fact is, your sexual organs really do stay younger longer, the more you use them. And to prevent hardening of the arteries, as well as hardening of the attitudes, there is nothing like regular sex! You need to know all the sexual tips, tricks

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and techniques to ensure that your sexual desire remains high and your orgasms are powerful - no matter how old you are.

At the heart of intimacy lies communication. For couples navigating the complexities of mid-life sexuality, honest and empathetic dialogue is essential. Discussing sexual needs, expectations, and challenges openly can bridge emotional gaps and foster closeness. Misunderstandings or unspoken frustrations often lead to distance in relationships, but candid conversations can rekindle the spark. Partners can work together to find solutions tailored to their unique needs, whether it involves addressing physical discomfort or exploring new ways to connect.

Consulting a sex therapist or counsellor can provide insights and strategies to address specific issues. Professionals can also suggest medical interventions where necessary. For instance, HRT can help women alleviate menopausal symptoms, while medications like Viagra can assist men in overcoming erectile difficulties. Such solutions, when combined with a focus on emotional intimacy, can significantly improve the quality of sexual relationships.

One of the most effective ways to enhance intimacy is to prioritise foreplay. At this stage of life, foreplay becomes more than just a precursor to intercourse; it serves as a means of building trust, connection, and arousal. Couples can experiment with prolonged kissing, sensual massages, or exploring erogenous zones that may not have been focal points earlier in the relationship. The key is to approach intimacy as an evolving journey rather than adhering to past routines.

Physical health is closely tied to sexual well-being. A healthy lifestyle can significantly improve stamina, libido, and overall satisfaction. Regular exercise boosts circulation and increases energy levels, while a nutritious diet supports hormonal balance and overall vitality. Reducing stress is equally critical, as mid-life often brings increased responsibilities at work and home. Practising mindfulness, engaging in yoga, or simply setting aside time for relaxation can create the mental and emotional space needed for intimacy.

Mid-life presents couples with a chance to redefine their sexual relationship. Adaptation, rather than resistance, to changes in the body is crucial. Vaginal dryness, a common issue for women, can be addressed with high-quality lubricants and moisturisers, making intimacy more comfortable and enjoyable. Similarly, men can explore treatments for erectile dysfunction or low libido under the guidance of a healthcare provider. However, it is not just about solving problems—it is about embracing new experiences.

Couples might consider exploring alternative forms of intimacy. Penetrative sex, while an important aspect of many relationships, need not be the sole focus. Activities such as oral sex, sensual touching, or even sharing fantasies can maintain and deepen the bond between partners. The goal is to sustain the emotional physical closeness that underpins a healthy sexual relationship. For many couples, the golden years bring a shift in perspective. The focus of intimacy often moves from performance to connection. Without the pressures of earlier years—such as raising children or advancing careers—partners have more time and emotional energy to invest in their relationship. This phase can be an opportunity to rediscover one another, rekindle romance, and explore aspects of intimacy that may have been overlooked.

Reigniting passion might involve small, thoughtful gestures, such as planning a surprise date, writing love notes, or simply dedicating time to each other without distractions. These actions reinforce emotional intimacy, which, in turn, enhances physical closeness.

Sex after fifty is not merely about sustaining a physical relationship; it is about celebrating the depth of connection that mature love brings. It is a time to cherish the shared experiences that have shaped the relationship and to explore new ways of expressing affection. By embracing change, couples can unlock a new dimension of intimacy that is both satisfying and enriching.



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