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DoP sets up panel on bulk drug parks

Laxmi Yadav, Mumbai

The Department of Pharmaceuticals (DoP) has constituted a high-level panel with industry representatives and technical experts to oversee the progress of bulk drug parks being set up in Gujarat, Himachal Pradesh and Andhra Pradesh.

The panel, chaired by Dr Mansukh Mandaviya, Union minister of chemicals and fertilizers, will ensure that the design, investments and infrastructure in the parks are aligned with the strategic objectives of the Scheme for Promotion of Bulk Drug Parks, stated a circular issued by the Department of Pharmaceuticals on November 10, 2022.

Bhagwanth Khuba, minister of state for chemicals and fertilizers will be deputy chairman of the committee while joint secretary, department of pharmaceuticals will be member secretary. The members of the panel include secretary, department of pharmaceuticals; Drugs Controller General of India; joint secretary (drug regulations), department of health and family welfare; additional chief secretaries/ principal secretaries, industry department, Gujarat, Himachal Pradesh, Andhra Pradesh; chief executive officers/managing directors of state implementing agencies; president of industry associations viz. Indian Pharmaceutical Alliance, Indian Drug Manufacturers' Association, Bulk Drug Manufacturers Association of India, Organization of Pharmaceutical Producers of India; two representatives from National Institutes of Pharmaceutical Education and Research (NIPERs), stated the circular.

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Centre to mandate QR code on 300 drug brands from Aug 1, 2023

Gireesh Babu, New Delhi

The Union Health Ministry has issued final notification amending the Drugs Rules, 1945, mandating barcode or quick response (QR) code on the label of top 300 brands of drugs from August 1, 2023. The move is in line with the recommendation of the DTAB in November, last year, in the top 300 brands to track & trace them through the manufacturing and supply chain.

The draft rule was released in June, this year, which introduced a new Schedule H2 with a list of 300 top brands, and inserts a new sub-rule under the Rule 96, under the Drugs Rules, 1945, after the sub-rule 5.

Under the new sub-rule 6, the manufacturers of drug formulation products specified in the Schedule H2 of the rule, shall print or affix QR code on its primary packaging label or, in the case of inadequate space in primary package label, on the secondary package label that store data or information legible with software application to facilitate authentication.

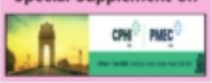
A sub-rule 7 has also been inserted into the Rules, defining the details thus to be added in the QR code. This include the particulars including unique product identification code, proper and generic name of the drug, brand name, name and address of the manufacturer, batch number, date of manufacturing and date of expiry along with the manufacturing license number.

The list of 300 drugs included in the Schedule H2 include certain strengths of Aciloc, Actemra, Allegra, Amlokind, Ascoril D Plus New, Asthalin inhaler, Becosules Capsules, Betadine ointment, solution and gargle, Calpol, Combiflam, Dolo 650 mg, Electral Sache, Fabiflu, Foracort, Gelusil, Glycomet, Janumet, Lantus, among others.

The Ministry said that it has considered the objections and suggestions received from the public on the draft rules, before finalising the amendment, which is now called the Drugs (Eighth Amendment) Rules, 2022.

The DTAB, in its meeting held in November, 2021, recommended introduction of QR code in top 300 brands of drugs available in Indian market to help track and trace these brands, in line with the discussions it has been carrying out in the last couple of years. ◆

This edition includes a 92-page Special Supplement on



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Indian pharmaceutical industry and its future prospects

Dr. Sanjay Agarwal

The Covid-19 pandemic is an economic disaster for many economies and a global health catastrophe. This period has been difficult for the manufacturing sectors, underscoring how urgently India has to achieve self-sufficiency. Despite a brief stop, the "Atmanirbhar Bharat" narrative predicted growth, but the ongoing pandemic has quickly changed the "self-reliant" mantra.

The outbreak made clear India's dependence on imports for basic medical supplies. Due to the export limitations, the supply inconsistencies caused a sharp increase in domestic pricing for several medications and disrupted international trade. The weak spots in India's pharmaceutical industry have been brought to light by the low availability of Key Starting Material (KSM).

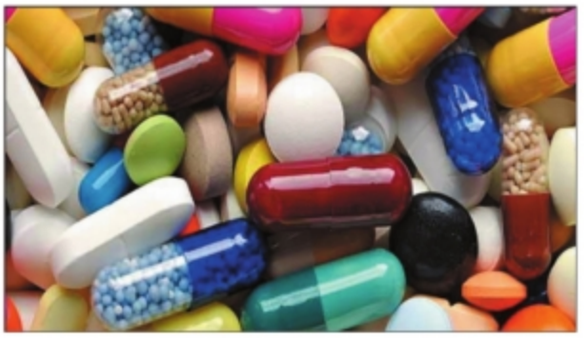
The pharmaceutical industry generates US $ 1.2 trillion in revenue annually. The pharmaceutical sector must embrace new technologies, patient design, and innovations and place a more significant emphasis on prevention and digital health, given the size of the stakes and the speed of technological disruption.

The pharmaceutical sector is dealing with several difficulties, including moral and financial ones. They may benefit from the digital revolution by embracing disruptive technology such as 3D printed medications, artificial intelligence-led therapies, and preventive medicine while collaborating with regulatory bodies to ensure patient safety.

Over- dependence on China

While addressing domestic demands, Indian businesses have positioned themselves as leaders in the global pharmaceutical industry. A fifth of all worldwide manufacturing facilities serving the U.S. market is reportedly located in India. It is the only nation with the most significant number of US-FDA-compliant pharmaceutical plants. It is the third largest country in the world by volume, with 253 European Directorate of Quality Medicines (EDQM) accredited plants and almost 1400 WHO-GMP (Good Manufacturing Practices) recognized pharmaceutical plants. Despite this, the Indian pharmaceutical business is still ranked as the 14th largest globally, with its exports making up only 3.5 of all pharmaceutical exports.

The Indian pharmaceutical industry performed well in formulations and homegrown medications, but as the market was further liberalized, a flood of imports from China entered. The nation heavily relies on imports to meet its drug needs. Chinese imports of fundamental raw materials, particularly APIs (Active Pharmaceutical Ingredients), the primary building blocks used to create completed drug formulations, provide about 70 per cent of the pharmaceutical industry's needs. The cost of these Chinese bulk medications or APIs is roughly one-third less than Indian-made APIs. As they successfully created affordable technology, China emerged as the API manufacturing and export leader. Large-scale manufacturing activities, inexpensive and shared utilities, and helpful government regulations helped them gain an advantage.



In India, domestic API production plants were shut down due to the heavily subsidized pricing of Chinese APIs. Since the capital investments in the manufacturing of APIs did not generate higher returns, Indian companies eventually stopped doing so. Due to several factors, including the high cost of technology and the extensive infrastructure needed for its production, API is more expensive in India.

Pharma and healthcare industry changes

How are the pharmaceutical and healthcare industries changing, and what the future of the sector might entail with other top professionals? Here are some pointers.

Getting used to the "new normal"

Budgets for world healthcare have been under tremendous strain due to the Covid-19 pandemic and the need to launch numerous vaccination efforts. In fact, between 2021 and 2026, it is predicted that global Covid-19 incremental spending will total $251 billion. However, now that the initial vaccination programmes have been implemented, the business focuses on recovery and the new normal. The pharmaceutical sector will probably undergo significant changes, which will be costly and challenging to negotiate. But what will the "new normal" include specifically?

Current health priorities must influence the market to address the opportunities and difficulties facing healthcare today. Network optimization, patient-centricity (where research and development will be more aligned with public health interests and preferences), and satisfying new capacity and efficiency requirements are likely the main areas of change at the industry level. Organizations are prioritizing operational resilience at the level of each company and accelerating efforts that allow for greater agility and transparency. Increased use of automation, digital technologies, and analytics tools has made this possible. Additionally, it is essential to continue to adapt because of shifting legislation.

Significance of stable supply chains

The pandemic has firmly shown that supply chains can be seriously jeopardized when they depend too heavily on an area that might be susceptible to disruption. There is a lot of anxiety in the industry, and many businesses are obliged to think about relocating their production and supply hubs closer to their target consumers. In contrast to before the pandemic, moving manufacturing locations to areas with lesser risk or less susceptibility to disruption is now a common consideration in risk mitigation. Additionally, fresh attempts have already been made to deal with the problem, such as the initial U.S. investment of $60 million to support domestic production.

Shift from prevention to therapy

Healthcare programmes must put more emphasis on prevention than treatment if they are to be long-lasting. Innovation is expected to prioritize prevention increasingly and explore the possibility of vaccines for non-communicable diseases, such as some malignancies, rather than focusing on treating individuals who are already ill and producing just vaccines for infectious diseases.

Patients no longer participate in their care as passive recipients. Patients are becoming more empowered and motivated to regain control over their health due to increased health education and literature and new prizes for leading better lifestyles. This has a significant impact on how the pharmaceutical business sees patients.

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AI makes discovering new medicines more affordable

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Healthcare has generally lagged behind other industries in implementing user-friendly technologies and systems, but the epidemic has forced it to offer patients a more decisive say. Most large pharmaceutical companies have already begun putting the patient at the centre of drug development. Due to the rising use of digital technologies, telehealth, and app-based ecosystems, supply chains are also becoming more patient-centric.

Rapid technological advancement

In the years following Covid-19, the pharmaceutical sector has undoubtedly risen to the challenge, as evidenced by the accelerated research and innovative technologies created during the crisis, such as mRNA-based vaccines. Operational teams have come together to handle changing government limitations, ensure the safe supply of essential medicines across borders, and start preparing for new vaccinations and therapies. Numerous businesses established plans to control and stabilize an otherwise tumultuous period.

It is anticipated that access to medicines will be significantly impacted by precision medicine, which includes personalized and predictive medicine. Taking into account individual heterogeneity in genes, environment, and lifestyle, precision medicine is a developing approach to illness treatment and prevention that enables doctors to more correctly forecast the therapy that will work best for a patient.

Trends shaping pharma industry future

Patients should be included in advisory boards

Patients should be considered equal partners in hospitals, pharmacies, and even pharmaceutical businesses as they take control of their own health and destiny with digital health. Patients who have used the products of the particular company should be on the advisory board for drug producers.

Creating new items would be more straightforward if the precise requirements of the market were fully understood. Only with their assistance would it be feasible to develop a futuristic healthcare system years after the initial designs were created.

Digital health strategy "around the pill."

Pharma businesses will emphasize novel techniques relying on technology to appeal to providers and payers rather than traditional drug manufacturing and marketing. "Around the pill" is about more than just creating and dispensing medications; it's about creating medicine and integrating digital health technologies into it.

These are frequently non-clinical, patient-support activities that can improve patient outcomes and strengthen the healthcare system. Through these initiatives, patients receive more than just a tablet. Pharmaceutical companies can capitalize on the data and feedback they collect and the potential loyalty of patients who value the extra attention.

Digital pills

For particular people with particular diseases, digital tablets and pharmaceuticals with embedded electronic circuits may be beneficial. Instead of smartphone logging apps, these refer to ingestible drugs with inbuilt electronic circuitry.

For those who routinely take medications, these pills may aid in adherence. Abilify Mycite, a medicine developed by the now-defunct pharmaceutical business Proteus, was the first tablet to receive FDA approval. It was intended to treat psychiatric illnesses like schizophrenia and bipolar disorder.

Virtual reality becoming reality

In hospitals, virtual reality (V.R.) is rapidly becoming a reality. You may help as a doctor in the operating room without using a scalpel. As a medical student, you may learn more about the human body and be better prepared for surgery. You might be able to combat your potential paranoia, schizophrenia, or fear of heights more successfully as a patient with mental health issues.

But one of the most effective uses of medical V.R. is stress management and pain management for people with chronic pain. Instead of developing brand-new painkiller varieties, pharmaceutical corporations could want to explore entering the market.

Pharmacogenomics-based precision medicine

Precision medicine is "an emerging strategy for illness treatment and prevention that takes into account individual diversity in genes, environment, and lifestyle for each person," according to the National Institutes of Health (NIH). Several trends in precision medicine are linked to the pharmaceutical industry. On the one hand, scientists test cancer medications targeting malignant cells without harming healthy tissues, such as those used to treat cervical cancer. Medical professionals work to incorporate genetics into developing tailored and targeted therapeutics. One approach to this is through pharmacogenomics.

AI to revolutionize healthcare

AI will soon revolutionize healthcare by mining medical information, creating treatment plans, accelerating medical imaging, or even creating new drugs. Drug development methods based on artificial intelligence are becoming more widely used. AI makes discovering new medicines more affordable and efficient. According to estimates, an experimental medication typically requires $2.9 billion and 12 years to develop from concept to commercialization. AI can significantly reduce these numbers.

Final note

It's time to rethink conventional business models and embrace new technologies that put the patient first if pharmaceutical businesses want to survive or, better yet, thrive in a future centred on prevention, early detection, and individualized therapies.

Learn how global leaders promote changes in the industry, from cannabidiol innovation to assisting clients in overcoming complicated formulation difficulties and finding pathways to more patient-friendly medications. ◆

(The author is pharmaceutical consultant)