VOICE OF FICCI

SHAPING THE AGENDA

March 2024

From the Secretary General

March as the last month of FY24 was an action-packed one for FICCI. We hosted the 24th edition of FICCI FRAMES in Mumbai which was attended by the doyens of the Media and Entertainment industry. In the 25th edition of FICCI FRAMES in 2025, the transformational changes required in the media and entertainment industry would be highlighted, focusing on the initiatives needed for India@2030.

FICCI worked with the Ministry of Development of North-Eastern Region (DONER), GoI for MoU Exchange Ceremony, between investors and the eight Northeastern states. A total of 82 MoUs to the tune of Rs 30115.26 crore were signed.

Minister of Chemicals & Fertilizers and Health & Family Welfare, GoI Dr Mansukh Mandaviya specially came to Federation House to launch the PLI Scheme for Bulk Drug and Medical Devices, organized by FICCI jointly with the Department of Pharmaceuticals. Secretary Mr Arunish Chawla and other senior colleagues visited FICCI for this. Major private companies active in the sector were present.

We welcomed Prime Minister of Bhutan HE Dasho Tshering Tobgay to Federation House, where FICCI Past President Dr Jyotsna Suri and Tourism & Culture Committee Chair Mr Dipak Deva had a business discussion on 'India-Bhutan Tourism: Expanding Horizons'. We fondly recalled FICCI's delegation to Bhutan in October 2023, and would work closely with Indian businesses looking at Bhutan.

We also hosted Hon'ble Minister of Foreign Affairs of the Republic of Belarus HE Mr Sergei Aleinik, Ambassador of Belarus to India HE Mr Mikhail Kasko, Director of National Center for Marketing and Price Study HE Mr Mikalai Barysevich and team for an exclusive interaction with senior industry representatives. They discussed doubling trade between India and Belarus and signed an MoU to re-energize bilateral ties. FICCI will support Indian industry to engage with businesses in Belarus.

Along with Defence & Homeland Security Committee Chair Mr Vinod Sahay and Co-Chairs Mr Ashish Kansal and Mr Ashok Atluri, I made a courtesy call on Mr Giridhar Aramane, Defence Secretary, Ministry of Defence. We discussed private participation in defence manufacturing, under the 'Make in India and Make for the world' initiative. We also deliberated on working together to achieve the objective of AatmaNirbhar and Viksit Bharat. Department of Defence Production Additional Secretary and Director General (Acquisition) Mr Samir Kumar Sinha, Additional Secretary (DP), Department of Defence Production Mr T Natarajan and Mr Anurag Bajpai were present during the interaction.

We took a FICCI CEOs delegation to Japan under the leadership of FICCI President Dr Anish Shah. The delegation met with State Minister of Economy, Trade and Industry, Japan HE Mr IWATA Kazuchika, and discussed trade and investment opportunities between India and Japan. We had an excellent meeting with Minister for Digital Transformation, Japan HE Mr KONO Taro. The discussions included learning from India's success in Digital Public Infrastructure, extending UPI payments between Japan & India, and digitalization in core banking services. Indian Ambassador to Japan, HE Mr Sibi George hosted a special reception wherein we met top business leaders from Japanese Industry and senior Government officials. We also met Mr Kenichi AYUKAWA, Executive Vice President, Suzuki Motor Company; Mr Ueno, Executive Director and Vice President, Sumitomo Corporation, and Padma Shri Ryuko Hira, Chairman, ICIJ (Indian Commerce & Industry Association Japan) during the visit.

S K Pathak

Proposal for Restarting Passenger Ship Service between Lakshadweep and Calicut Port (Beypore Port), Kerala

The Proposal concerns the urgent need to re-establish the passenger ship service between Lakshadweep and Calicut Port, which has been suspended since the Covid-19 pandemic. The importance of this service in providing affordable transportation, sustaining essential aspects of daily life such as education and medical services, and supporting the development of Lakshadweep, particularly in the tourism sector. It highlights previous correspondence from FICCI and the Maritime Board, Government of Kerala, and urges the administrator to consider the representation favorably. This was submitted to Hon'ble Administrator, Lakshadweep.

For detailed recommendation, please write to
Mr Savio Mathew at savio.mathew@ficci.com

Suggestions from FICCI National Committee on Insurance on The Draft 'INDIAN STAMP BILL, 2023

The Department of Revenue, Ministry of Finance, Government of India, has prepared a draft 'Indian Stamp Bill, 2023' to align it with modern stamp duty regime. Once enacted, the Bill shall replace the Indian Stamp Act, 1899. It has been proposed that the Indian Stamp Act, 1899 is repealed and a new legislation is enacted to reflect the present realities and objectives.

FICCI has put forward recommendations drafted in consultation with insurance industry members.

The industry suggested to have reduced stamp duty for short-term insurance products. Further, health, travel and group term insurance products should be kept outside the ambit of stamp duty, as this will reduce the cost of such insurance products significantly. This will increase insurance penetration. Further, single window approach may be adopted for remission of stamp duty, and all transactions relating to stamp duty may be made online and there should be no manual intervention for the same. In addition to the exemptions provided to PMJJBY under the Bill, 2023, industry is of the view that similar exemptions should be provided for other government schemes as and when introduced.

It was further recommended that the policy riders should not entail the levy of stamp duty and hence be exempted from the levy of stamp duty. It is suggested that no stamp duty is to be levied at the time of renewal irrespective of whether the renewal is sought from the same insurer or a different insurer for existing members. Industry is also of the view that

Voice of FICCI is a service to all our members and shared with key policy makers and thought leaders. The document is a compilation of FICCI's views on macro-economic issues. These issues come to us directly from members, or through deliberations in conferences and seminars on sectoral issues, as also through Government notifications.

stamp duty applicable on life insurance products should be reduced and made at par with shares and mutual funds.

For detailed recommendations, please write to
Mr Anshuman Khanna at anshuman.khanna@ficci.com

Pre-monetary Policy Consultation

The Reserve Bank of India held a pre-monetary policy consultation with industry members on March 5, 2024. Besides apprising the Reserve Bank of India about the recent FICCI Survey findings, the recommendations made to the Central Bank were focused around climate risk, priority sector guidelines and account aggregator framework. Some specific suggestions made to the Reserve Bank included:

- Need for communicating a common sustainability taxonomy which is applicable and indicating industries/activities and will enable banks to appropriately tag exposures as sustainable finance.
- Need for redesigning Priority Sector Lending (PSL) by preparing a list of Climate adaptation and Climate risk mitigation activities as a new category
- Securitisation of physical collateral such as land and vehicles, which would allow for digital verification and lien-marking Fast tracking Account Aggregator framework.

For detailed recommendations, please write to
Mr Anshuman Khanna at Anshuman.khanna@ficci.com

Submissions on Companies (Significant Beneficial Owners) Amendment Rules, 2019

As part of review being undertaken by the Ministry of Corporate Affairs with respect to provisions under the Companies Act, 2013 and Rules framed thereunder, Ministry had constituted a Committee to review Companies (Significant Beneficial Owners) Amendment Rules, 2019. FICCI had submitted industry suggestions on SBO Rules.

For detailed recommendations, please write to
Ms Abha Seth at abha.seth@ficci.com

Rules prescribed under Companies Act, 2013

Pursuant to Hon'ble Finance Minister's Budget announcement to have a comprehensive review of regulations, the Ministry of Corporate Affairs instituted a public consultation process seeking suggestions on all the Rules prescribed under the Companies Act, 2013 with the objective of improving ease of doing business in India. Based on inputs received from members, FICCI submitted a detailed representation on industry concerns and suggestions on Companies Rules.

For detailed recommendations, please write to
Ms Abha Seth at abha.seth@ficci.com

Amendment to Reglns 35, 37 & 50 of CCI (General) Regulations 2009-Confidentiality Rings

With the objective of streamlining the processes and for timely & effective disposal of matters pertaining to Confidentiality Rings, the Competition Commission of India had issued draft Amendment Regulations for public consultation. Based on suggestions received from members, FICCI submitted a detailed representation on the draft regulations. This included recommendations on proposals related to prescribing a time limit for making a request to set up a confidentiality ring, requirement of affidavit, time limit for inspection of confidential case records and so on.

For detailed recommendations, please write to
Ms Abha Seth at abha.seth@ficci.com

Implementation of Audit trail in accounting software under Companies Act

Based on concerns highlighted by members, FICCI has submitted a representation that scope of 'accounting software' under the requirement of audit trail as per Section 128(1) of the Companies Act, 2013 read with Rule 3(1) of Companies (Accounts) Rules, 2014 may be clarified. It has been further submitted that implementation of audit trail in the supporting/ periphery accounting software and systems & tools, if covered under the scope of 'accounting software', may be deferred by one year and be made applicable, if at all, with effect from 1st April 2025.

For detailed recommendations, please write to
Ms Abha Seth at abha.seth@ficci.com

Extension of timeline for registration of M2M Service Providers and WPAN/WLAN Connectivity Providers for M2M Services

The recommendation letter submitted to Department of Telecommunication, highlighted the crucial role of unregistered M2MSPs (Machine-to-Machine Service Providers) in various sectors such as utilities, finance, transportation, strategic entities, manufacturing, and healthcare, contributing significantly to the success of Digital India. It further mentioned that the M2MSPs are integral to critical systems, and their impact on the telecom business landscape is substantial, and disconnecting resources could disrupt essential networks and services. Recognizing the government's intention to support M2M services, the letter requests an extension of the registration deadline by 180 days from the initial date of March 31, 2024. This extension is deemed necessary due to the volume of M2MSPs applying for registration, the importance of continuing critical M2M services, and efforts by Telecom Service Providers (TSPs) to expedite registration.

For detailed recommendations, please write to
Ms Sarika Gulyani at sarika.gulyani@ficci.com

Regarding the Issues and Recommendations Concerning the Biodiversity Act in the Ayush Sector

The Biodiversity Act was designed to uphold the conservation and sustainable utilization of bioresources, alongside ensuring equitable benefit sharing with local communities. However, the Ayush sector notably lacks involvement with local knowledge and instead relies on traditional knowledge that is already publicly available. Despite a willingness to contribute to Access Benefit Sharing (ABS) with the National Biodiversity Authority (NBA) for some time, companies have not seen tangible benefits in return like the sustainable supply of bioresources. Concerns arise as the NBA now seeks ABS payments based on company turnover rather than the agreed raw material value, which contradicts the 2014 ABS guidelines and may discourage investment in India. (Few more recommendations regarding this topic were submitted along). These were submitted to Joint Secretary, Ministry of Ayush.

For detailed recommendations, please write to
Mr Praveen K. Mittal at praveen.mittal@ficci.com

FICCI's Request for Exemption or Extension: Export of Indian Pharma Products to Neighboring Countries

The concern is related to the Indian domestic pharma manufacturers were being stopped from exporting their products meant for India Market Only. When the OM was issued by the office (for merchant exporters), there was a lot of ambiguity regarding whether regular pharma exports will also be impacted. FICCI request for a detailed clarification that may be issued on this OM because regular pharmaceutical export consignments should not be stopped due to less available information and lack of clarity at the port offices. The same clarification on the OM must then be immediately disseminated to ports and all concerned offices.

Additionally, mention that a Memorandum of understanding (MoU) was signed between the Indian Pharmacopoeia Commission (IPC) and Ministries of Health of certain countries (the latest being signed in June 2023) to enable the export of Indian medical products – as a step towards boosting foreign exchange earnings and fulfilling India's vision of Atmanirbhar Bharat. At present, the Indian Pharmacopoeia (IP) is officially recognized by five countries: Nepal, Afghanistan, Ghana, Mauritius, and the Republic of Suriname.

International recognition of the IP has several benefits to the Indian pharmaceutical sector, including:

- The recognition of the IP in few countries (Nepal, Afghanistan, Ghana, Mauritius, and the Republic of Suriname) is a step towards an 'Atmanirbhar Bharat', generating foreign exchange earnings and reinforcing India's pharmaceutical industry on the global stage – providing India a competitive edge in the global pharmaceutical landscape.
- The recognition of IP by these countries eliminates the need for duplicative testing and checks, thus reducing regulatory hurdles.
- Importing nations have access to quality Indian medical products at affordable prices.

With this in the backdrop, we would like to draw your attention to the following countries:

- Nepal: IP grade Indian pharma products are registered and approved in Nepal (also approved production plants). Additionally, the IP treaty signed with the country makes Indian pharma products eligible for sale in Nepal. Hence, we should be allowed to export domestic packs as per IP.
- Afghanistan: Although IP grade products are not registered in Afghanistan, the IP treaty signed with Afghanistan should allow India Market Only label products to be exported to the country. Also, as per the treaty, in case of an emergency tender supply, wherein Indian manufacturers are unable to manufacture export products due to paucity of time, the importing country may accept domestic labels – because patients cannot suffer.
- Other non-registered countries: In other neighbouring countries like Bhutan, Sri Lanka and Maldives, Indian pharma manufacturers should be allowed where our products aren't registered so to export domestic packs to enable access to quality affordable medicines.
- In multiple countries where Ministry of Health and Family Welfare has also issued special import permit stating IP grade packs are allowed to be imported due to shortages/emergency requirement.

In view of the above, your consideration on the request to grant exemption for neighbouring countries, considering the paucity of time and the lesser requirement of quantity in these countries compared to the batch size manufactured, will greatly benefit the industry by alleviating the current burden.

These were submitted to Drugs Controller General of India, Central Drugs Standard Control Organization, Government of India.

For detailed recommendations, please write to
Mr Praveen K. Mittal at praveen.mittal@ficci.com

FICCI's request to resolve existing challenges with Form 1, Para 2(u) of DPCO 2013 price approval of new product launches in the domestic market

Member companies with reference to the Retail Price Approval process for new drugs under Form 1, as stipulated in Para 2 (u) of the DPCO 2013:

According to para 2(u) of DPCO 2013, an existing manufacturer of a drug must apply for prior price approval for a new drug in Form 1:

- The drug must have dosages and strengths specified in the National List of Essential Medicines
- The new drug can be a combination of drugs, listed or not listed in the National List of Essential Medicines

Background & Issues:

The introduction of new drugs and their timely launch in the market is key to the growth of the Indian Pharmaceutical industry. Under current practices, when a new drug is launched in the market after years of research and development by the pioneering company, the subsequent players follow almost immediately thereafter, as per the existing provisions in Drug Laws.

National Pharmaceutical Pricing Authority (NPPA), in many cases takes a minimum of two months, and often more for retail price fixation of a new drug after the submission of the application under the provisions of DPCO 2013, including submission of Marketing Authorization (MA) permission from the Drug Controller General of India (DCGI).

This delay in price approval often negates the advantages gained by the pioneering company, who invests considerable resources in research and development. Furthermore, the subsequent manufacturers/ applicants face similar delays, impacting their ability to bring innovative and potentially life-saving drugs to the market promptly.

The detailed procedure followed is as under for reference:

- Once the new drug is approved by the Subject Expert Committee (SEC) meeting, CDSCO uploads the minutes on the website.
- After 30 to 45 days from the date of the SEC approval, the DCGI issues a formal communication on approval for "Manufacturing & Marketing" to the respective company.
- The company then seeks a license for manufacturing from the State FDA which typically takes two weeks. Post obtaining the license, the company applies for Price approval to NPPA (Form-I). The copy of DCGI and State FDA approval are prerequisite documents for making an application in Form I.
- After processing the application, the NPPA takes up to the next Authority Meeting for Price approval. This process typically takes 45-60 days, including release of draft working sheet over the website.

- Moreover, in cases where there is no market data available for the new drug, the application is additionally taken to the Multidisciplinary Committee of Experts (MDC) Meeting for their views; in such case, the process takes up to 60 - 90 days.

Recommendation:

We request to accepting Form-I application and parallelly accept for processing for the retail price approval of New Drugs, as soon as the SEC minutes approving the product are uploaded by the CDSCO on their website, this will save close to 60 days' time for making the new drug available to patients. These were submitted to Chairman, National Pharmaceutical Pricing Authority (NPPA), Ministry of Chemicals & Fertilisers, GoI.

For detailed recommendations, please write to
Mr Praveen K. Mittal at praveen.mittal@ficci.com

Regulatory Guidelines for samplings of Drugs, Cosmetics, Medical Devices by Drug Inspectors of Central & State Drug Authorities

FICCI Pharma Industry Comments, feedback & suggestions on recent guidelines for "samplings of Drugs, Cosmetics, Medical Devices by Drug Inspectors of Central & State Drug Authorities".

Firstly, we commend the initiative taken to streamline and rationalize the sampling procedure, as outlined in the attached guidelines. The move towards maintaining a centralized monthly database is particularly welcomed, as it promotes efficiency and transparency in regulatory processes.

Having thoroughly reviewed the guidelines and consulted with industry stakeholders, we are confident that these measures will bridge communication gaps between regulatory officers and ensure optimal resource utilization for comprehensive coverage across territories and product categories with identified risks. This guidance document marks a significant step towards harmonizing sampling practices. These were submitted to Drugs Controller General of India, Central Drugs Standard Control Organization.

For detailed recommendations, please write to
Mr Praveen K. Mittal at praveen.mittal@ficci.com

Inputs for allocation and utilization of proposed Corpus of Rs 1 lakh crore for Research and Innovation

The Global Innovation Index (GII) ranks world economies according to their innovation capabilities across all sectors Mechanism for Allocation. India's spending on R&D is around 0.7% of GDP, whereas many other countries spend 2.5-3%. In terms of investment in R&D by pharma companies, it is approximately 7% of net sales, compared to the 15-20% spent by global companies.

- Pharmaceuticals, Biotechnology and Lifesciences are an essential industry that impacts the health of the nation. India is positioned well to move up the value chain from generics to innovation. FICCI has identified some of these priority areas wherein biopharmaceutical innovation should be funded:
  - Antimicrobial Resistance (AMR)
  - Next generation Biosimilars
  - Regenerative Medicine
  - Innovative Technologies
  - Some Other Areas like Novel biologics, mRNA, NCEs, NMEs, cell and gene therapy, orphan drugs, complex generics etc; leveraging. Oligonucleotides (some of them applicable to rare diseases), Antibody Drug Conjugates (ADCs), Peptides, Drug-delivery devices, Implants/Depots/Long Acting injectables, etc. (for better patient compliance) should be also considered.
  - Precision medicine, Cell and Gene Therapy, companion diagnostics based on biomarkers for personalized medicine. The criteria or parameters that should be considered during the allocation process like quality, novelty and innovation .Utilization Guidelines:
  - The aim of this fund should be to develop a self-sustaining ecosystem for innovation. Ecosystems involve diverse participants with their own incentives, which means that promoting innovation could require shaping the incentives correctly.

For detailed recommendations, please write to
Mr Praveen K. Mittal at praveen.mittal@ficci.com

FICCI Seek Support on expediting clearance of the licenses by granting approvals before March 31, 2024, for in process applications for Class C&D Devices for which industry has submitted query response

The representation was made to DCGI seeking his support in granting license approvals for in-process applications for class C & D Devices prior to March 31st 2024 for which industry has submitted query responses.

Class C & Class D medical devices were mandated for registration until September 30, 2023. The extension was requested through applications submitted on or before September 30, 2023, and was extended for a period of up to six months, until March 31, 2024, as per circular F. No. 29/Misc/03/2023-DC (344) dated October 12, 2023.

We have been approached by our members companies who have adhered to the requirements by completing the registrations which was initially voluntary in nature and has applied for manufacturing/import within the stipulated timeline of 01.10.2023. Several applications submitted are still under review, and the licenses are awaited, though most of the queries raised by CDSCO were address through query responses. Through this representation, an earnest request was made to DCGI for his kind support in expediting the clearance of these pending applications for import licenses of Class C & D devices by granting approvals before March 31, 2024 as our companies foresee business loss if the approvals are not granted timely and fear that the unavailability of import licenses may hinder vital patient access to essential medical devices classified under Class C & D,

A compiled list of all pending applications for Class C&D devices from our members including status of the application on MD online was submitted to DCGI along with the representation.

For detailed recommendations, please write to
Mr Praveen K. Mittal at praveen.mittal@ficci.com

FICCI Medical Devices member's challenges and recommendations for Import of Refurbished/Used High-end and High-value Medical Equipment to India

The representation addressed some key concerns faced by industry members related to the additional requirements set forth by Ministry of

Environment, Forest and Climate Change ('MoEFCC') on the import of refurbished high end and high value medical equipment to India.

The office memorandums dated December 15, 2023, and January 9, 2024 issued by MoEFCC have emphasized enforcement on the import of refurbished medical equipment, affecting the timely provision and supply of high-end and high value medical equipment like MRI, CT, and Cath Lab machines. In addition, MoEF is coming up with additional requirements and eligibility criteria as provided in the minutes of the 130th meeting held by Expert committee on 7th February 2024 regarding the import of refurbished medical equipment. These requirements are neither provided nor mandated in MoEF's own office memorandums.

Concerns around additional requirements including residual life, used life amongst others set forth by the expert committee along with corresponding recommendations and justification was submitted to MoEFCC for their timely intervention and resolution of the industry's concerns. The representation was well supported by the necessary documentation.

An addendum to this representation was submitted on 28th March 2024 to the Secretary, Ministry of Environment, Forest and Climate Change.

For detailed recommendations, please write to
Mr Praveen K. Mittal at praveen.mittal@ficci.com

Request issuance of CDSCO License for refurbished/ reuse Medical Devices

The representation relates to critical challenges faced by our industry members pertaining to issuance of CDSCO license for refurbished/ preowned medical devices for import/refurbishment for sale within the country. Until recently, it was understood that if an application had been submitted and the CDSCO had not reached a decision (either approval or rejection), the application was considered valid, allowing import/ refurbishment of medical devices. However, due to current turn of events, our members after multiple discussions with CDSCO have been made to understand the following challenges:

- The release of a refurbished/used policy by Niti Aayog is deemed necessary for CDSCO to approve any products under this category. Until then, approvals are on hold.
- All applications related to refurbished/used medical devices have been suspended, preventing their importation.

In light of the above circumstances and in the absence of a clear regulatory framework for refurbished/reused medical equipment, our industry is not only grappling with significant financial losses but also, more importantly, patients in underserved communities are being deprived of access to cost-effective medical equipment. these devices fall under the regulated category and therefore necessitate licenses for both import and refurbishment within our country. Through this representation we earnestly made an appeal to Secretary, Health for assistance in ensuring the uninterrupted continuation of business operations for the import and refurbishment of medical devices within the country. The representation was well supported by necessary documentation including best regulatory practices from other international countries with regards to refurbished devices and was submitted to Secretary, H&FW with copy to DCGI.

For detailed recommendations, please write to
Mr Praveen K. Mittal at praveen.mittal@ficci.com