VOICE OF FICCI

SHAPING THE AGENDA

June 2023

From the Secretary General

Hon'ble Prime Minister Shri Narendra Modi had his second state visit to the USA in June at the invitation of US President Biden. The visit was seen as a major boost to the Indo-US relationship. Both countries signed several agreements on defence, semiconductors, trade, space, and technology cooperation. India and the USA also agreed to work together on a range of global issues including climate change. FICCI welcomed these landmark agreements and said that PM's landmark visit to the US and productive discussions with President Biden have led to many substantive outcomes and laid the foundation for a new chapter in the bilateral relationship.

In June, FICCI Forum of Parliamentarians (FoP) took a delegation of Indian Members of Parliament (MPs) to the UK to engage with their counterparts, government, industry, and academicians with an aim to enhance bilateral relations between India and United Kingdom. The multi-party group of the MPs was led by Lok Sabha MP and Chair of FICCI FoP Shri Rajiv Pratap Rudy. The group comprised MPs from both houses including Lok Sabha MPs Mr NK Premachandran, Dr Heena Vijaykumar Gavit, Mr Krishna Devarayalu Lavu and Mr Brijendra Singh and Rajya Sabha MPs Ms Vandana Chavan and Mr Sujeet Kumar and along with FICCI President Mr Subhrakant Panda, Past Presidents Dr Jyotsna Suri (also the Co-Chair for FICCI FoP) and Mr Harshavardhan Neotia, and myself.

An Indian business delegation organised by FICCI along with other stakeholders had an exclusive interaction with the President of India, Smt Droupadi Murmu during her maiden state visit to Belgrade (Serbia).

To help India Inc accelerate its climate action in line with the government's net zero commitment, FICCI along with Hindustan Unilever Ltd, set up a Centre for Sustainability Leadership. The centre intends to institutionalise sustainability leadership across FICCI members, focusing, particularly on decarbonisation, green entrepreneurship, and nature-based solutions. This will help the MSMEs, who require considerable handholding in their journey to sustainability.

FICCI submitted various representations and recommendations on critical issues affecting industries to the government on various policy matters. These representations cover a wide range of issues, including the Indian space policy, the ship building industry, cosmetics, regulation, and foreign exchange regulations.

Shailesh Pathak

Industry feedback on ISP 2023

Recognizing the critical importance of the Indian Space Policy 2023 and the profound impact it would have on the nation's socio-economic development, FICCI shared observations and concerns that arose within the Indian space industry w.r.t. Definitional Challenges, Space Resources, activities permitted to be undertaken by NGEs, role of IN-SPACe; Exemptions, clarity on role of NSIL, ISRO and Timelines. This was submitted to the Secretary, Department of Space.

For detailed recommendation, please write to
Mr Vivek Pandit at vivek.pandit@ficci.com

Representation for restoration of Customs duty exemptions related to Shipbuilding Industry beyond April 1, 2024

The Indian shipbuilding industry plays a pivotal role in the economic development of the nation and holds strategic significance in fulfilling India's Defence needs. Government has always provided fiscal incentives to support the 'Make in India' initiative and has ensured a level playing field for the growth of the Indian Shipbuilding Industry.

The Finance Act 2023, through Customs Notification 02/2023 dated 01.02.2023, amended notification No. 50/2017 to restrict the validity of Customs duty exemptions for fully constructed vessels. Impact of withdrawal of Custom duty exemption on Indian Shipyards in general: The ship building industry is import intensive and withdrawal of the exemption on import of raw materials/parts will impact the industry adversely.

Representation: The amendment made vide Customs Notification 02/2023 dated 01.02.2023 be revoked and exemption be extended beyond 31.03.2024 for fully constructed vessels. This measure is crucial considering the strategic importance of the Shipbuilding Industry, particularly for SEZ-based shipyards involved in Defence shipbuilding for India. This was submitted to Secretary – Revenue, Commerce Secretary – MoCI and Defence Secretary & Secretary (Defence Production), Government of India.

For detailed representation, please write to
Mr Vivek Pandit at vivek.pandit@ficci.com

FICCI Representation on request for Exemption of Insecticide for household purposes from the Purview of Retail License

Removing the requirement to obtain additional licences would promote Ease of doing Business & the objective of the Insecticides Act is to

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.

regulate the import, manufacture, sale, transport, distribution, and use of insecticides with a view to prevent risk to human beings or animals. The registered and licensed manufacturers follow strict quality standards, test products for home use, and submit periodic reports to the authorities. This ensures safety and protection to the consumers. This representation was submitted to the Secretary, Department of Agriculture & Farmers Welfare, Ministry of Agriculture & Farmers Welfare, Government of India.

For detailed representation, please write to
Ms Leena Jaisani at leena.jaisani@ficci.com

Rationalization of licensing requirements for retail trade to improve for Ease of Doing Business & NSWS

There is a need to implement sector specific measures to improve the ease of doing business in this space and galvanize its growth from regulatory uncertainty. In order to support government efforts towards making this possible, FICCI proposed certain reforms related to reducing licensing requirements for the entire retail industry in sync with the vision of the Draft Retail Trade Policy. These were submitted to the Joint Secretary, Internal Trade & E-Commerce Section, DPIIT, Ministry for Commerce & Industry, Government of India.

For detailed representation, please write to
Ms Leena Jaisani at leena.jaisani@ficci.com

FICCI Representation on extension of interim arrangement for Custom Clearance for in-process EPR Applications for 85 EEEs items

The industry concerns pertaining to the issues with operationalization of the online EPR portal during the month of May-2023 and miscellaneous errors during login and submission of application process. FICCI have been informed by the industry members that during this period many industry members/ producers were not able to submit online applications and the portal became fully functional only from last week of May-2023, and the industry members initiated submitted / are in process of submitting EPR applications in June-2023. In the meantime, while the EPR applications were being processed at CPCB, and earnestly requested for providing 2-3 months extension for interim arrangement to facilitate custom clearance of imported consignments for applicants which have submitted the online EPR applications till 30-June-2023. FICCI also requested to expedite the processing of submitted EPR applications and grant issuance of registration certificates at the earliest. This was submitted to Scientist-F and DH (WM – III), Central Pollution Control Board (CPCB), New Delhi.

For detailed representation, please write to
Ms Leena Jaisani at leena.jaisani@ficci.com

FICCI Representation on the Draft Cosmetics Rules (Amendment), 2021

The draft rules have rightly so focused to expand into specific provisions governing cosmetics to bring greater clarity for the concerned industry. It also attempts to bring clarity on various substantive and enforcement provisions of the existing regulations. However, considering the revamp of the regulations, it is imperative to review the same holistically to ensure that the new law is forward looking and balancing the interests of the public, industry, and economy of our nation. While the Draft Rule Amendment is a welcome step, there are certain aspects and concerns pertaining to the Draft Rules that the industry would like to bring to the notice of the Ministry. This was submitted to Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India.

For detailed representation, please write to
Ms Leena Jaisani at leena.jaisani@ficci.com

MCA Proposal on demat for certain private companies

Ministry of Corporate Affairs (MCA) had sought FICCI' comments on its proposal to extend the applicability of dematerialization provisions to private companies which have paid-up share capital of Rs. 5 crore or more; or turnover of Rs. 100 crore or more; or outstanding debt/ deposit of Rs. 50 Crore or more. FICCI has submitted that the proposal should be implemented on voluntary basis initially. The benefits that dematerialisation offers viz. free transferability of shares and increased liquidity of the investment, are not a pressing concern for private companies or their shareholders and therefore voluntary implementation would encourage such companies to appreciate the benefits and on-board themselves. This was submitted to the Assistant Director, MCA.

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

Challenges w.r.t. amendment to ODI/OPI/LRS Rules

FICCI has highlighted industry concerns pertaining to recent amendments to Foreign Exchange Management (Overseas Investments) Directions, 2022 dated August 22, 2022 and amendments to Master Direction - Liberalized Remittance Scheme (LRS) dated August 24, 2022. As per the amendments, only CCPS is being treated as equity capital and other instruments such as Convertible Note (CN), SAFE (Simple Agreement for Future Equity) Note etc. are not being treated as equity capital. However, CN and SAFE are also compulsory convertible into equity capital and thusthese instruments should be covered in the definition of equity capital. Further, due to the 180-day period rule, a resident individual has to face lots of issues like where to park the fund to get better return and may also not able to invest the amount within the given time of 180 days. It has been submitted that this requirement may be dispensed with. These were submitted to the Governor of RBI.

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

SEBI Consultation Paper on Review of Total Expense Ratio charged by AMCs to unitholders of schemes of Mutual Funds to facilitate greater transparency and accrual of benefits of economies of scale to investors

Based on feedback received from members, FICCI has submitted to SEBI, the inputs on the challenges that industry would face if the proposals on TER charged by AMCs were to be implemented such as whether GST should be included while calculating TER, whether Mutual Funds should be provided with an option to have schemes with performance-based TER etc.

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

SEBI consultation paper on proposed review of the definition of UPSI to bring greater clarity and uniformity of compliance in the ecosystem

Based on feedback received from members, FICCI has submitted to SEBI, that the current definition of UPSI should be retained, and the proposed change should not be implemented, due to several technical and practical implementation issues, blurring of distinction between material information and price sensitive information etc. It has been submitted that the objective of the amendment could potentially be achieved by issuing necessary clarifications / Guidance Note / FAQ related to the identification of UPSI, which would provide listed entities with a set of guidelines to adhere to and bring clarity on the actual intent of PIT Regulations. It has been further suggested that in the event if the proposal is made applicable, rather than taking a blanket and uniform approach of treating all the material events/information under SEBI LODR Regulations as UPSI for the purpose of PIT Regulations, SEBI may consider expanding the scope of the term 'is likely to materially affect the price of the securities' under the definition of UPSI by inserting in Regulation 2(1)(n) of PIT Regulations, those scenarios which are likely to potentially impact the share price of the company and/or as a guidance state that, any information to qualify as UPSI/price sensitive, should have an upside or downside effect of 5% or more on the market price of the security.

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

Classification of bonus shares in prohibited sector

It has been submitted to Joint Secretary, DEA, MoF, to clarify that rights issuances and bonus issuances are to be treated separately, so as to avoid any scope for misinterpretation. Since the shareholding pattern of the company remains unchanged in a bonus issuance and there is no possibility of any increase in the foreign shareholding or any inflow of foreign capital on account of bonus issuance, a clarification may be issued that bonus issuances are freely permissible under FEMA so long as (i) the bonus shares are subject to the same conditions of repatriability as the original shares; and (ii) the bonus issuances are compliant with the applicable securities laws. The Government may therefore delink the bonus issuances from rights issuances under Foreign Exchange Management (Non-Debt Instruments Rules), 2019. Resolving this bottleneck in the FDI Policy would significantly improve the ease of doing business in India.

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

Extension for holding AGM through VC/OAVM upto 31 Dec 2023

In view of apparent benefits of AGMs organised through VC/OAVM and pending implementation of this provision as a permanent dispensation, as recommended under the Report of Company Law Committee, FICCI has submitted to the Joint Secretary, Ministry of Corporate Affairs to consider extending the relaxations provided by the MCA Circular dated 28th December 2022 read with General Circular No. 20/2020 dated 5th May 2020 - uptil 31st December 2023.

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

Ease of doing business issues wrt regulations falling under the remit of PMAC

SEBI had sought inputs from FICCI with respect to ease of doing business issues falling under the purview of SEBI-PMAC. With the objective of reducing cost of compliance, simplifying submissions, digitizing submissions, registrations etc. FICCI has submitted recommendations under SEBI Regulations on LODR, ICDR, SAST and Delisting.

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

Manual of Methods of Analysis of Foods- Honey and Other beehive products and Microbiological Examination of Food and Water

In the submitted representation to FSSAI, FICCI shared comments on the FSSAI notification related to the manual of methods of analysis of foods-Honey and Other beehive products and Microbiological examination of food and water.

For detailed representation, please write to
Mr Abhinav Singh at abhinav.singh@ficci.com

CIFTI – FICCI representation on FSSAI draft notification on FSS (Foods for Infant Nutrition) Amendment Regulations, 2023

In the submitted representation, FICCI shared comments on the FSSAI draft notification on FSS (Foods for Infant Nutrition) Amendment Regulations, 2023, wherein we proposed to revise the norm of iron in Processed cereal-based complementary Food from 2.00 - 5.65 to 3.00 – 7.00 and Manganese, mcg limit from 5-400 to 500mcg/100g for Lactose free Follow up Formula.

For detailed representation, please write to
Mr Abhinav Singh at abhinav.singh@ficci.com

CIFTI – FICCI representation on FSSAI draft notification on FSS (Prohibition and Restrictions on Sales) Amendment Regulations, 2023

In the submitted representation, FICCI shared comments on the FSSAI draft notification on FSS (Prohibition and Restrictions on Sales) Amendment Regulations, 2023, wherein we proposed to delete the clause "It shall be compulsorily sold in sealed packages weighing not more than 500g. under Agmark certificate mark.", in alignment with the draft proposal.

For detailed representation, please write to
Mr Abhinav Singh at abhinav.singh@ficci.com

FICCI Inputs/agenda for Second Inter-Ministerial Committee (IMC) for periodic Sectoral review and policy/ schematic orientation/ intervention required by MoFPI-reg.

In the submitted representation to Ministry of Food Processing Industries, FICCI shared issues for discussion in the second Inter-ministerial Committee meeting, which included:

- Lower Taxes for Beverages with Zero/Low Sugar

- Classification and rate of GST on "marinated chicken"
- Input tax credit available for the restaurant sector with 12% GST slab
- Import duty on cocoa beans

For detailed representation, please write to
Mr Abhinav Singh at abhinav.singh@ficci.com

Applicability of Stamp Duty on Bank Loans / Mortgage by deposit of Title Deeds under Article 5, 6, 37(b) & 50 of the Rajasthan Stamp Act 1998

At the outset, FICCI would like to state that as a matter of consistent practice for availing any loan facility from any bank by a Company, several documents, like Agreement relating to Deposit of Title Deeds, Guarantee Deed, Hypothecation Deed, Letter of Indemnity, and various other documents, are executed where upon loan facility is disbursed to the Company. The Stamp Authorities are now seeking to demand stamp duty on each of these Supplementary documents separately executed every time the borrower seeks an additional loan facility from the bank. Whereas the suggested approach should be taking stamp Duty only once on the principal instrument which is chargeable with the highest rate of Duty which can either be agreement relating to Deposit of Title deeds or Hypothecation Deeds (as the rates are same for both the documents- 0.25% with a maximum cap of Rs 15 lacs). This was submitted to ACS - Finance, Government of Rajasthan.

For detailed recommendation, please write to
Mr Atul Sharma at atul.sharma@ficci.com

Request to allow MSMEs to switch from RIPS-2019 to RIPS-2022

FICCI would like to draw your kind attention toward an ambiguity created by an order dated 10 February 2023 wherein large projects, under customized package, ich got registered under RIPS-2019 and have only availed the benefit of stamp duty and registration charges exemption, may switch to RIPS-2022. This option is not available to other investments including MSMEs with the same criterion. This was submitted to ACS - Finance, Government of Rajasthan.

For detailed recommendation, please write to
Mr Atul Sharma at atul.sharma@ficci.com

FICCI representation on Export Policy of Cough Syrup

The Amendment in Export Policy of Cough Syrup, as per DGFT Notification No. 06/2023 dated 22.05.2023 and DCGI letter File no. DCGI/MISC/2023/09 dated 25.05.2023, mandates that Cough syrup can be exported only after the export sample is tested and a Certificate of Analysis (CoA) is obtained from designated laboratories. The laboratories mentioned are the Indian Pharmacopoeia Commission in Ghaziabad, Uttar Pradesh, and any NABL accredited State Drugs Testing Laboratory. The government's initiative aims to strengthen the business, innovation, and healthcare environment while prioritizing quality.

However, certain challenges have been raised by FICCI regarding its implementation. These challenges include overloaded NABL accredited government laboratories and the impact on existing export orders and timelines.

FICCI Pharma Committee requested to address these challenges, including the avoidance of testing every batch for well-established reputed manufacturers, mandating random or representative sampling, granting waivers for companies inspected by importing country regulators, granting waivers if testing is already mandated at the port of the importing country, permitting private sector NABL accredited labs for testing, and granting exemptions from testing if specific conditions are met. Clarification is also sought regarding the timing of batch testing, whether it should be done before export or at the time of batch release from the manufacturing site. These were submitted to Special Secretary (Health), Department of Health & Family Welfare, Ministry of Health & Family Welfare and Additional Secretary & Director General, Directorate General of Foreign Trade, New Delhi.

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

FICCI Recommendations post 16th May meeting- Request for participation in the upcoming Industry Consultation on DPCO by NPPA "On 16th May, an industry stakeholder consultation/workshop was conducted by NPPA to gather suggestions for DPCO 2013 and NPPA 2012

FICCI submitted detailed para-wise recommendations/inputs for the Pharma sector to the Chairman, National Pharmaceutical Pricing Authority (NPPA), including long-pending asks of industry: market-based pricing model should be retained, as outlined by the Pronob Sen Committee in 2005 and the Group of Ministers in 2012. Furthermore, it was recommended that not all drugs included in the NLEM need to be subjected to price control. Instead, a finite list of drugs requiring ceiling price fixation should be filtered out.

Few New suggestions were also highlighted in the written recommendation submitted: Exemption of Low-cost drugs, Implementation of scheduled formulations from the prospective batch manufactured, Incentives for Incremental innovation, Discontinuation of scheduled formulations, and Incentive for Quality.

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

FICCI Request for Exemption/ Concessional rate of duty/Rationalization on import of drugs used in the treatment of life-threatening rare disease conditions

The National Policy for Treatment of Rare Diseases (NPTRD) was released by the Ministry of Health and Family Welfare in March 2021. The policy emphasizes the need to increase the affordability of drugs used in the treatment of rare diseases. Notification No. 02/2022-Customs, issued by the Ministry of Finance on February 1, 2022, granted exemption from Basic Customs Duty to these drugs when imported by the Centres of Excellence (CoEs) established under the NPTRD.

In March 2023, the Central Board of Indirect Taxes and Customs (Ministry of Finance) fully exempted all drugs and food for special medical purposes imported for personal use, for the treatment of rare diseases listed under the National Policy for Rare Diseases (NPRD) 2021, from basic customs duty.

However, a significant number of patients receive treatment at

Government and Non-Government hospitals not covered under CoEs. Drugs provided to such patients are subject to a 10% customs duty, which places a heavy burden on them and hampers their access to these drugs.

To enhance treatment accessibility and drug affordability for all rare disease patients, in accordance with the National Policy for Rare Diseases, FICCI, on behalf of member industries, requests the following:

1. Extend the full exemption of basic customs duty on the import of drugs to all government and private hospitals/importers that provide treatment for rare disease patients listed under the National Policy.

   Additionally, it is suggested to establish a help desk to address any queries patients may have during the drug importation process.

2. BCD concession and Duty rationalization:

   (A) Grant concessional rates of Basic Customs Duty (BCD) and Goods and Services Tax (GST) on the import of drugs used in the treatment of life-threatening rare disease conditions, such as C1 Esterase Inhibitor (Human) for Hereditary Angioedema (HAE), Agalsidase Alfa for Fabry disease, Velaglucerase for Gaucher disease, and Idursulfase for Hunter syndrome.

   And,

   (B) Requested duty rationalization for the following:

   The GST should be reduced from 12% to 5% on Tecentriq is 12% for cancer immunotherapy treatment.

   Existing GST and customs duty exemptions be extended to all anti-Haemophilia A drugs for Factor VIII and IX deficiencies.

   Full waiver on GST and Customs Duty for Evrysdi, in line with other rare disease products.

3. Include Tafamidis Soft Gelatin Capsules (VyndaMx® 61 mg) for Transthyretin amyloid cardiomyopathy (ATTR-CM) as a new rare disease in the National Policy for Treatment of Rare Diseases (NPTRD).

These were submitted to Special Secretary (Health), Department Of Health & Family Welfare, Ministry Of Health & Family Welfare, Government of India.

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

FICCI Request on PPO Expert Committee

The attention is drawn to the challenge faced by patients in accessing patented medicines not manufactured in India due to the Public Procurement Order. The Department initiated the process of identifying non-local devices and drugs in 2021, based on representations from the pharma and medical devices industry. In November 2022, the government exempted 90 medicines from the provisions of the Global Tender Enquiry (GTE) list until 31st March 2023.

However, in an order dated 3rd April 2023, the government extended the exemption for one year but reduced the number of exempted medicines to 70, excluding certain patented medicines. This exclusion raises concerns about the public procurement system's uncertainty and impact on patient healthcare. The possibility of providing infringing generic medicines instead of the original innovator drug also raises concerns about IP rights protection.

Requests have been made to implement a transparent and time-bound process for the inclusion and exclusion of medicines from the GTE list, with involvement from industry associations. Additionally, the time frame for exclusion should be 2-3 years, and consideration should be given to the patent validity of the medicine and inclusion of proprietary medicines from a single manufacturer.

A recent meeting held by the DGHS indicates a plan to implement a transparent and consultative process for evaluating the current list and including new medicines, along with the establishment of a portal for real-time information. Industry associations advocate for their inclusion in the committee to provide their perspectives on the inclusion/exclusion of medicines and medical devices from the GTE exemption list. These were submitted to Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India.

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

FICCI Request for issuance of 'one-time export NOC/manufacturing license followed by COPP for Pharmaceutical and Biological products which falls under Unapproved/Banned drugs/New drugs solely for export purpose' instead of 'country specific and quantity specific approvals'.

FICCI recommended to Drugs Controller General of India, Central Drugs Standard Control Organization

Government of India, the issuance of a 'one-time export NOC/manufacturing license followed by COPP for Pharmaceutical and Biological products' instead of 'country specific and quantity specific approvals'. The current process of obtaining country-specific and quantity-specific approvals for pharmaceutical and biological product exports from India is time-consuming and hampers the industry's competitiveness.

The proposed recommendation suggests streamlining the process by granting a one-time export NOC and manufacturing license that is not specific to quantity or country. Currently, applicants need to obtain these approvals for each export purchase order, resulting in delays. The suggested approach would involve granting the export NOC and manufacturing license within 15 days and the COPP within 30 days, reducing the total time required from 180 days to 45 days.

For biological products, the current process requires an export NOC from CDSCO HQ in New Delhi and a manufacturing license with a counter sign from CLA. This process takes around 8 to 10 months, causing significant delays for repetitive export orders. The recommendation proposes granting a one-time export NOC for manufacturing unapproved/banned drugs and new drugs derived from r-DNA technology solely for export purposes. This would be followed by obtaining a manufacturing license and subsequently a COPP within a total time frame of 75 days instead of the current 8-10 months.

Implementing these recommendations would alleviate the burden on exporters and promote export growth by eliminating the need to reapply for NOCs for repeat orders. This recommendation aims to

expedite the approval process, reduce the burden on exporters, and leverage India's potential as the 'pharmacy of the world' and align with the objectives of the recent Foreign Trade Policy.

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

Representation and meeting request highlighting urgent approval of regulatory framework and list of medical equipment's allowed for importing as refurbished

A detailed representation and discussion on Refurbishment process done by Medical Devices Companies and suggested list of high-end-high value medical devices submitted to Special Secretary, Ministry of Health and Family Welfare.

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

Industry's opinion on minutes of stakeholders' engagement issued by SNCM was made by member companies manufacturing Coronary Stents

Post Inclusion of Coronary Stents in National list of essential medicines by SNCM chaired by DG ICMR, NPPA has to refix the ceiling price of Coronary Stents, member companies requested for further stakeholder engagement and consideration of Randomized Clinical Trials data for sub-categorization of Coronary Stents as per availability of Clinical Data, to which requestion for sharing clinical data was made by FICCI on behalf of members. These were submitted to Secretary DHR & Director General, ICMR.

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

Regarding - Submission to support sub categorization of Drug Eluting Stents (DES)

Detailed submission of RCTs data by 6 companies and 2 research articles describing sub-categorization of Coronary Stents; submitted to SNCM. SNCM has been requested to do sub-categorization of DES basis RCTs and arrange larger stakeholder consultation involving industry and medical experts. These were submitted to Secretary, DHR & Director General, ICMR.

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

Request for extension of June 30th deadline due to inability of industry to comply with Reduction of Hazardous Substances [RoHS] compliance under E-waste Rules 2022

It was highlighted that the industry is unable to meet the 30th of June 2023 deadline for submission as the Reduction of Hazardous Substances [RoHS] exemption on the lines of EU2011/65 /EU (RoHS) Directive is still awaited from the Ministry. Without the Annex IV exemptions OF THE EU2011/65 /EU (RoHS) Directive for medical technology, medical devices cannot be used in the Indian market from April 2023. [Cadmium, Mercury of, Hexavalent Chromium, polybrominated biphenyls and polybrominated diphenyl ethers] Request for Exemption in line with EuROHS was made. These were submitted to Additional Secretary, Ministry of Environment, Forest and Climate Change and Member Secretary, Central Pollution Control Board.

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

Request for issuance of pending exemption of Reduction of Hazardous Substances [RoHS] compliance under E-waste Rules 2022

An exemption of the Sub-rule (1) Rule 16 of Chapter VII under E-Waste (Management) Rules, 2022 in line with EuROHS guidelines is asked for Medical Devices. This was submitted to Additional Secretary, Ministry of Environment, Forest and Climate Change.

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

For more details contact FICCI Membership at:
tripti.kataria@ficci.com/9818000591