OPPI
भारत के लिए
Organisation of Pharmaceutical Producers of India

JUNE MEDIA COVERAGE

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FINANCIALS & MAINLINES

Publication	Economic Times
Date	14-June-24
Edition	Online
Headline	Govt allows global tenders to access 120 key, patented drugs

Govt allows global tenders to access 120 key, patented drugs

By Teena Thacker, ET Bureau • Last Updated: Jun 14, 2024, 08:17:00 AM IST

Synopsis
In what could ease access to some patented medicines, the government has allowed global tenders to be floated for procurement of 120 drugs, including anti-diabetic medication Semaglutide, after the health ministry raised concerns over lack of domestic options.

In what could ease access to some patented medicines, the government has allowed global tenders to be floated for procurement of 120 drugs, including anti-diabetic medication Semaglutide, after the health ministry raised concerns over lack of domestic options.

The decision was notified by the finance ministry last week, people in the know told ET.

With this, it will become easier for people in India to procure medicines which are either not available in the country because they are patented, or are not being produced here due to technological barriers. "This will open doors to various such products and will benefit the Indian patient," said an industry insider.

The government's public procurement policy prohibits global tendering to source goods and services worth up to ₹200 crore as part of a strategy to bolster the domestic industry.

Among the 120 medicines for which global tenders can now be floated are anti-diabetic drug Dulaglutide; Evrysdi, which is used for treatment of spinal muscular atrophy; Fabrazyme, for fabry disease; Kadcyl, for breast cancer; Lemtrada, for multiple sclerosis; and Semaglutide, used for treatment of type-2 diabetes and obesity.

Publication	The Hindu Business Line
Date	24-June-24
Edition	Online
Headline	Redefining the regulatory pathway for nutraceutical and pharmaceutical products

A $6-B maze. Redefining the regulatory pathway for nutraceutical and pharmaceutical products

PREMIUM

Updated - June 24, 2024 at 07:00 AM

As the nutraceutical landscape grows, experts call for clarity in the manufacturing debate

BY PT JYOTHI DATTA

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At crossroads: Disallowing nutraceuticals from being made at pharma production units would be contrary to global practice, say experts | Photo Credit: istock.com

After years of deliberation whether nutraceuticals are a food or drug, the decision was taken to classify it as food. But as the nutraceutical landscape grows, with some products claiming therapeutic benefits — the nutra–pharma discussions have come up again.

Publication	The Hindu Business Line
Date	24-June-24
Edition	Print
Headline	Redefining the regulatory pathway for nutraceutical and pharmaceutical products

Redefining the nutraceutical and pharma pathways, again

A $6-B MAZE. As the nutraceutical landscape grows, experts call for clarity in the manufacturing debate

PT Jyothi Datta

After years of deliberation whether nutraceuticals are a food or drug, the decision was taken to classify it as food. But as the nutraceutical landscape grows, with some products claiming therapeutic benefits — the nutra–pharma discussions have come up again.

Government representatives and experts are revisiting streamlining the regulatory framework. And a critical part of this discussion involves manufacturing — allowing a plant that produces pharmaceutical products, to make nutraceutical products, as well.

Industry-insiders explain that turning the regulatory clock back and disallowing nutraceuticals from being made at pharma production facilities would be contrary to global practice.

AT CROSSROADS. Disallowing nutraceuticals from being made at pharma production units would be contrary to global practice, say experts ISTOCK.COM

LEGAL BINDINGS

Currently, nutraceuticals are regulated under various laws and regulations, including the Food Safety and Standards Authority of India (FSSAI) regulations, the Drugs and Cosmetics Act, and the Ayurveda, Yoga & Naturopathy, Unani, Siddha, and Homoeopathy (AYUSH) guidelines.
Source: Assocham

DECONTAMINATION RULES

Pharma plants have cleaning and decontamination protocols in place, as they make multiple products, says Sanjaya Mariwala, Executive Chairman and Managing Director, OmniActive Health Technologies, and President of the Association of Herbal and Nutraceutical Manufacturers of India.

Drug-makers can make nutraceuticals in their plants (following cleaning protocols) — the reverse is not allowed, he clarifies, adding, it is the right approach. Responding to concerns that nutraceutical producers may claim pharma-level manufacturing standards (adhering to current Good Manufacturing Practices), Mariwala said, that should be seen as a positive. There are about a 1,000-odd nutraceutical producing plants in the country, he estimates

Nutraceutical production is governed by the FSSAI rules says Mariwala, and companies exporting to regions including the US, for example, meet their regulatory requirements. He estimates the domestic nutraceuticals market at $6 billion.

The recent nutraceuticals/pharmaceuticals discussion traces back to a few industry practices, including possibly circumventing price control, says a regulatory veteran familiar with the details. For example, pharma producers of vitamins or mineral products may have shifted to the food classification, by reformulating their product to meet food standards and avoid price control, the expert observed. This is not illegal, but could impact the requirement of similar pharma products required to treat certain health issues, and that is a concern, the official added. Also, nutraceutical products are now available in convenient formats like capsules, tablets and syrups – usually seen with drugs.

The way forward is to tighten regulation, so products meeting the pharmaceutical definition (in terms of composition and percentage of active ingredient) and making therapeutic claims are regulated by the Drug Controller General of India; and those products meeting the food requirements are classified as nutraceuticals, the expert suggested.

Production facilities can make both products on a "campaign basis", the expert added, where few days of the week are dedicated to making nutraceuticals and the rest for pharmaceuticals, after decontamination protocols are followed. That is the global practice, the industry-veteran said.

'ALLOW BOTH'

Anil Matai, Director General with the Organisation of Pharmaceutical Producers of India (OPPI) foresees "significant challenges" in implementing the proposed changes.

"Limiting manufacturing premises exclusively to drug production, as outlined in the revised Schedule M, could impact companies that produce both drugs and dietary supplements, affecting both domestic supply and exports. This is particularly important as India is poised for significant manufacturing opportunities, with global companies considering it a viable alternative to China. Ensuring our companies can meet their commitments is crucial for maintaining credibility," he says.

The Indian pharmaceutical industry already aligns with global standards, such as US FDA and European Union regulations, "where facilities adhering to stringent drug manufacturing protocols are permitted to produce FDA-licenced dietary supplements," Matai points out.

"Safety and quality standards should continue to meet WHO GMP guidelines," says Matai, adding that OPPI have submitted comments to the Government, advocating that "companies be allowed to manufacture both drugs and nutraceuticals/dietary supplements if they meet the revised Schedule M requirements for good manufacturing practices and premises, plant and equipment standards."

The regulatory landscape is fragmented, says a recent Assocham report, and it "often leads to ambiguity and inconsistency in compliance requirements, hindering industry growth." The requirement is, for a "unified regulatory framework that provided clarity and consistency in standards," it points out.

ONLINE & TRADE

Publication	Exchange4Media
Date	1-June-24
Edition	Online
Headline	Presenting e4m PR & Corp Com 40 Under 40 Awards 2023 Winners

Publication	Pharmabiz
Date	25-June-24
Edition	Online
Headline	DoP further expands list of special invitees into committee constituted to reform pricing framework

DoP further expands list of special invitees into committee constituted to reform pricing framework

Gireesh Babu, New Delhi
Tuesday, June 25, 2024, 08:00 Hrs [IST]

The Department of Pharmaceuticals (DoP) has once again expanded the list of special invitees for its Committee for reforms in the pricing framework for drugs and medical devices, formed in March this year to include representatives from the largest pharmacy trade organisation, healthcare service providers' organisation and the doctor's association along with various patient advocacy groups.

This is the second time the list is broadened, after it expanded the list of special invitees in April, to include all major pharma manufacturing industry organisations in line with the request of the representatives from the organisations.

It has now issued an order to add seven more members to the list of special invitees with the existing 12 invitees. With this, there would be 19 special invitees with representation from 19 organisations.

The Department said that representatives from All India Drug Action Network (AIDAN), Healthcare Foundation of India (NAT Health), Patient Safety and Access Initiative of India Foundation, Indian Medical Association (IMA), All Indian Organisation of Chemists and Druggists Association (AIOCD), Laghu Udhyog Bharti, and Medecines Sans Frontieres (MSF) India have been included in the committee as invites.

The terms of reference of the Committee shall remain the same as mentioned in the Office Memorandum issued on March 12, 2024, it added.

It may be noted that the initial notification on March 12, had a provision to have two special invitees from the industry, one each from the Indian Pharmaceutical Alliance (IP Alliance) and Indian Drugs Manufacturers' Association (IDMA). However, the number of special invitees was broadened to 12, through an order on April 22, 2024.

Publication	Pharmabiz
Date	27-June-24
Edition	Online
Headline	Centre expands MedTech pricing committee; includes 7 associations

Centre expands MedTech pricing committee; includes 7 associations

June 27, 2024

Centre has expanded the committee for drugs and medical devices pricing reforms and included industry representatives as special invitees.

This follows the request by different associations for their inclusion in the committee

"Based on the requests received by the Department from various associations for inclusion of their representatives as Special Invitees in the Committee above, it has been decided to broaden the list of special invitees," said Khayi Leishingam, Joint Director, Department of Pharmaceuticals (Pricing Division), Ministry of Chemicals and Fertilisers, in the order.

The new special invitees include the All India Drug Action Network (AIDAN); Healthcare Federation of India (NAT Health); Patient Safety and Access Initiative of India Foundation; Indian Medical Association; All India Organization of Chemists and Druggists Association; Laghu Udhyog Bharti; Médecins Sans Frontières (MSF) India.