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PHARMEXCIL DIGEST

MARCH & APRIL 2025

YOUR MONTHLY UPDATE ON EXPORT TRENDS, REGULATORY CHANGES , NOTIFICATIONS & GLOBAL MARKET INSIGHTS

WHAT'S INSIDE

Edition: March & April 2025

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PUBLISHED BY

Pharmaceuticals Export Promotion Council of India

(Set up by Ministry of Commerce & Industry, Government of India)

Foreword

Namit Joshi

Welcome to a New Era of Pharmaceutical Export Excellence!

Quality, Innovation, Affordability, and Accessibility—these pillars define the backbone of the pharmaceutical industry. India has emerged as a key force in this ecosystem, distinguished by cutting-edge manufacturing capabilities and an unwavering commitment to quality. As the industry confronts evolving challenges, ranging from regulatory shifts to dynamic market trends, the need for strategic, well-informed decision-making has never been greater.

Pharmexcil's newsletter serves as a vital resource for India's pharmaceutical exporters, delivering timely, precise, and actionable intelligence. With global trade policies and regulatory frameworks in continuous flux, this publication simplifies complex developments, offering insights into key regulatory updates, trade dynamics, government initiatives, and Council actions. More than just a compilation of news, it empowers stakeholders with clarity, ensuring they remain agile in an increasingly competitive landscape.

India continues to strengthen its position as the "Pharmacy of the World," built upon decades of excellence in generics, bulk drugs, vaccines, and biosimilars. This reputation stems from relentless innovation, stringent quality standards, and a forward-thinking approach to research and development. Despite regulatory challenges, India's pharmaceutical industry has shown resilience, achieving USD 30.46 billion in exports with 9.40% growth during FY 2024-25. Congratulations to the industry for its dedication and excellence, reinforcing India's position as the "Pharmacy of the World" and advancing global healthcare.

The unwavering trust and active participation of our member companies are the driving forces behind our collective success, and I place my special thanks to the Members of Committee of Administration in this context. Their dedication not only fuels individual achievements but also fortifies India's standing in the global healthcare ecosystem. We deeply appreciate your confidence in Pharmexcil, it is this shared vision that propels the industry forward, despite uncertainty.

I would also like to recognize the dedicated Pharmexcil team whose expertise and meticulous analysis ensure that this newsletter remains insightful, relevant, and practical. Their ability to distill intricate trade and regulatory information into a streamlined, accessible format makes this publication an indispensable tool for decision-makers.

I hope this edition delivers valuable perspectives, inspires innovative strategies, and serves as a catalyst for India's pharmaceutical expansion on the international stage. May it provide clarity and vision as we collectively pave the way for the future of global healthcare leadership.

Raja Bhanu

Welcome to the first edition of Pharmexcil's Monthly Digest!

At Pharmexcil, we are committed to empowering our valued member exporters by providing timely, relevant, and strategic insights that support international trade and business growth. This bulletin serves as a vital resource, offering concise updates on regulatory developments, export trends, government notifications, and member achievements—all designed to help you navigate the evolving pharmaceutical landscape with confidence.

As India continues to strengthen its position as a global pharmaceutical leader, we remain dedicated to ensuring our stakeholders have the knowledge and tools needed to seize emerging opportunities. Through this initiative, we not only highlight key council activities but also bring forward industry voices, policy perspectives, and collective efforts toward expanding international market access.

We sincerely appreciate the unwavering support of our member companies and extend our gratitude to the Pharmexcil team for their dedication in curating this knowledge-driven publication. We hope this edition serves as a valuable guide in your global outreach journey. Here's to continued success and growth!

Pharma Export Performance

Period : APRIL 24-MARCH25

Total Export Value
USD Bn
30.46

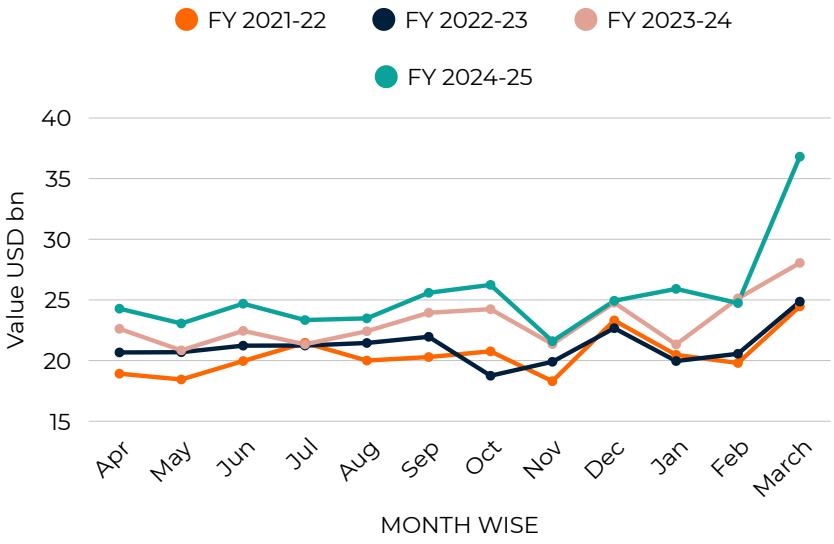
Y-o-Y Growth :
+9.40%

Average Monthly growth
9.17%

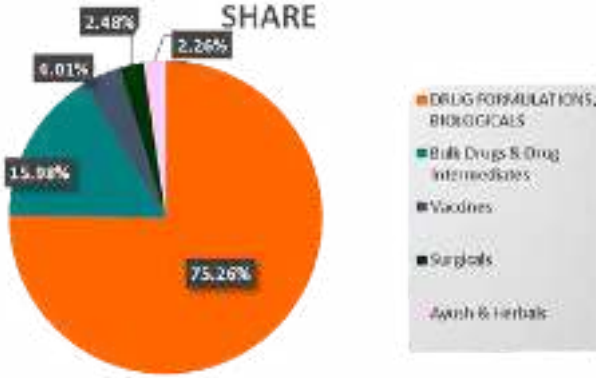
Export Trends

- **NAFTA Region** (Strongest regional contributor -USD 11.46 bn) — **%19.65** ▲
- **Drugs formulations & Biologicals** (Leading Category - (22.92 bn ;75.26% share) — **%11.65** ▲
- **Surgicals & Ayush & Herbals** (Categories with lowest share i.e. 2%) — **5.01% & 6.11 %** ▲
- **Africa & NEA Regions** (Notable contraction in regional export value) — **%-0.42 & % -4.8** ▼

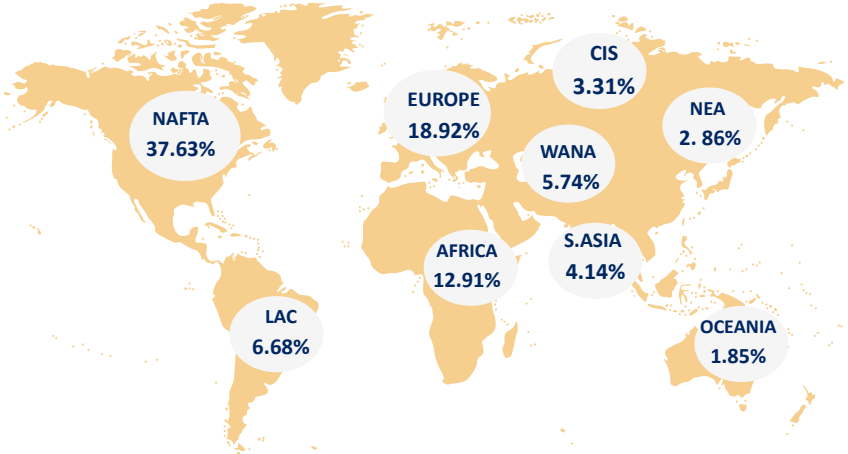
Export trends Apr-Mar, FY23, FY24 and FY25



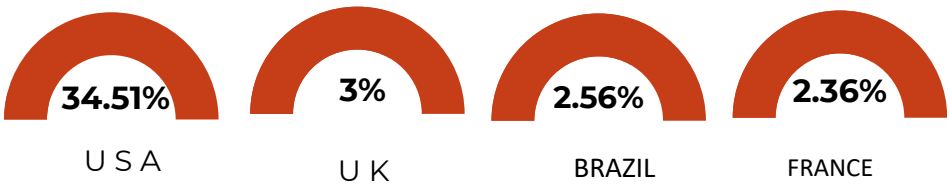
Category Wise Pharma Exports



Region Wise Pharma Performance



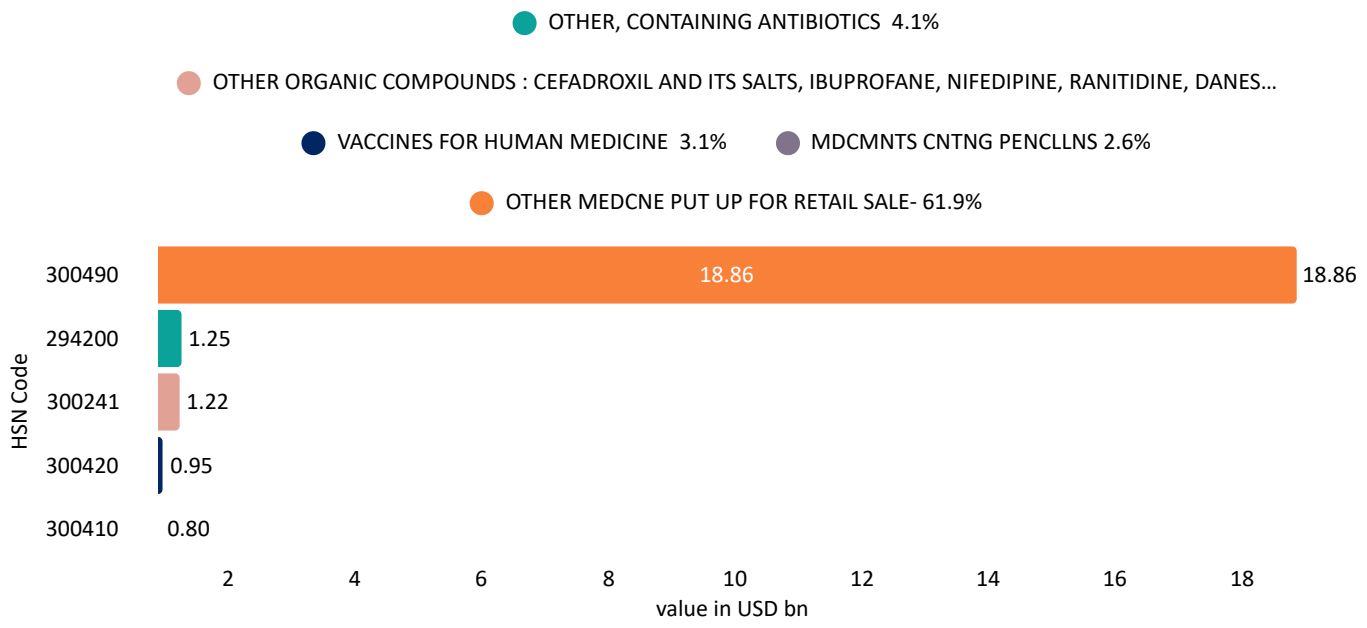
Top 5 Exporting Destinations Share in Total Exports

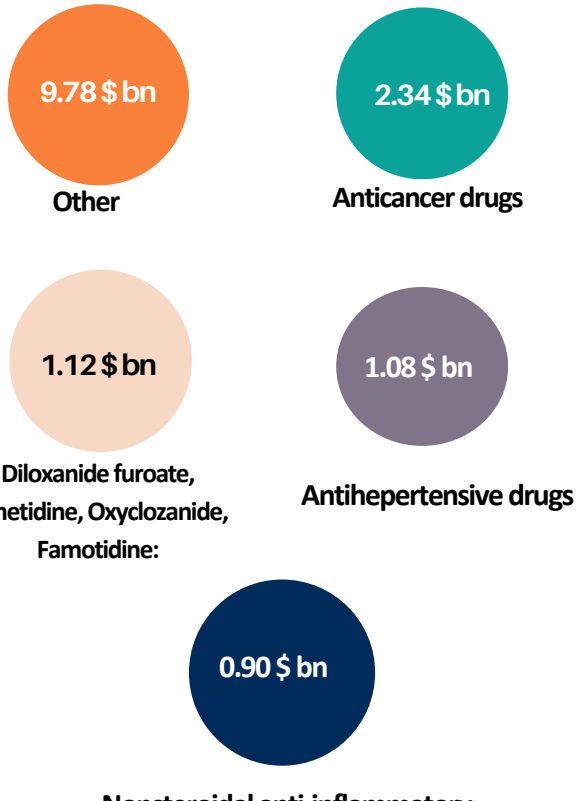


(Source: DGCIS)

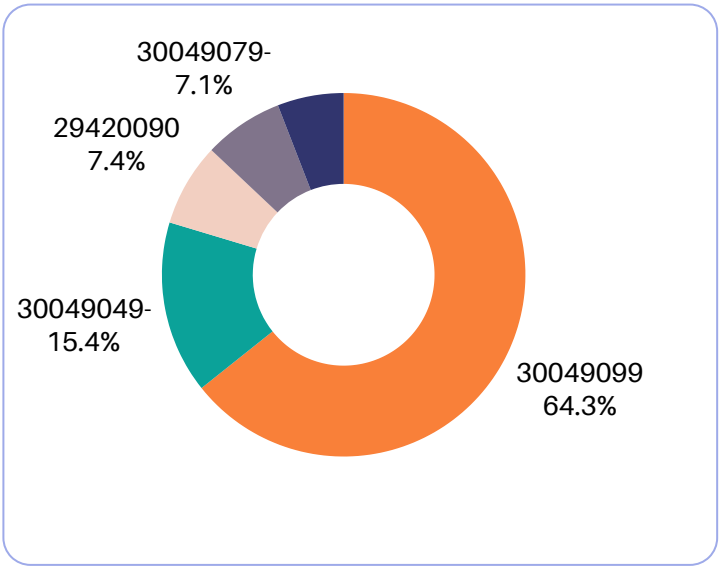
TOP 5 PRODUCTS OF PHARMA EXPORT BY VOLUME & THERAPY

THERAPEUTIC WISE EXPORT PERFORMANCE





PRODUCT WISE EXPORT PERFORMANCE BY HSN CODE



(Source: DGCIS)

PHARMEXCIL ACTIVITIES

03-11 MARCH 2025: ASEAN DELEGATION (VIETNAM, PHILIPPINES & MALAYSIA)

In a significant step towards strengthening the pharmaceutical trade ties between ASEAN region, Pharmexcil lead a 39-member company Business Delegation to ASEAN countries commencing with Vietnam (Ho Chi Minh City) during 02-05.March.2025, Philippines (Manila) during 05-07 March.2025, and Malaysia (Kuala Lumpur) during 08.March-11.March.2025.

Vietnam: Associated with Vietnam Chamber of Commerce & Industry (VCCI) and hosted by Consulate General of India, "India-Vietnam Pharma Forum" Graced by Consul General Dr.Vipra Pandey,IFS & Mr.Tran, General Director, VCCI, HCM. Held B2B meetings with 70 companies from Vietnam.

Health Sector in Vietnam is going through major changes, prioritizing local manufacturing. Delays in the product approvals perhaps meant for the local manufacturing. Technical prowess to be improved for evaluation of High-end products/new molecules resulting in delays for product launches.

Philippines:

"India-Philippines Pharma Forum" hosted by the Embassy of India supported by Philippines India Business Council (PIBC). Graced by H.E Harsh Kumar Jain,IFS, Ambassador, H.E Lokin, President/CEO, Philippines Pharma Procurement Incorporation (PPPI), Mr. Jhonny Chotrani, President, PIBC, Mr.Bhanu, DG Pharmexcil.

Renewed MoU with Philippines Pharma Procurement Incorporation(PPPI) , the largest Government Procurement Agency. Mr.Raja Bhanu, Director General discussed scope of collaboration and medicine supplies in FDF & API with Hon. Maria Blanca, President/CEO of Philippines Pharma Procurement Incorporation (PPPI). Held B2B meetings with 125 companies from Philippines side.

Malaysia

"India-Malaysia Pharma Forum" hosted by the High Commission of India supported by Local pharma associations. Graced by High Commissioner HE BN Reddy, IFS, Pn. Nik Salleh, Head, Generic Medicines, National Pharmaceutical Regulatory Authority (NPRA), Mr.Selvam, President (FICCIM), Mr.Bhanu DG Pharmexcil

Pharmexcil visit to Malaysia for the first time has identified market opportunities for Oncology. Local industry sources mention shortage of medicines and opportune time for supplies from India side. Held B2B meetings with 150 companies from Malaysia.

Had exclusive meeting with Dr. Azuana, Director, NPRA & team on the regulatory procedures, collaboration on medicine supplies. Delays in approvals and plant audits were discussed and sought cooperation for fast track clearances. Met M/s. Pharmaniaga (lead importer) SCM Head, Mr.Affandi and explored the procurement model & supply sources.

The Delegation was led by Mr.Raja Bhanu, Director General and coordinated by Mr. Murali Krishna S, Director.

03 MARCH. 025: VC MEETING OF INDUSTRY STAKEHOLDERS REGARDING COOPERATION IN PHARMACEUTICALS AND MEDICAL DEVICE INDUSTRY WITH THE KINGDOM OF SAUDI ARABIA HOSTED BY DOP

A video conference chaired by Ms. Gayatri Nair (DoP) set the agenda for the upcoming India-Saudi Arabia webinar on pharmaceutical collaboration, hosted by Invest India with Saudi Arabia's MISA and LCGPA. Ms. Lakshmi Prasanna, Sr.Director highlighted the SFDA president's 2023 India visit and emphasized boosting Indian medicine registrations in Saudi Arabia. Suggestions included detailed deliverables and planning in-person sessions to strengthen bilateral ties.

07 MARCH 2025: HYBRID MEETING ON THE INDIA-ARMENIA BUSINESS FORUM IN THE PHARMACEUTICAL SECTOR

The India-Armenia Business Forum in the Pharmaceutical Sector, organized by the Indian Embassy in Armenia with Pharmexcil, focused on strengthening bilateral trade, exploring opportunities, and fostering regulatory collaboration. It featured 148 Indian and 45 Armenian pharma companies, a presentation on India's pharma sector, and discussions on regulatory harmonization, market access, and healthcare collaboration. The hybrid format enabled impactful engagements aimed at improving healthcare and promoting innovation.

12 MARCH 2025: SEMINAR ON "INDIA-JAPAN PARTNERSHIP TOKUSHIMA" ORGANIZED BY EMBASSY OF INDIA, TOKYO

The Embassy of India in Japan organized a seminar on "India-Japan Partnership Tokushima" to celebrate Tokushima Day, attended by Ambassador H.E. Mr. Sibi George and Governor H.E. Mr. Gotoda Masazumi. The event emphasized enhancing India-Japan ties, particularly with Tokushima Prefecture, in trade, investment, tourism, and human resources. Mr. Bhanu, DG Pharmexcil, highlighted India's pharmaceutical strengths, inviting Japanese companies to explore CDMO opportunities and collaboration in biosimilars.

21 March 2025: Opportunity Africa: Business Synergies for India organised by Andhra Chamber of Commerce :

The Andhra Chambers of Commerce organized a seminar on "Opportunities in Africa Region," graced by Chief Guest Mr. Jayesh Ranjan, IAS, Special Chief Secretary, Industry & Commerce, IT Departments, Government of Telangana. Representatives from African embassies, including Zambia, Kenya, and Uganda, highlighted trade potential and investment opportunities, encouraging industries to explore setting up units. Mr. Raja Bhanu, Director General of Pharmexcil, provided an overview of Pharmexcil's initiatives in Africa and emphasized India's significant role in supplying affordable antiretroviral (ARV) medicines to the region.

24 MARCH-01 APRIL 2025: AFRICA DELEGATION (ZAMBIA, TANZANIA AND ETHIOPIA)

Pharmexcil, in collaboration with the Ministry of Commerce and Industry and Indian missions in Zambia, Tanzania, and Ethiopia, organized Buyer Seller Meets:

India Zambia Pharma Business Forum (Lusaka, March 24, 2025)
India Tanzania Pharma Business Forum (Dar Es Salaam, March 27)
India Ethiopia Pharma Business Forum (Addis Ababa, April 1, 2025)

A delegation of 62 pharmaceutical companies participated. Events in Zambia and Tanzania attracted over 200 delegates, including representatives from the Ministry of Health, regulatory authorities, and private industry.

The Ethiopia event took place on April 1, 2025, graced by Hon'ble Health Minister H.E. Dr. Mekdes Daba, H E Anil Rai Ambassador of India to Ethiopia, H.E. Dr. Zeleke Temesgen Commissioner, Ethiopia Investment Commission, Mr.Bhavin Mehta ,Vice Chairman, Pharmexcil, Hon'ble Ms. Heran Gerba, Director General ,EFDA, and Mr.Kamal Bharadwaj,Director, Pharmexcil and deliberated on strengthening India-Ethiopia trade realations and greater market acces. B2B meeting held with over 200 delegates from Ethiopia.

25 MARCH 2025: MEETING WITH HIGH-LEVEL MINISTERIAL DELEGATION FROM NETHERLANDS LED BY HON'BLE MS. BARBARA GOEZINNE, VICE MINISTER, CURATIVE CARE, MINISTRY OF HEALTH, WELFARE AND SPORT IN GARDEN ROOM, TAJ KRISHNA, HYDERABAD

Mr.Namit Joshi, Chairman Pharmexcil welcomed the business delegation. Discussion took place on the present trade from India with the Netherlands in pharmaceutical products, access to generic medicines for Netherlands & EU, collaboration opportunities & the barriers that pharma companies encounter and the requested the Netherlands Government to facilitate trade and greater market access to medicines. Ms. Barbara Goezinne, Vice Minister shared that India and Netherlands share excellent trade relations and the country is looking to engage with India on sourcing the generic medicines and ensure uninterrupted supply chain.

Mr.Bhanu, DG sought cooperation for the fast track approvals for both product approvals and facility audits. The delegation met representatives from Sun Pharma, Cipla, MSN, Aurobindo, Hetero, Mylan etc as the existing suppliers.

29 MARCH 2025: STAKEHOLDER CONSULTATION MEETING WITH DCGI

Pharmexcil hosted a Stakeholder Consultation with DCGI on the new export NoC Directive, joined by Chairman & Vice Chairman of Pharmexcil, President of IDMA, BDMA, industry majors and about 250 companies virtually. Discussions covered NoC simplification, challenges like halted exports of specific APIs, and proposals for streamlined processes. Exporters had to obtain a Product Registration Certificate from the importing country's FDA or CDSCO approval, making shipments more complicated and slower. This led to delays in exporting APIs used for clinical trials and regulatory filings, prompting industry stakeholders to request exemptions for recognized APIs and the creation of a distinct category for unapproved drugs that required multiple NoCs.

Additionally, the industry pushed for automated approval mechanisms, streamlined processes for NDPS drug exports, and improved online platforms to enhance efficiency. Companies also advocated for shelf-life flexibility for unapproved drugs and the acceptance of alternative forms of documentation to support export NoCs.

Stakeholders emphasized the need for timely approvals from CDSCO and state licensing authorities, with a recommended five-day timeframe for those of SRA certified sites. They also proposed a centralized online repository for product and facility approvals, differentiation between commercial and exhibit batches for faster clearance, and explicit website revisions to clarify manufacturing license applications.

The meeting was joined by
Mr.Rajeev Wadhawan, Advisor (Cost), Ministry of Health & Family welfare
Dr Rajeev Singh Raghuvanshi, Drugs Controller General (India)
Mr Binay Kumar Samantray, Deputy Drugs Controller (India), CDSCO (Hq)
Mr.Naveen Mehta, Assistant Drugs Controller (India), CDSCO (Hq)
Mr.Namit Joshi, Chairman, Pharmexcil
Mr.Bhavin Mehta, Vice Chairman, PharmexcilMr.R K Agrawal, President, BDMA
Dr.Viranchi Shah, President ,IDMA
Mr.Raja Bhanu, Director General, Pharmexcil
Mr.Subba Reddy, Managing Director, Virupaksha Labs
Mr.Devesh Malladi, MD, Embio
Dr.P.V.Appaji, Chairman, Meenaxy Pharma

04 April 2025: CoA Meeting of Pharmexcil

The Committee of Adminstration meeting held on 04.April.2025 and deliberated on the Bharat Health 2025,space requirements and allied sectors joining the event. Concerns with respect to Export NoC for unapproved /new APIs and also FDFs were dsicussed.

09 April 2025:Meeting chaired by HCIM with EPC's in Vanijya Bhawan, New Delh

Mr Raja Bhanu, Director General participated in the meeting along with Mr Kamal Bhardwaj, Director,R/o Delhi and submitted the reprsentaions and on going issues with the HCIM w.r.t the Export NoC/Regulatory and other issues faced by member exporters. Sought support for Bharat Health 2025 scheduled for 04-06 Sep.2025 at Bharat Mandapam, New Delhi

10 April 2025:Invitation as Guest of Honor for the 19th Edition of PharmaTech Expo & LabTech Expo in Parade Ground, Sector 17, Chandigarh

Mr Raja Bhanu, Director General attended the19th Edition of PharmaTech Expo & LabTech as Guest of Honor for the inauguration and also to participated in the Panel discussion on "Revised Schedule M - Gap Analysis"

Korea Pharmaceutical Import and Export Association and India Pharmaceutical Export Council (PHARMEXCIL) discuss expansion of pharmaceutical trade

11.April.2025: The Korea Pharmaceutical Import and Export Association (Chairman Ryu Hyung-sun) announced on the 11th that it has agreed to cooperate with the Pharmaceutical Export Association -PHARMEXCIL (Chairman Namit Joshi), which participated in the CPHI JAPAN 2025 exhibition in Tokyo, Japan on the 10th. The two sides agreed to sign a business agreement on the stable supply of essential medicines at the BHARAT Health Expo event to be held in India in September. "The Indian pharmaceutical market is expected to grow to about $130 billion (about 189 trillion won) by 2030," said Chairman Ryu Hyung-sun, adding, "Through the signing of this MOU, it is expected that exports of high-quality Korean medicines to India will increase, and exchange and cooperation such as pharmaceutical trade and investment joint projects between the two countries will be further activated, such as securing a stable supply chain of essential medicines in Korea."

11 April 2025: Meeting with Federation of Pharmaceutical and Allied Products Merchant Exporters

Mr.Sandeep Modi, Secretary, FPME met Mr Raja Bhanu, Director General and sought support on the Export NoC clearances, and other matters relating to recognition of Indian Pharmacopeia, Banking Charges, Rupee trade etc.

16 April 2025:2nd Monthly Meeting to review the trade performance of Pharma and Medical Devices chaired by Mr.Nitin Kumar Yadav, JS, DoC

Mr.Nitin Kumar Yadav Joint Secretary, IAS chaired the meeting and deliberated on the issues concering exports and reasons for the dip in few countries and requested the industry to come up with strategies for emerging markets and also preparatory measures for facing tariffs globally. Discussion centered around the directive of Export NoC and its impact on businesess, delays in approvals by DCGI leading to loss of first mover advantage, Online CoPP system etc. Mr.Bhanu, DG Pharmexcil along with representatives from Aurobindo Pharma, Granules Pharma, Mylan Labs, MSN Pharma , Nosch Labs Mr.Nipuj Jain ,Member of CoA joined the meeting.

22 April 2025: VC meeting on Sector Specific Strategy for achieving 1 Trillion Merchandise Exports in Vanijya Bhawan, Conference Room No. 321, New Delhi

The meeting was convened under the Chairmanship of Shri Nitin Kumar Yadav, JS, EP(Pharma) and Dr. Tamanna Chaturvedi, Vice President of Invest India made a presentation on outlining the Pharma exports of major HSN codes from India and imports of other countries vis a vi potential supplies from India. Regulatory challenges, especially for market access and patent-related exports, were seen as major hurdles. MSMEs face additional issues such as inverted duty structures and ambiguous interest subvention policies. Support from the government is critical in easing these burdens and enhancing India’s competitiveness globally. t

The meeting highlighted the need for better global positioning, with India currently holding just a 2.5% share (ranked 10th). Two key strategic frameworks were proposed: the C6 strategy—focusing on country identification, cost competitiveness, compliance with trade barriers, and branding; and the P6 strategy—focusing on high-potential products, current performance, production surplus, trade policies, and value addition opportunities.

To strengthen exports, India must scale up production and diversify exports of high-potential medicaments, including products containing penicillins, hormones, and steroids. It was noted that the world import demand is rising, but India has not yet tapped into many of these opportunities.

Action points included incentivizing API-based manufacturing under the PLI scheme, negotiating preferential terms under FTAs, safeguarding export data, reviewing regulatory bottlenecks, and addressing pricing and compliance issues such as the Minimum Import Price (MIP) and anti-dumping duties.

There was also an emphasis on forging international MRAs (Mutual Recognition Agreements) and addressing localization requirements through partnerships or profit-sharing models. Feedback from the industry will be collected via a structured questionnaire from Invest India to ensure alignment and implementation of these strategies. Mr. Raja Bhanu, DG; Ms Lakshmi Prasanna, Sr Director, Mr Murali Krishna, Director and Mr Rollins John,Director joined from Secretriat. Dr.Venkatesh, Mr.Bharat Desai, Dr.Vishal Rajgharia ,Members of the CoA joined the meeting.

23 April 2025: RIS in partnership with the Embassy of Mexico in India, Delhi is organising the Public Lecture by Dr Gabriela Ramos, Assistant Director-General for the Social and Human Sciences, UNESCO, on the topic of "AI and Ethics" in Casuarina Hall, India Habitat Centre, New Delhi.

Mr Raja Bhanu, Director General participated virtually in the Public Lecture by Dr Gabriela Ramos, Assistant Director General for the Social and Human Sciences, UNESCO, chaired by Dr V. K. Saraswat, Member, NITI Aayog organized by RIS in partnership with the Embassy of Mexico in India, New Delhi is organising the on the topic of "AI and Ethics" at the Casuarina Hall, India Habitat Centre , New Delhi.

24 April 2025: Meeting organised by Pharmexcil & NSF, UK on Nutraceuticals/Dietary Supplement/OTC Drug Manufacturers in Hyderabad

Dr.Vinay Kumar ,Assistant Drugs Controller graced the event as Chief Guest. Ms.Lakshmi Prasanna gave the welcome note followed by a presentation by Mr.David Trosin,Group Tecnical Director ,NSF on ensuring excellence and quality in nutraceuticals in 2025.A strong quality ecosystem involving manufacturers, regulators, certification bodies, and laboratories is essential to ensure safety and efficacy. The Government of India reimburses 50% of certification costs for nutra and herbal products under the MAI Scheme to support compliance. The discussion involved manufacturers, industry experts, regulators, and NSF representatives, highlighting the need for government intervention to boost global competitiveness. Dr.Gayatri ,Deputy Director participated as Panelist and shared the incentives available for nutraceutical products

24 April 2025: Interactive session with trade and officers of customs for filing/processing the online refund application in light of the automation of refund process with effect from 01st April 2025

The session trained exporters and Customs officers on filing online refund applications via ICEGATE, the CBIC's national e-filing platform. Officials present included Ms. Sarita Girish (Pharmexcil), Mr. Ranu Juyal, Mr. Farah, and Mr. Hans Raj (Customs).

ICEGATE enables electronic submission of Bills of Entry, Shipping Bills, e-payments, and IGST refunds, serving over 12.5 lakh users. Mr. Ranu Juyal explained the Customs Refundable Application, highlighting two components: Re-assessment Application and Refund Application. Re-assessment of Bills of Entry is mandatory before filing a refund claim, after which a pre-filled refund form is generated. Starting March 31, 2025, only online refund applications will be accepted, with rare exceptions at the Customs Commissioner's discretion. Exporters must submit separate applications for each Bill of Entry, though portal simplifications are in progress. For delays, exporters can reach the ICEGATE Helpdesk using their Ticket Number. The session concluded positively, answering queries and encouraging further engagement via email for a smoother transition to automated refunds.

29.April.2025: Mr.Raja Bhanu, Director General met Prof.Dr,Taruna Ikrar, Chairperson of Indonesian Food and Drug Authority and sought support of fast track product approvals

30 April 2025: Consultation seeking inputs on "Export Promotion Mission"

A meeting under the chairmanship of the Commerce Secretary Mr.Sunil Barthwal held on 30 April 2025, to hold consultations on the implementation of the Export Promotion Mission (EPM). Mr.Ajay Badoo, DFGT presented the overview of the Export Promotion Mission and the components under the Niryat Protsahan and Niryat Disha initiatives. EPCs are requested to provide the framework and the incentive mechanism focused to MSMEs, for those of NTBS/NTMs and address the disabilities.

Mr.Murali Krishna S, Director Pharmexcil joined the meeting and requested for restoring the MAI benefit with out any cap / scale up the benefit of MAI upto 500 crores in line with the new definition of MSME. It is also requested to consider Regional iPHEX (for instance iPHEX LAC in Argentina and inviting buyers from other LAC countries) and in incentivizing buyers from the neighboring countries.

MEMBERS ACHIVEMENTS

1 **USFDA grants QIDP designation to Venus Remedies Novel Polymyxin B formulations**

Venus Remedies has received a Qualified Infectious Disease Product (QIDP) designation from the US FDA for its investigational antibiotic, VRP-034, which is designed to treat bloodstream infections caused by specific polymyxin B-susceptible strains in adults. The QIDP status allows for priority FDA review, potential fast-track designation, and additional market exclusivity.

2 **Zydus Lifesciences bags USFDA approval for Urinary tract infection drug**

Zydus Lifesciences has secured final US FDA approval to manufacture Methenamine Hippurate Tablets USP, 1 gram, for urinary tract infection prevention. The medication generated $32.6 million in US sales as of January 2025. This approval boosts Zydus' presence in the US pharmaceutical market, bringing its total approvals to 419. Production will take place at the company's Ahmedabad facility.

3 **Jubliant Pharmova arm salisbury facility gets USFDA Establishment Inspection Report**

Jubilant Pharmova's subsidiary, Jubilant Cadista Pharmaceuticals Inc., has received an establishment inspection report from the US FDA for its solid oral formulations facility in Salisbury, Maryland. The FDA classified the inspection as voluntary action indicated and confirmed its closure. The facility is not expected to manufacture any products

4 **USFDA concludes inspection at Shilpa Medicare Raichur unit & Shilpa Medicare receives US approval for Varenicline Tablets, 0.5 mg and 1 mg**

Shilpa Pharma Lifesciences Ltd passed a US FDA inspection at its Raichur facility marking its second consecutive clean review. Approval for generic Varenicline Tablets (0.5 mg and 1 mg) for smoking cessation. The US market for this product is valued at approximately $203 million.

5 **Strides Pharma sciences singapore arm to acquire 100 percent stake in AMEXEL & Strides Pharma approves demerger from Arco Labs**

Strides Pharma shares rose 2.8% on BSE after proposing to acquire Amexel Pte. Ltd. to expand in India, China, and Southeast Asia. The company continues to strengthen its global presence in generic medicines. Strides Pharma will demerge from Arco Labs, following board approval, creating a new entity focused on life sciences and manufacturing solutions. The new company will leverage advanced technology and domain expertise.

6 **Sovereign Pharma gains EU approval for aseptic and terminally sterilised injectable product**

Sovereign Pharma has received EU approval for aseptic and terminally sterilised products, including vials, ampoules, cartridges, and pre-filled syringes (PFS). This marks a significant milestone in the company's commitment to quality, safety, and global healthcare excellence. The company has also received approval from ANVISA, Brazil's Ministry of Health, and MHRA

7 **West Bengal Chemical Industries Ltd. (WBCIL) has been awarded the "National Intellectual Property Award 2024"**

WBCIL for its exceptional contributions in patent-led innovation, IP commercialization, and export excellence in Active Pharmaceutical Ingredients (APIs) got National Intellectual Property Award. The award, presented by Union Minister Shri Piyush Goyal, places WBCIL and Indian MSMEs on the global pharma innovation map.

8 **Alembic Pharma receives USFDA final approval for Pantoprazole Sodium Injection**

Alembic Pharmaceuticals received final US FDA approval for Pantoprazole Sodium to treat gastroesophageal reflux disease and erosive esophagitis. The approved ANDA matches Wyeth Pharmaceuticals' Protonix I.V. Alembic now holds 221 USFDA ANDA approvals.

9 **Finecure Pharmaceuticals Ltd proudly announces its US-FDA approval**

Finecure Pharmaceuticals Ltd has achieved US-FDA approval, showcasing their dedication to excellence and global healthcare innovation. This milestone was made possible through the steadfast support of their team, partners, and stakeholders, remain committed to Making Lives Healthier

10 **Laurus Labs bets on cell and gene therapies, eyes CDMO role**

Laurus Labs is investing in disruptive technologies to expand beyond its core expertise. This decision, made during a board meeting, focuses on supporting startups and academic research in innovative scientific areas. The goal is to foster collaboration and drive advancements in fields where the company lacks expertise.

“"We warmly invite member exporters to showcase their company’s achievements on the Pharmexcil website every month. We are delighted to feature these accomplishments in our newsletter, further amplifying their visibility and impact within the industry."."”

Celebrating Excellence

Pharma News

March 2025

DGFT notifies new SION for metronidazole gel to facilitate ease of doing business. Click the LINK

CDSCO eases rules, pharma firms can now get 1-year NoC online via Sugam portal Click the LINK

DGFT eases compliance burden as pharma exporters face hurdles in advance authorization closure Click the LINK

DGFT seeks industry feedback on proposed amendments to "stock and sale" export authorization for SCOMET items Click the LINK

Panel recommends programme for uniform high standard drug regulation nationwide. Click the LINK

Commerce ministry seeks inputs from industry to address challenges posed by non-tariff barriers.Click the LINK

Centre brings in Boilers Bill to help bulk drug manufacturers. Click the LINK

DGFT extends deadline for filing Annual RoDTEP Return

CDSCO launches online system for SMEs to submit application for extension on Revised Schedule M implementation. Click the LINK

April 2025

Pharma Exemption from Tariffs Highlights Generic Medicines' Role Click the Link

DoP notifies establishment date of NIPER Council Click the Link

CDSCO Revised Classification Drafts for cardio and neuro medical devices, seeking industry feedback by month-end. Click the Link

Manufacturers urged to apply online for extension of timeline for revised Schedule M Click the Link

NPPA revises ceiling price of diagnostic agent following DoP's review order. Click the Link

The government will end RoDTEP benefits for exports under Advance Authorizations, SEZs, and EOUs from February 6, 2025. Exporters must adjust to this policy shift aimed at aligning with global trade norms. Click the LINK

"Quality is the cornerstone of success, but thriving pharma exports take it to a whole new dimension."

India's API industry at a key juncture, guided by global supply chain dynamics & shifting regulatory landscape Click the Link

Online stall reservation for iPHEX and Bharat Health begins Click the Link

India streamlines pharma trade compliance with revised fee structure for import monitoring systems Click the Link.

Pharma Exports Cross $30 bn, Domestic Market Grow 8.4 pc to Rs 2.2 Lakh Crore
Link

Bulk drug imports decline 15.7 per cent in February.
Link

PHARMAP 2025 brings together global pharma leaders to discuss innovation and drug safety
Link

Tariff shockwaves on China cause short-term agony but will extend global cooperation in long-term: Dr Li Jin.
Link

DGFT introduces new field in eBRCs to track service exports from May 1
Link

MSMEs poised to capture global generics & biosimilars markets through collaborative efforts: FPME
Link

Pakistan activates 'emergency measures' for pharma needs amid trade halt with India after Pahalgam attack
Link

FOPE urges NPPA to reconsider ceiling prices allowing 5 decimal points for low priced drugs Click the Link

Indian pharma moving towards Green Pharma 2.0 where AI, digital twins, sustainable molecule design prevail Click the Link

Gujarat FDCA to strengthen drug quality control with procurement of 25 advanced handheld spectrophotometers Click the Link

March & April 2025 Notification

Key circulars, policy updates, and government notifications Impacting pharmaceutical Exports

CUSTOMS, DGFT & CDSCO Notifications

Customs to notify the fourth tranche of tariff concessions under India-UAE CEPA
28 March 2025 (Click the Link) (Click Excel link)

Customs to notify the fifth tranche of tariff concessions under India-Mauritius CECPA
28 March 2025. (Click the Link) (Click the ExcelLink)

New Online Export NOC System on Sugam portal- CDSCO
07 March 2025(Click the Link)

Government Extends RoDTEP Support for Exports Until February 5, 2025
20 March 2025(Click the Link)

Online application for extension of time to comply with Revised Schedule M on ONDLS portal
24 March 2025

DGFT Operationalizes Global Tariff and Trade Helpdesk.
(Click the Link)

Customs(Circular)
8 April 2025
Click the Link)

Manufacturing and marketing of unapproved FDC's
11 April 2025
(Click the Link)

Updates to CAROTAR, 2020 and Section 28DA of the Customs Act, 1962 Click the Lin

Key Highlights from the Finance Minister's Budget Speech 2025-26 Click the Link.

Amendments to the Goods Imported (Conditions of Transhipment) Regulations, 2025 Click the Link.

Anti-Dumping Duty on Acrylic Solid Surfaces from China Click the Link.

New SION for Export of Doxycycline 100 mg Dispersible Tablets Click the Link

Prohibits to Import, manufacture, sale, distribution and use in any food producing animal rearing system of drug formulations containing "Chloramphenicol or Nitrofurans drugs" with immediate effect
02 April 2025 (Click the Link)

Anti-Dumping Duty on Acrylic Solid Surfaces from China Click the Link.

NEW MEMBERS ADDED FOR MARCH & APRIL

DRUGS FORMULATIONS & BIOLOGICALS

68

SUN MOON PHARMACEUTICALS PVT LTD
JAIWIK BIOTECH PVT LTD
VITALDEW PHARMACEUTICALS PVT LTD
L'AMAR LIFESCIENCES & BIOTECH PVT LTD
SHAH TC DISTRIBUTION LLP
AKRITI PHARMACEUTICALS PVT LTD
JPEE DRUGS
NATHAN PHARMA PVT LTD
JAGANNATHCHEMICAL AND PHARMACEUTICAL WORKS PVT LTD
MECOSON PHARMACEUTICALS PVT LTD
PARB PHARMACEUTICALS PVT LTD
HAMAX HEALTHCARE LLP
SARVA PHARMACEUTICALS PVT LTD
BDR PHARMACEUTICALS INTERNATIONAL PVT LTD
CENTURY NOVA DRUGS PVT LTD
4CARE LIFESCIENCE PVT LTD
SUCANTIS BIOTECH PVT LTD
OLIVE PHARMASCIENCE PVT LTD
QALYS PHARMA LLP
PRAMUKH SWAMI PHARMA LTD
SWISS GARNIERS BIOTECH PVT LTD
UMANG ENCAPSULATION SOLUTIONS PVT LTD
BEREF PHARMACEUTICALS PVT LTD
INLINE PHARMACEUTICALS PVT LTD
SYNTHETIC MOLECULES PVT LTD
ATMAN PHARMA PVT LTD
RAVAXO BIOTECH PVT LTD
GLESSOM COSMED PVT LTD
VASU ENTERPRISES
METINA PHARMACEUTICALS PVT LTD
AETHER LIFECARE LLP
UDVELL THERAPEUTICS PVT LTD
OVERSEAS PHARMACEUTICAL
HERTIZ PHARMA PVT LTD
MEDYUR PHARMACEUTICALS LTD
CALIAN HEALTHCARE
AKAAY PHARMACEUTICALS
CHANDRA BHAGAT PHARMA LTD
HNV PHARMA LTD
VANTRIO HEALTHCARE PVT LTD
GARICON LIFE SCIENCES
SG ENTERPRISES
VISION EXPORTS
INNMEDICS GLOBAL PHARMA PVT LTD
MEDCELL PHARMA PVT LTD
MARTEL OVERSEAS
ALLOTAB HEALTHCARE LLP
TASHI PHARMA
NS PHARMACEUTICALS
DAKSH PHARMA
VEDZON HEALTHCARE PVT LTD
SHORYANSH PHARMACEUTICALS
BIOFIYA HEALTHCARE LLP
FORTUNE PLUS AGENCIES
DEEKNISC SERVICES & SOLUTIONS PVT LTD
VK PHARMACEUTICALS
AIDONAK HEALTHCARE PVT LTD
ASPK INTERNATIONAL TRADE
ANAIZA LIFE
SOLUXCTION SPACE LLP
MEDISPARK HEALTHCARE LLP
FLAVOCAST HEALTHCARE LLP
BIOREACH PHARMA EXPORT PVT LTD

NEW MEMBERS ADDED FOR MARCH & APRIL

BULK DRUGS & DRUG INTERMEDIATES

5

ALKALOIDS BIOACTIVES PVT LTD

SANOZEN PHARMA PVT LTD

LAXAI LIFE SCIENCES PVT LTD

MANA PHARMA PVT LTD

ARR MOLECULES

NUTRACEUTICAL PRODUCTS

14

WALPAR NUTRITIONS LIMITED

MAX NUTRACEUTICALS

ACUVITS HEALTHCARE LLP

ELITE HEALTHCARE

EVAKENKO WELLNESS PVT LTD

TRITON HEALTH CARE PVT LTD

ISHNA NUTRISCIENCES

AERONUTRIX SPORTS PRODUCTS PVT LTD

PRINCE SUPPLICO PHARMA PVT LTD

VAEGI NUTRA

MEDGLOBE THERAPEUTICS LTD

MELIORATE HEALTH PVT LTD

GLATRIX BIOTECH PVT LTD

AUSTIZEN PHARMA

SURGICALS

1

RAJA SURGICALS

"We extend a warm welcome to the companies that joined Pharmexcil in March and April 2025 and wish them great success in their global endeavors.

PHARMEXCIL REPRESENTATION TO THE MINISTRY OF COMMERCE & DCGI

EXPORT NOC SYESTEM

New Export NoC Directive

The Indian pharmaceutical industry is facing significant challenges due to the new export NoC system, which is causing delays and business losses.

Key issues include:

Export NoC Directive: The new directive requires a Product Registration Certificate from the importing country's FDA or CDSCO approval, complicating exports.

Product Registration Certificate: Obtaining this certificate involves extensive documentation, posing a trade barrier.

Export of APIs: APIs for clinical trials and DMF/ANDA filings face approval delays.

API Export Exemption: Requesting exclusion of APIs from the export NoC directive.

Pharmacopeial API Treatment: Suggesting recognized APIs be considered approved for export.

Category for Unapproved Drugs: Proposing a distinct category for unapproved drugs with multiple NOCs.

Timely Approvals: Emphasizing the need for expedited approvals from CDSCO and State Licensing Authorities.

Automated Approval: Suggesting automated approval for certified sites within 5 working days.

Streamlining NDPS Drug Export: Recommending elimination of redundant procedures for NDPS drug exports.

Leveraging Online Platforms: Utilizing existing online platforms for NDPS drugs.

Online Central Repository: Creating a central repository for product and facility approvals.

Shelf-Life Flexibility: Requesting flexibility in shelf-life restrictions for unapproved drugs.

Adherence to Guidelines: Urging strict adherence to existing guidelines by Assistant Drug Controllers.

Website Clarification: Revising the official website to include the application process for manufacturing licenses.

Alternative Evidence for Export NoC: Proposing acceptance of alternative evidence for export NoCs.

Third-Country Exports: Requesting permission for exports to third countries.

Separation of Batches: Differentiating between commercial and exhibit batches for expedited clearance.

The industry seeks prompt resolution of these issues to maintain its global reputation and ensure smooth trade operations.

PHARMEXCIL REPRESENTATION TO THE MINISTRY OF COMMERCE

DGFT & BANKING ISSUES

Key issues include:

Inverted Duty Structure: Because of inverted duty structure lot of money is stuck in the hands of MSME Pharma manufacturers. Raw Material is taxed at 18% whereas Finished Product is taxed at 12%. MSME pharma do not have 50% Value Addition leading to accumulated GST credit in the books of MSME which leads to Financial constraints and hinders growth of MSME Pharma.

> Mitigation measures
>
> Inverted Duty Structure to be rationalised at either 18% or 12% as deemed fit.

EPDMS System maintained by RBI: Banks even PSU Banks officers sometimes makes mistakes in adjusting export proceeds as well deemed export proceeds which leads to non-issuance of Bank Realization certificate. Due to non-issuance many receivable are still outstanding in the EPDMS list of RBI, which leads to receiving of notices from Enforcement Directorate. Also small deductions such as overseas bank charges are not adjusted by Banks despite Exporters justification. Also EPDMS list is asking documents pertaining to 2000 when it was unheard of such RBI list.

> Banks should be given power to do manual entries if any mistakes have been committed in the past by the same branch. Secondly EPDMS list should ask for documents pertaining to 2017 and therein after

International defaulters names to be published on EPC website:
Many importers in various countries do not pay to Indian exporters and then the same importers buy from other pharma exporters

> A list by Pharmexcil can be published after due diligence and seeing the pharma exporter has exhausted all methods to recover money

OFAC countries: Banks do not issue Bank Realisation certificate for proceeds from OFAC related countries

> RBI to instruct all Banks working in India to issue BRC in case of Drugs and Pharmaceuticals

RODTEP against Advance License: RODTEP against Advance Licenses have been withdrawn which leads to weakening of Indian exports as KSM or API sourced from China constitute may be 50% but we lose out remaining 50% of Inputs.

> DGFT to resume RODTEP against Advance Authorisation

Levy of Health Cess on medical devices: Under the Advance Authorisation scheme, all customs duties are exempted for inputs required for exports. However the Health Cess (5%) continues to be levied on medicinal products significantly impacting the company's cost structure and financial viability. The export of output taxes for antisera finished gods remains non-claimable.

> Seeking Exemption from Health Cess and addressing Export Tax Challenges (Heading 9018-9022).Aligning the Health Cess exemption with the BCD exemption would be fair and consistent with the principles of the scheme

REGULATORY UPDATES

March 10, 2025| FDA's Labeling Resources for Human Prescription Drugs

The FDA focuses on industry personnel creating human prescription medication labeling, including FDA-approved patient labels, prescribing information, and scientific data for safe and efficient usage.Link

April 8, 2025| Martin A Makary M.D., M.P.H, New Commissioner of Food and Drugs - Food and Drug Administration

Dr. Martin Adel Makary, the 27th Commissioner of Food and Drugs, oversees the FDA portfolio and executes the Federal Food, Drug, and Cosmetic Act. With over 250 peer-reviewed scientific articles and numerous awards, Makary has worked at Johns Hopkins University and Johns Hopkins Carey Business School Link

PApril 10, 2025| FDA Announces Plan to Phase Out Animal Testing Requirement for Monoclonal Antibodies and Other Drugs

The FDA is replacing animal testing in drug development with advanced, human-relevant methods to enhance safety and efficiency. AI-based models, organoid toxicity testing, and global safety data will refine or replace traditional animal trials. Updated guidelines will support companies in submitting non-animal safety data. These innovations aim to accelerate drug development while maintaining rigorous safety standards.Link

April 17, 2025| FDA Commissioner Makary Announces New Policy on Individuals Serving on FDA Advisory Committees:

FDA Commissioner Martin A. Makary has restricted pharmaceutical company representatives from serving on FDA advisory committees to enhance public trust. The policy aims to reduce industry influence, prevent conflicts of interest, and emphasize patient and caregiver perspectives. These committees provide independent expert advice on scientific and policy matters. While company employees can't be official members, they can still attend and share their views.Link

April24,2025|Oncology(Cancer)/Hematologic Malignancies Approval Notifications

FDA does not issue approval announcements for every approval or drug label update that occurs in oncology and hematologyLink

March 25, 2025|MHRA launches new monthly safety bulletin and redesigned safety alerts

The new MHRA Safety Roundup provides a monthly summary of the latest safety advice for all medicines, medical devices, and healthcare products regulated by the MHRA, as part of our 3-year strategy to improve safety communications.Link

April 10, 2025| Fezolinetant (Veoza): risk of liver injury; new recommendations to minimise risk

Fezolinetant treatment is associated with a risk of drug induced liver injury. New recommendations have been introduced to minimise this risk. Liver function should be monitored before and during treatment in all patients taking fezolinetant. Fezolinetant should be avoided in patients with known liver disease or at a higher risk of liver disease.Link

April 15, 2025| MedTech regulatory reform and the importance of partnerships

The UK's 10 Year Health Plan relies on medical technologies, requiring balanced regulation to ensure safety while fostering innovation. The MHRA's Innovative Devices team collaborates with stakeholders to advance transformative technologies. The UK Centres of Excellence for Regulatory Science and Innovation (CERSIs) aim to strengthen future regulatory systems. Seven CERSIs recently met to discuss goals, challenges, and collaboration strategies.Link

April 24, 2025| Short-acting beta 2 agonists (SABA) (salbutamol and terbutaline): reminder of the risks from overuse in asthma and to be aware of changes in the SABA prescribing guidelines

Healthcare professionals and patients are reminded of the risk of severe asthma attacks and increased mortality associated with overuse of SABA with or without anti-inflammatory maintenance therapy in patients with asthma. Healthcare professionals should be aware of the change in guidance that no longer recommends prescribing SABA without an inhaled corticosteroid.Link

April 29, 2025| MHRA Safety Roundup: April 2025

Summary of the latest safety advice for medicines and medical device usersLink

March 04, 2025| SAHPRA Strategic Plan 2025 and 2026 – 2029 and 2030

SAHPRA's 2025–2030 Strategic Plan emphasizes ensuring access to safe, effective, and high-quality health products. With a vision to be an agile and globally recognized regulator, it aims to enable access across South Africa. SAHPRA is committed to navigating the evolving regulatory landscape with resilience and innovation. This plan reaffirms its dedication to safeguarding public health and enhancing healthcare outcomes.Link

April 04, 2025|SAHPRA joins the Medical Device Single Audit Programme

SAHPRA has joined the Medical Device Single Audit Programme (MDSAP), an international audit programme aimed at improving efficiencies in the regulation of medical device manufacturers. As an affiliate member, SAHPRA will expand its ability to monitor manufacturing of medical devices beyond its borders. This membership will improve SAHPRA's regulatory reach and enable it to leverage resources from other MDSAP participants to audit and monitor quality standards by medical device manufacturers globally

Comprehensive Guide to USFDA Pharmaceutical Registration

WHO NEEDS TO REGISTER?

- All domestic and foreign establishments involved in the manufacture, repacking, or re-labelling of drugs for U.S. distribution.
- Facilities involved in biologic, prescription, and over-the-counter (OTC) drug production. (Link)

Process Overview

Create an FDA Account: Register online via the FDA's Electronic Drug Registration and Listing System (eDRLS) (Link)

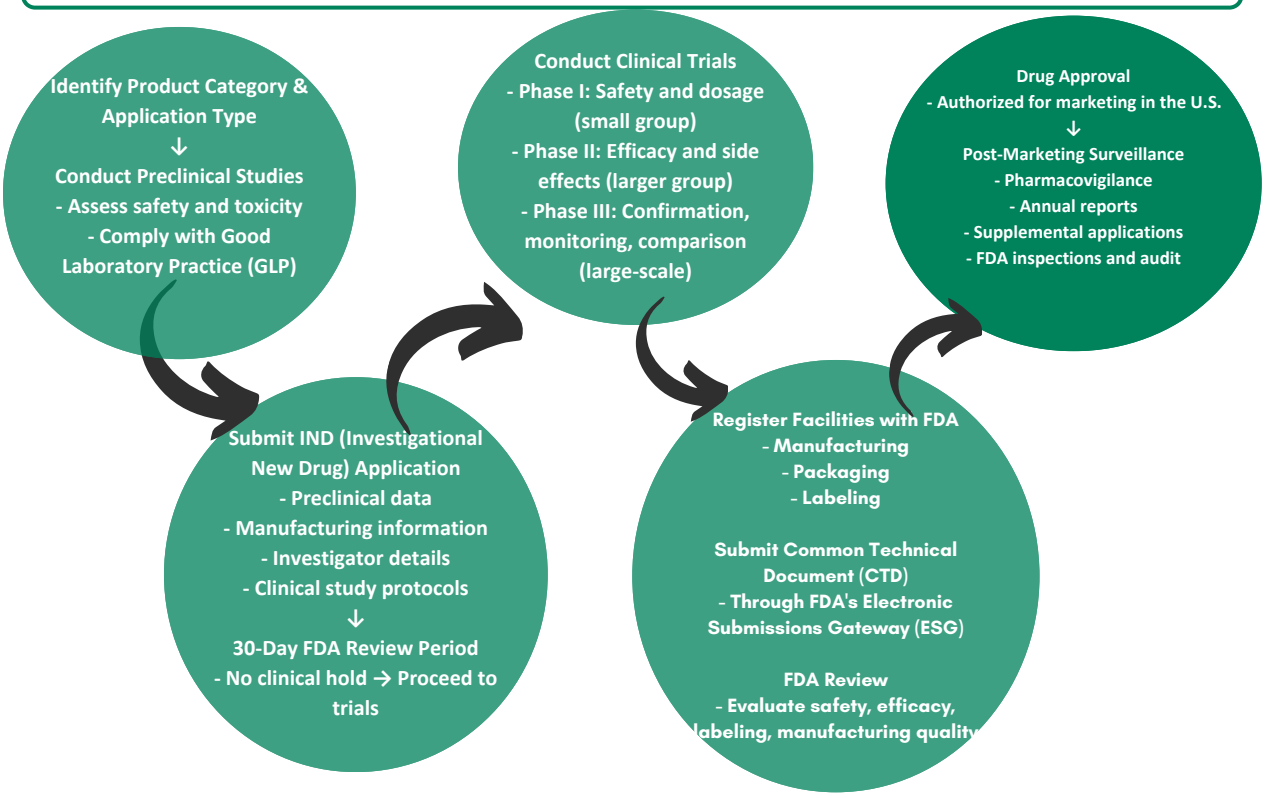
Submit Required Information:

- Facility name, location, and ownership details.
- Type of pharmaceutical products manufactured.

Annual Renewal: Maintain registration with annual updates by December 31.

Key Compliance Factors

- Adherence to Good Manufacturing Practices (GMP)
- Facility inspections and compliance audits.



Drug Listing Requirements:

Overview

- Drugs need to be registered with Structured Product Labelling (SPL) format.(link)

Submission Process

1. Assign a National Drug Code (NDC): (Link)
2. Prepare Labeling Data: (Link)
3. Upload SPL Files (Link)

Submit via FDA's eDRLS portal. (Link)

Special Considerations

- Prescription & OTC Drugs require different regulatory pathways.
- Biological products undergo additional scrutiny.

Foreign Facility Requirements

U.S. Agent Designation

- Foreign manufacturers must appoint a U.S. agent to facilitate communication with the FDA.
- The agent is responsible for:
  - Responding to regulatory inquiries.
  - Assisting in inspections and submissions.

Importer Identification

- Each facility must identify importers associated with their drug products.
- FDA Import Alerts may apply to non-compliant facilities.

Compliance and Regulatory Documentation (Link)

Electronic Submission Requirements (Link)

For official guidance, refer to the FDA Registration Portal.

Click the Link for more information: USFDA Drug approval process

MAI BENEFICIARY

MAI - REIMBURSEMENT OF PRODUCT REGISTRATION CHARGES

The Ministry of Commerce, under its Market Access Initiative (MAI)scheme, has approved and disbursed reimbursements for pharmaceutical Product Registration charges for the fiscal year 2024-25 with 294 Companies of amount of Rs. 55,55,00,024 /-.

Beneficiaries Under MAI Scheme (Airfare) F.Y. 2024-25

The Ministry of Commerce, under its Market Access Initiative MAI Scheme (Airfare), has approved and disbursed reimbursement of Airfare participation in events for the financial year 2024-25 with 39 Companies of amount of Rs. 23,56,470/-.

MAI Scheme (Airfare) FY 2024-25 (Link)

MAI-Reimbursement of product Registration charges for 2024-25 (Link)

COMMITTEE OF ADMINISTRATION (2024-26)

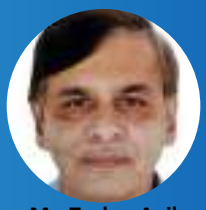
Chairman
Mr. Namit Joshi
Director
Centrient Pharmaceuticals
India Pvt Ltd

Vice Chairman
Mr. Bhavin Mehta
Director
Kilitch Drugs India Ltd

Mr. Nitin Kumar Yadav IAS
Joint Secretary
Ministry of Commerce & Industry
Special Invitee

Mr. Bharat Desai
Managing Director
Bharat Parenterals Limited

Dr. A.R. Venkatesh
CEO
Global Pharma
Healthcare Pvt. Ltd.

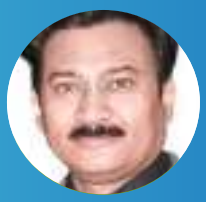


Mr. Tushar Anil
Director
Emil Pharmaceutical
Industries Pvt. Ltd.

Mr. Niraj Doshi
Director
AccusynthSpeciality
Chemicals Pvt. Ltd.

Mr. Amit Chawla
Director
McW Healthcare Pvt. Ltd.

Mr. Vijay Shah
Director
Stallion Laboratories Pvt. Ltd.



Dr. Viranchi Shah
Director
Saga Lifesciences Limited

Mr. Devang Shah
Director
Aadivighnesh Chem Pvt Ltd

Mr. Siddharth Daga
CEO
Vins Bioproducts Ltd

Dr. Meera Gandhi
Managing Director
Vital Healthcare Pvt. Ltd.

Mr. Brijesh Patel
Director
Makcur Laboratories Ltd.

Dr. Vishal Rajgarhia
Director
Finecure Pharmaceuticals
Limited

Mr. Shashank Sandu
CEO
Sandu Brothers Pvt. Ltd.

Mr. Bhavin A Patel
Partner
Mediwin Pharmaceuticals

Mr. Nikunj Goswamy
Managing Director
Jai Radhe Sales

CO-OPTED MEMBERS

Mr. Bala Subba Reddy
Executive Director
Virupaksha Organics Ltd

Mr. Nipun Jain
Director
Pharmchem

Mr. Kamlesh Patel
Managing Director
West Coast pharmaceutical
works Ltd

Mr. Raja Bhanu,
Director General & Member Secretary
PHARMEXCIL

FORMATION OF WORKING GROUPS

With a view to have active engagement with industry, Council under the leadership of Chairman & Vice Chairman formed the Working Committees to handle the concerns of the industry and also to build export strategies for greater market access for pharmaceuticals globally

Committee	Head of the Committee	Email
Finance & Bulk Drugs	Mr. Namit Joshi	api.coa@pharmexcil.com
	Mr.Tushar Korday	finance.coa@pharmexcil.com
Events, Admin & HR	Mr. Bhavin Mehta	hr.coa@pharmexcil.com
Regulatory	Dr. Viranchi Shah	ra.coa@pharmexcil.com
Merchant Exporter	Mr. Devang Shah	me.coa@pharmexcil.com
Public Relationships	Mr. Vijay Shah	pr.coa@pharmexcil.com
MSME/Customs/DGFT	Mr. Nipun Jain	msme.coa@pharmexcil.com
International Delegation/Indian Pharmacopoeia	Mr. Bharat Desai	delegations.coa@pharmexcil.com
Herbals/Nutraceuticals/Others	Mr. Shashank Sandu	nutra.coa@pharmexcil.com
Membership	Dr. Vishal Rajgarhia	members.coa@pharmexcilil.com
CRO/ Formulations & Biologicals	Mr.Siddarth Daga	biologics.coa@pharmexcil.com

Member companies are advised to reach out subject Committees Heads for sharing the concerns/suggestions/inputs for taking up the matter with concerned Department appropriately

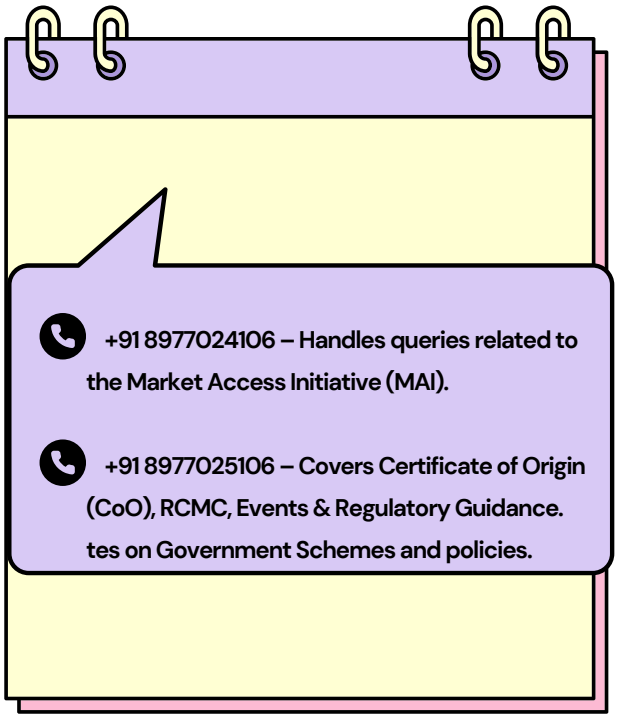
Pharmexcil Help Desk

11.07.20204

The Pharmexcil Helpdesk WhatsApp service, launched on July 11, 2024, enhances communication for members by providing dedicated contact points:

10AM- 6:30 PM

Members can interact via chat only (no calls) during working hours (10 AM – 6:30) PM, weekdays) for real-time assistance, clarifications, and update



SUBMIT YOUR

FEEDBACK

Dear Members,
Greetings from Pharmexcil!

Subject: Request for Data Submission – Trillion-Dollar Trade Target for Pharma Sector-Submit inputs by 05.May.2025

We wish to inform you that we have received a communication from the Department of Commerce regarding the trillion-dollar trade target for the pharmaceutical sector. This was discussed during a presentation by Invest India before Shri Nitin Kumar Yadav, Joint Secretary, on 22nd April 2025 at Vanijya Bhawan, New Delhi.

In this regard, Invest India has developed a sector-specific questionnaire to gather relevant data from stakeholders. The completed questionnaire is to be submitted to the EP (Pharma) Division, Department of Commerce.

We kindly request your cooperation in reviewing the attached questionnaire and providing the requisite information wherever possible (country wise, product wise) at the earliest.

Please ensure that your response reaches us by May 5th 2025, to enable us to consolidate and submit the data within the stipulated timeline. Questionnaire for Pharma 2025

Subject: Request for Inputs - Review of All Industry Rates (AIR) of Duty Drawback for the year 2025-Date Extended till 10.May.2025

The Government of India is reviewing the 2025 All India Rates (AIR) of Duty Drawback, focusing on Customs and Central Excise duties on export goods. Member companies are requested to provide complete export data for April–September 2024, detailing all inputs used in the manufacturing process. Only Customs Duty on inputs and Central Excise duty on petroleum products should be included; other taxes like IGST, CGST, SGST, or Anti-Dumping Duty should be excluded.

The data should represent exports from small, medium, and large manufacturers, certified by both manufacturers and Chartered/Cost Accountants. Relevant supporting documents, such as Bills of Entry, Shipping Bills, and excise invoices, must accompany the submission. Data should also be provided in Annexure II (**Excel format**).

Members are encouraged to share their views and suggestions for rationalizing entries in the AIR Drawback Schedule, including those not previously covered, with proper justification. Submissions should be sent by 10.May.2025 to **dbk.dbk@gov.in** with a copy to support@pharmexcil.com, enabling consolidation and timely submission to the Committee.

BLOCK YOUR DATES
SEPTEMBER

04	05	06
Day 1	Day 2	Day 3

mail@iphex-india.com