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PHARMEXCIL DIGEST

MAY 2025

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"The UK-India collaboration event was a fantastic showcase of industry dialogue and its impact. The recent UK-India FTA announcement highlights the UK's commitment to free and fair trade. We look forward to deeper engagement with India's life sciences sector, particularly at the upcoming Bharat Health 2025, organized by Pharmexcil, to further strengthen the UK-India relationship ." **Gareth Wynn Owen**
British Deputy High Commissioner

"PHARMEXCIL's unwavering support following the devastating earthquake in Myanmar has been invaluable. Their swift coordination and medical aid have significantly contributed to relief and rehabilitation efforts. This solidarity has further strengthened the bond between our nations, reflecting a true spirit of friendship and cooperation. We deeply appreciate PHARMEXCIL's dedication in times of crisis. Thank you for your commitment to humanitarian assistance".**-Zaw Oo-Ambassador for Republic of the Union of Myanmar**

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Chairman
Namit Joshi

India's Pharmaceutical Growth & Global Collaborations – Monthly Digest

The overwhelming response to Pharmexcil Digest reaffirms its significance for India's pharmaceutical exporters. This edition explores next-generation pharmaceutical technologies, expanding beyond exports to highlight industry innovations.

A major milestone is the India-UK Free Trade Agreement (FTA) and Pharmexcil extends our Heartfelt congratulations to Hon'ble Mr.PM Narendra Modi, Commerce & Industries Minister Mr. Piyush Goyal, and Commerce Secretary Mr. Sunil Barthwal. The FTA enhances supply chains, improves access to affordable medicines, and fosters foreign direct investment (FDI). It opens opportunities in contract development and manufacturing (CDMO), joint research, and pharmaceutical innovation.

Pharmexcil continues to simplify essential processes through digital services, ensuring efficiency for industry stakeholders. Online services include RCMC application/renewal, Certificate of Origin issuance, GST and Export Turnover Certification, and Market Access Initiative Scheme components.

Global collaboration is key to India's leadership. My participation in "India Meets Brazil", organized by the Embassy of Brazil in India, reinforced trade relations and pharmaceutical cooperation, ensuring high-quality, affordable medicines for global healthcare.

On the regulatory front, discussions with DCGI emphasized the need for greater flexibility in Export NoC procedures, helping ease compliance challenges while maintaining India's competitive edge.

With each edition, Pharmexcil Digest provides deeper insights and strategic direction for India's pharmaceutical industry, driving leadership in innovation, affordability, and excellence.

Director General
Raja Bhanu

Expanding Horizons: Pharma Trade & Market Trends

The success of our first edition affirms its value in providing key insights for India's pharmaceutical exporters. We deeply appreciate the positive feedback from member companies and the dedication of the Pharmexcil team in creating this publication.

We are grateful for the support of Joint Secretary Mr. Nitin Kumar Yadav, IAS, Department of Commerce, in addressing regulatory matters and organizing iPHEX 2025 under Bharat Health 2025. This collaboration strengthens India's global pharmaceutical presence, fostering industry growth and international partnerships. A significant development includes my discussions with Dr. Win Kyaing, Chairman MCCPMD, leading to MCCPMD's consent to sign a MoU at Bharat Health/iPHEX 2025, expanding global pharmaceutical cooperation.

Our interaction with Hon'ble Minister Mr. Piyush Goyal, Commerce & Industries Minister, emphasized emerging global opportunities and the creation of a facility to enhance Indian exporters' visibility for overseas buyers. iPHEX 2025, scheduled for 4-6 Sep. 2025 under Bharat Health, will provide a B2B web platform for increased accessibility. Creation of an exclusive B2B web domain going forward for member companies offering enhanced accessibility and visibility for their products and services, along with accreditations, enabling overseas buyers to interact and place orders digitally.

We appreciate pharma companies participating in iPHEX 2025, showcasing India's excellence in pharmaceuticals and affordable healthcare solutions.

Pharmexcil Digest remains committed to providing timely industry insights, fostering collaboration, and driving India's global pharmaceutical leadership. Thank you for your support—we look forward to shaping the industry's future together.

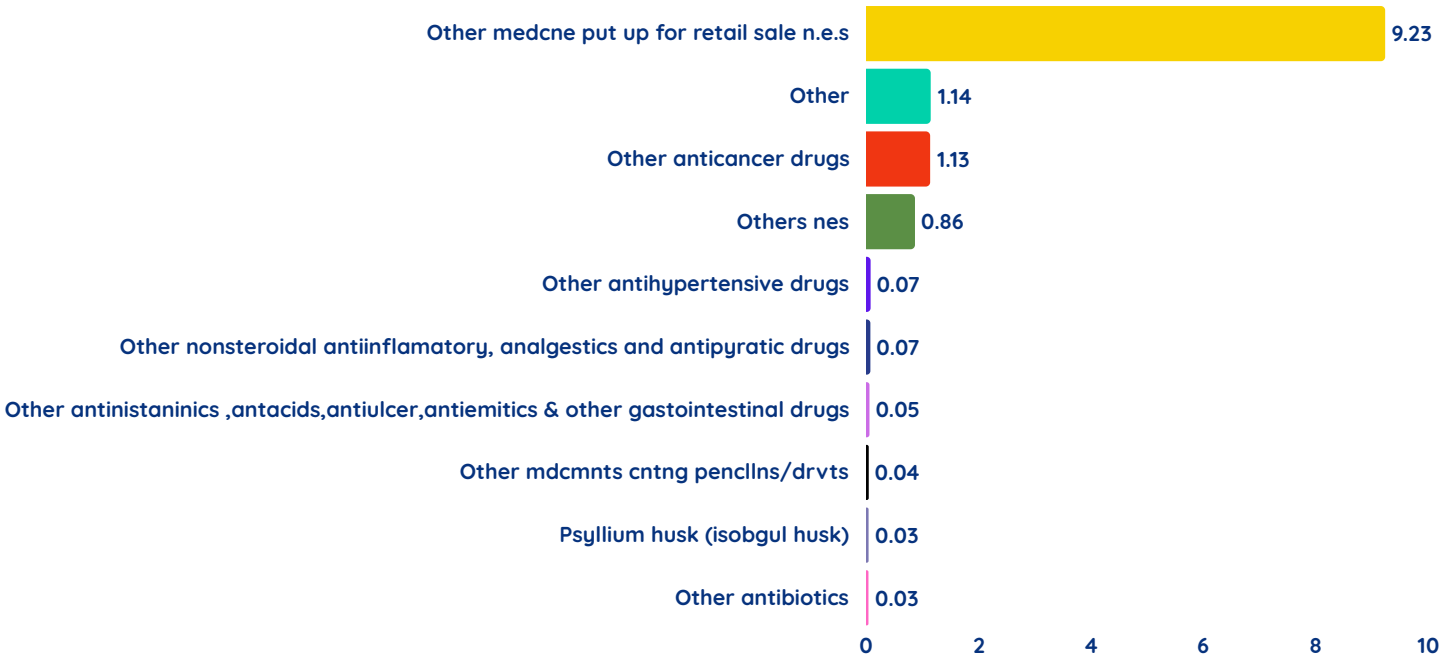
Pharmaceutical products Export Performance- April 2025

Exports	Growth	Imports	Growth
24.86 $Mn	2.37%	7.48$Mn	9.50%

Export Performance Breakdown

Drug formulations, biologicals	↓ -1.10%
NAFTA & NEA	↓ -5.68% & -8.93
Vaccines	↑ 50.27%
OCEANA	↑ 25.26%

Product wise Export performance (value in USD Mn)



India's Exports of Pharmaceuticals (top countries by share value in %)
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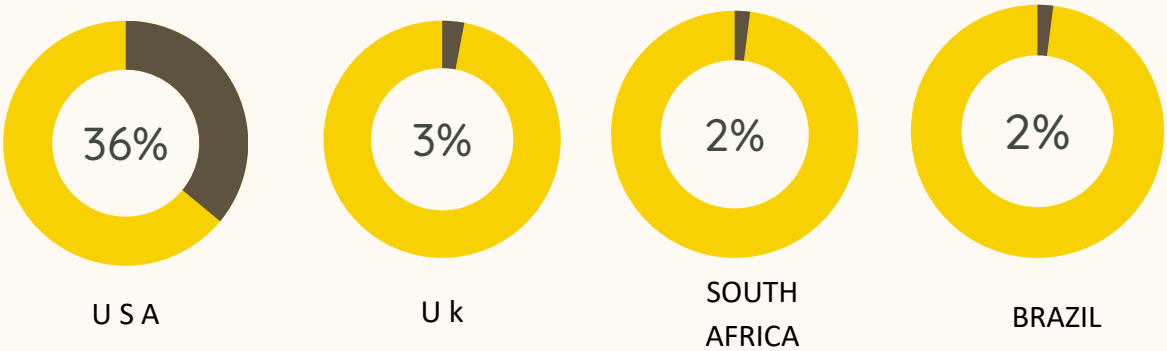
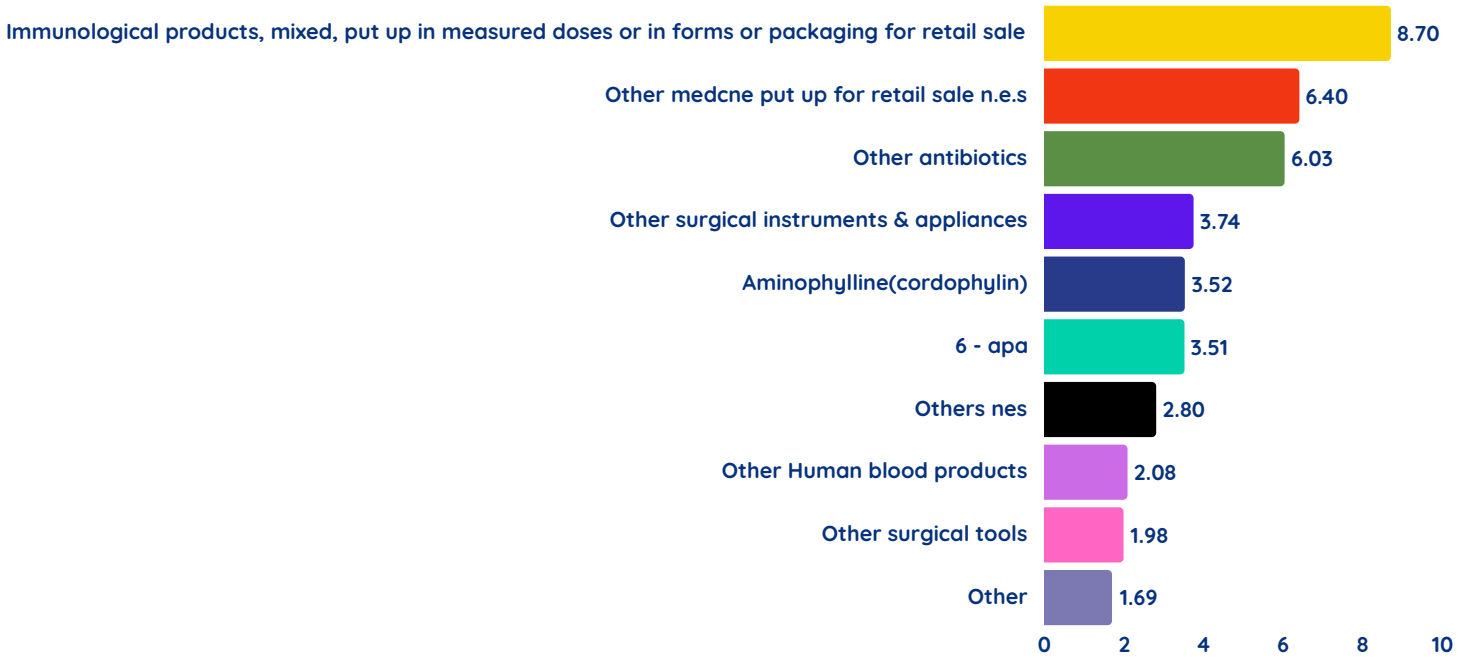


Import Performance Breakdown APR 25

Bulk drugs, drug intermediates & Vaccines	↓	-2.19% & -29.79
LAC & AFRICA	↓	-62.52% & -58.75
Ayush and herbal products	↑	61.42%
EUROPE	↑	31.29%

TOP 10 Importing pharmaceutical products value in USD Mn



India's imports of Pharmaceuticals (top countries (by share value in %
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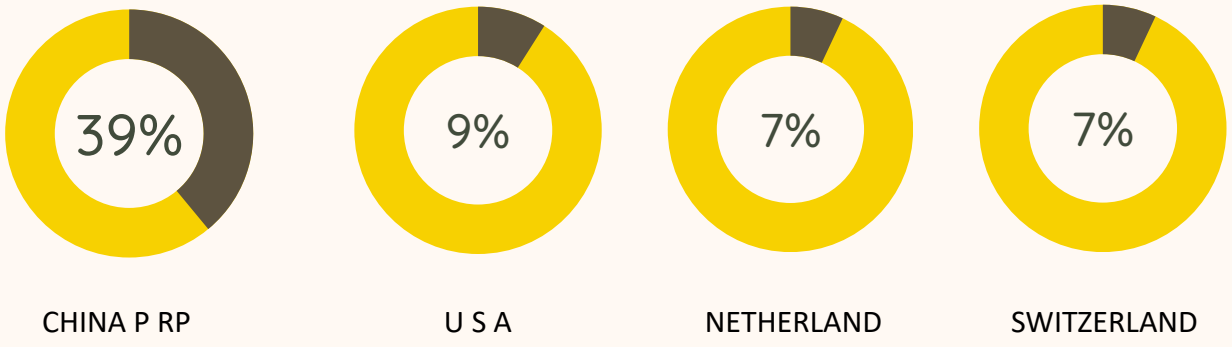
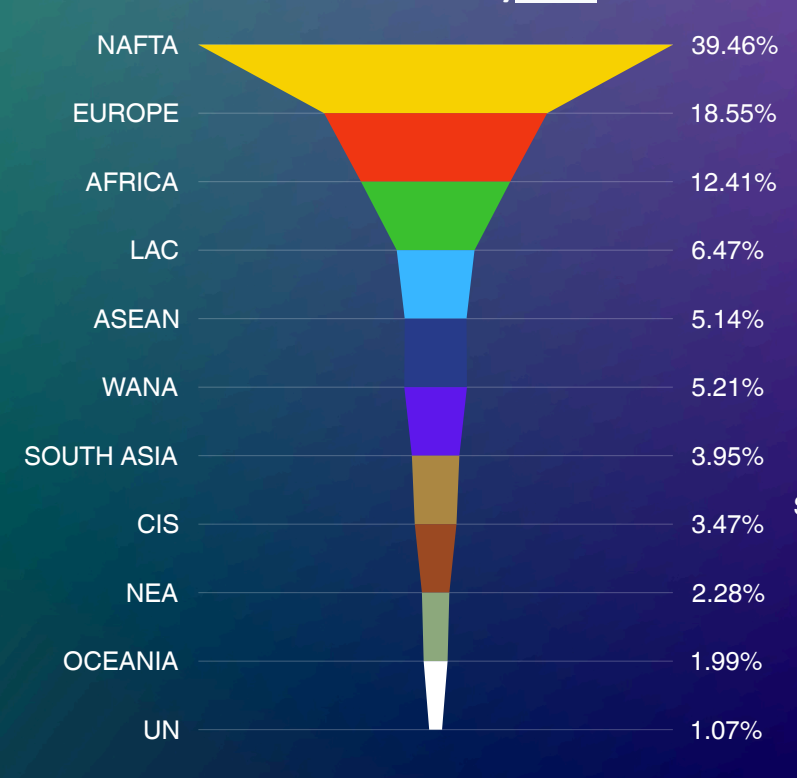
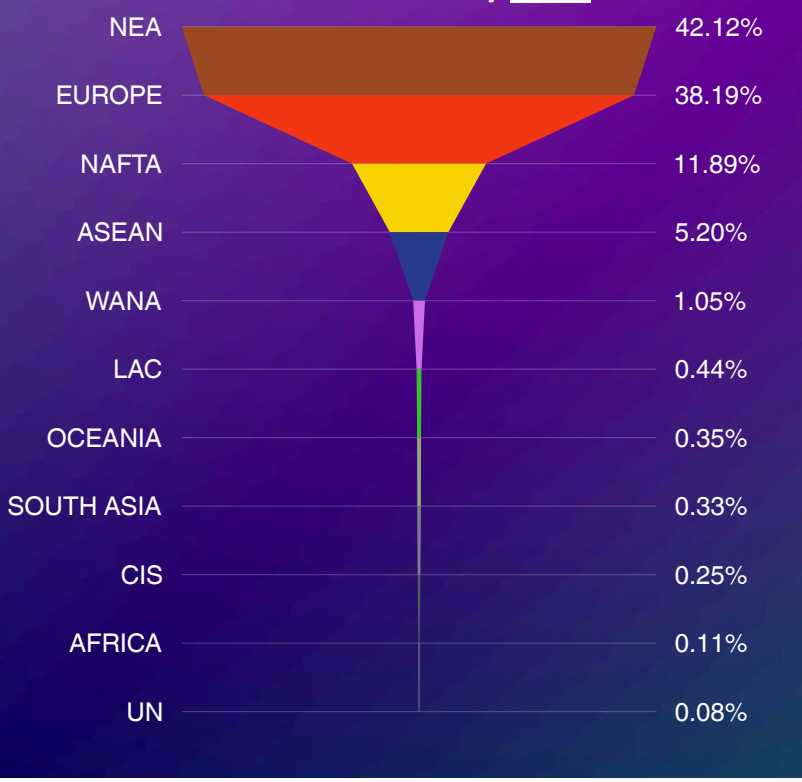


Region wise Export and Import performance -April 2025

Region wise Export performance (by share value in %) Link



Region wise Import performance (by share value in %) LINK



Exports

NAFTA, EUROPE, and AFRICA are the three major regions for pharma exports, together accounting for approximately 70.46% of total exports in April 2025.

• NAFTA comprised 39.46% of total exports during April 2025, valued at USD 981.02 million, reflecting a decline of -5.68% compared to April 2024.

• EUROPE (5.06%), LAC (5.95%), ASEAN (0.46%), WANA (15.64%), CIS (10.08%) all registered positively growth during April 2025 compared to April 2024.

AFRICA (4.47%), NEA (-8.93%), OCEANIA (25.26%) exhibited mixed trends, with NEA region experiencing a contraction of -8.93%, followed by Africa with 4.47% growth, and Oceania showing the highest growth of 25.26%.

Imports

India's total imports in 2024-25 amounted to 8,188.26 Mn USD, with April 2025 imports at 748.56 Mn USD. NEA held the largest share at 42.12% with 3,772.84 Mn USD, followed by Europe at 38.19% with 2,774.68 Mn USD.

NAFTA contributed 11.89% at 908.04 Mn USD, while ASEAN accounted for 5.20% at 479.71 Mn USD. LAC had a 1.05% share with 91.34 Mn USD, and WANA represented 0.44% at 53.54 Mn USD.

Oceania held 0.35% with 40.76 Mn USD, South Asia 0.33% at 44.05 Mn USD, and Africa 0.25% at 12.59 Mn USD. UN contributed 0.11% at 6.39 Mn USD, while CIS had the smallest share at 0.08% with 4.31 Mn USD.

Analysis of Pharmaceutical Export Trends (April 2020 - April 2025)

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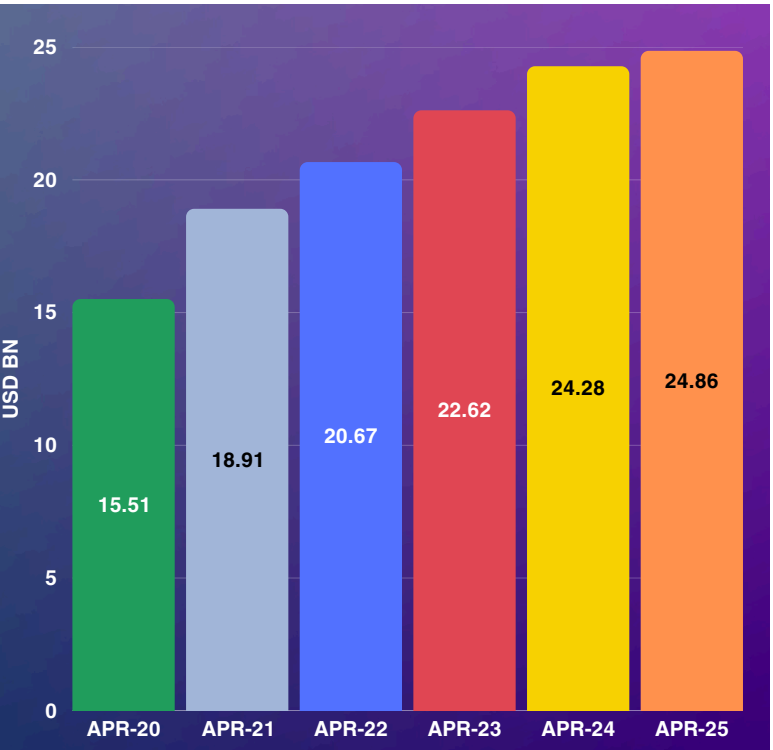


The data reveals a steady year-over-year growth in pharmaceutical exports, with the most significant increase observed between April 2020 and April 2021 (22%). Following this peak, the expansion rate has gradually stabilized, suggesting potential market maturity or the influence of external factors. While exports continue their upward trajectory, the moderating growth rate signals a shift in industry dynamics, highlighting the need for strategic adjustments to sustain momentum.

Factors Driving Growth

1. Rising Global Demand – Increased focus on healthcare and advancements in medicine.
2. Regulatory Approvals – Streamlined processes for export licensing.
3. Technological Innovations – Enhanced manufacturing efficiency.
4. Strategic Partnerships – Collaborations with international distributors.
5. Economic Stability – Favorable financial conditions boosting investments

Analysis of Pharmaceutical Imports (April 2020 - April 2025)

LINK

While imports peaked in April 2021, they experienced a slight contraction in April 2023, followed by recovery in subsequent years. This volatility could be attributed to regulatory shifts, global supply chain dynamics, or domestic production strategies. Despite these fluctuations, the data confirms an overall upward trajectory, highlighting the continued necessity of imports in supplementing local production and meeting demand.

Imports play a crucial role in ensuring a diverse and uninterrupted supply of pharmaceutical products. Encouraging imports fosters:

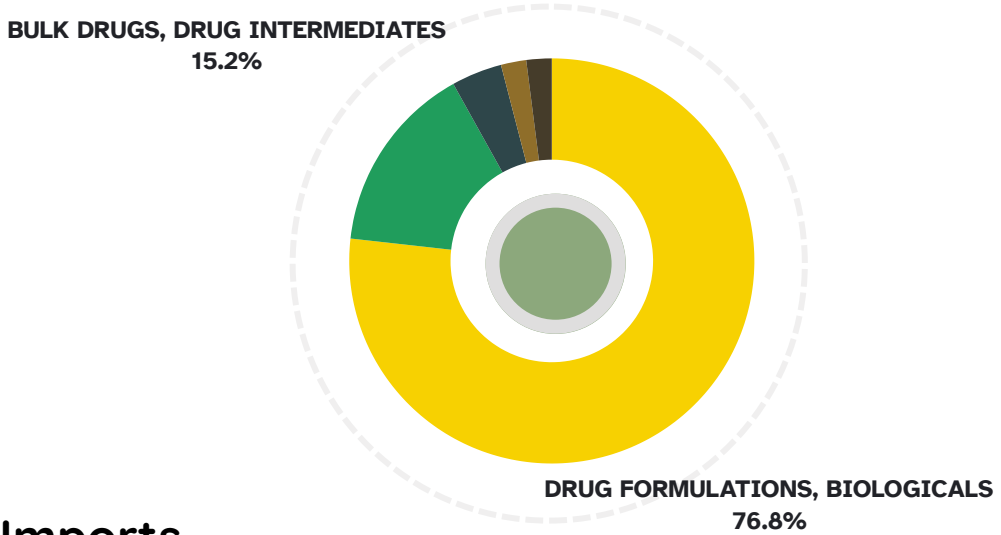
- Product Availability – Ensuring consistent supply of essential medicines.
- Competitive Pricing – Expanding options to optimize costs.
- Innovation Access – Introducing advanced formulations from global markets.
- Resilience Against Disruptions – Mitigating risks from local production constraints.

Category wise Pharma Exports & Imports Share percentage (value in USD mn)

Exports

LINK

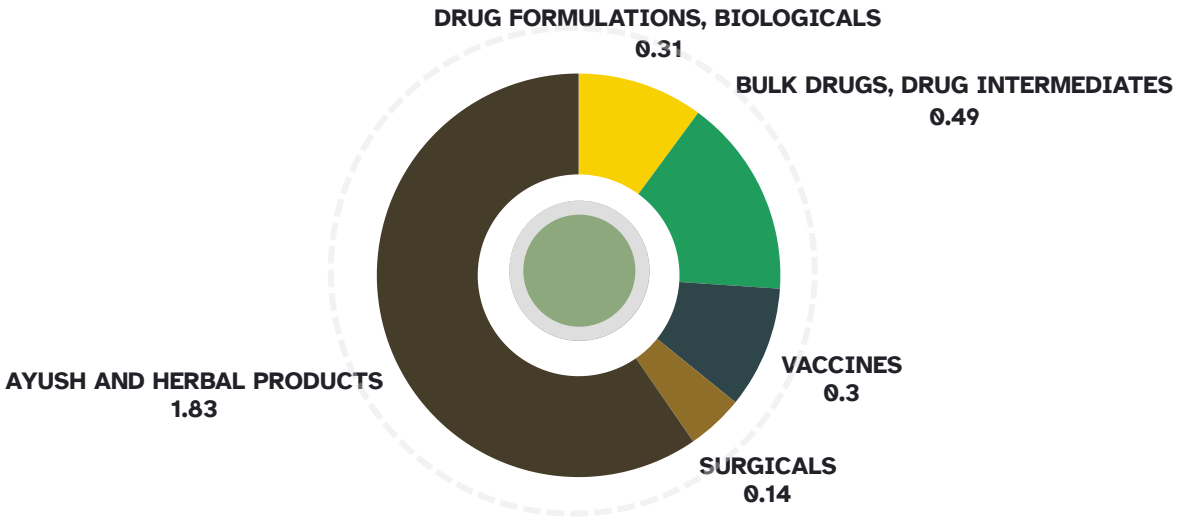
- Drug Formulations, Biologicals-18.81$Mn
- Bulk drugs, Drug Intermediates-3.79 $Mn
- Vaccines- 1.05$Mn
- Surgicals-0.60 $Mn
- Ayush& Herbal Products - 0.59 $ Mn



Imports

LINK

- Ayush& Herbal Products - 13.69 $ Mn
- Bulk drugs, Drug Intermediates-3.68$Mn
- Drug Formulations, Biologicals-2.35 $Mn
- Vaccines- 0.23$Mn
- Surgicals-1.08 $Mn



Pharmexcil Activities

"Brazil Meets India: Health Regulatory Ecosystem" 02 May 2025

"Brazil Meets India: Health and Regulatory Ecosystem," held on 2nd May 2025 at Embassy of Brazil in New Delhi under the leadership of H.E. Kenneth Felix Haczynski da Nóbrega, Ambassador of Brazil to India, to promote collaboration between Brazil and India in the health sector, strengthening existing agreements and fostering new business collaborations, particularly in the areas of Contract Manufacturing Organizations (CMOs) and the co-development of innovative molecules.

Discuss Regulatory Affairs and Challenges between Brazil and India and address the impact of new Brazilian regulations and highlight the institutional support the Embassy can provide to both Indian and Brazilian companies.

"Brazil Meets India" joined by

The event brought together influential voices from the health and pharmaceutical sectors of both nations, creating a valuable platform for dialogue, collaboration, and strategic partnerships. It was especially meaningful to welcome representatives from regulatory authorities, leading pharmaceutical companies, and key trade organizations. The opening remarks by Dr. Vikrant Pandey, Resident Commissioner of Gujarat Bhawan, set the tone for a forward-looking exchange.

H.E Kenneth da Nóbrega emphasized the strengthening of Brazil-India relations, particularly in sectors such as healthcare and pharmaceuticals. Ambassador Nóbrega has consistently highlighted the deepening bilateral ties between the two nations, focusing on shared values, mutual trust, and collaborative efforts in various domains.

Mr. Namit Joshi Chairman of Pharmexcil, underlined the council's crucial work in promoting Indian pharmaceutical exports, supporting exporters, and advancing bilateral market access between India and Brazil.

The event also underscored the growing strength of Brazil–India pharmaceutical relations. India's rising exports to Brazil signal trust in its pharmaceutical capabilities, while imports from Brazil into India demonstrate the balanced and mutually beneficial nature of this trade partnership. This two-way flow is not only a commercial success—it is a symbol of our nations' shared vision for global health security and equitable access to quality medicines.

Meeting with the First Secretary, Embassy of India in USA, Washington DC, 03 May 2025

Mr. Raja Bhanu, Director General met Mr.Akhilesh Singh, Counsellor, Commerce, Indian Embassy, USA and discussed matter pertaining to tariffs and impact on the pharmaceutical industry. This preparatory meeting focused on strengthening trade frameworks, addressing regulatory challenges and enhancing India's global pharmaceutical presence.

As India's pharmaceutical exports continue to grow, such engagements play a vital role in reinforcing trade partnerships and ensuring sustainable industry expansion.

Mr. Raja Bhanu, Director General met Mr.Akhilesh Singh, Counselor, Indian Embassy, USA

USP Convention 2025, in the Bethesda North Marriott Hotel & Conference Centre, Rockville, Maryland, USA, 05-08 May 2025

The 5th South Asia Regional Chapter Meeting, opened by Dr. Suresh Bhojraj, USP South Asia Regional Chapter Chair, reaffirmed the importance of collaborative stakeholder engagement in enhancing API manufacturing quality and achieving regional pharmaceutical self-reliance. Dr. Bhojraj emphasized the need for the chapter to evolve into a more dynamic, outcome-oriented platform, while Dr. Girish Kapur Senior VP, and USP India Site Head, showcased USP Hyderabad's advanced capabilities and global integration. Dr. Kishor Mogulluru, Associate Director, provided the context for the meeting, aligning it with India's policy goals and highlighting the initiative's multi-phase approach. Dr. Annu Uppal, Director, Scientific Affairs, outlined key quality issues identified through research and outreach, including pharmaceutical water quality, cross-contamination, nitrosamine impurities and cleaning validation-setting the stage for solution-driven discussions.

During the breakout session moderated by Dr. Rajiv Desai, Senior Technical Advisor, Indian Pharmaceutical Alliance provided valuable insights on Indian Pharmaceutical Industry. The Directorate General of Drug Administration (DGDA), Bangladesh, highlighted the country's dependence on imported APIs and requested technical assistance and regional collaboration to build domestic capabilities. Dr Chandrasekhar Ranga, Director IGRA & Deputy Drugs Controller, The Central Drugs Standard Control Organization (CDSCO) emphasized the need for better industry-regulatory dialogue to address outdated monographs and evolving manufacturing practices.

Mr. Raja Bhanu Director General, PHARMEXCIL suggested USP to establish a feedback platform for industry-reported issues, modeled on their export-linked issue tracker. The IDMA, represented by Mr. Dara Patel, Secretary General highlighted environmental compliance as a key challenge in API manufacturing, citing inadequate pollution control infrastructure. He urged USP's support for best practices in effluent treatment and policy advocacy for green chemistry and sustainability. Dr Nitish Sharma, Assistant professor from NIPER Ahmedabad underscored the need for early-stage risk assessments for nitrosamines and leachables, while the ABLE Foundation stressed responsible solvent use should be science-led rather than economically driven, urging for education-focused interventions.

In his closing remarks, Dr. Chaitanya, Director IGRA from USP reflected on the journey since the chapter's inception in 2020 and acknowledged the regional platform's unique ability to tailor global quality standards to local needs. He appreciated the leadership of Dr. Bhojraj and contributions from all stakeholders, reaffirming USP's commitment to strengthening South Asia's API manufacturing ecosystem. Key next steps include development of a practical SME toolkit, expanded training programs, continuation of regional roundtables and policy-level coordination to guide the 2025–2030 strategic roadmap for API self-reliance.

Program Overview

The United States Pharmacopeial Convention (USP) held its 2025 Convention Meeting from 5–8 May 2025, bringing together representatives from across the health and science ecosystem to launch the 2025–2030 cycle. The Convention Meeting served as a platform for USP's Voting Member Delegates to cast their votes on critical governance matters, including the election of the Council of Experts and the Board of Trustees for the 2025–2030 cycle. Additionally, the meeting included discussions on proposed resolutions aimed at guiding USP's strategic direction over the next five years.

Pharmexcil's response to the USP resolutions for 2025-2030.

Resolution II: Expanding Access to Quality-Assured Biologic Medicines Globally

Harmonizing regulations for biologics, especially biosimilars, is crucial to ensuring affordable and equitable access, particularly in low- and middle-income countries. India, as the "Pharmacy of the World," aspires to lead in the biosimilar space with a robust framework and an expanding portfolio of approved biosimilars. Streamlined regulatory processes and global alignment would greatly benefit regional manufacturers by minimizing duplication and speeding up approvals.

USP could view India as a strategic partner in advancing global biosimilar accessibility, leveraging its regulatory expertise and manufacturing capabilities. Pharmexcil is eager to collaborate with USP in identifying market enablers, addressing capacity-building requirements and bridging skill gaps among exporters. Together, we can empower quality advocates like USP to ensure broader access to safe, effective, and affordable biosimilars worldwide.

Resolution III: Enhancing the Global Pharmaceutical Supply Chain's Resilience

This initiative aligns well with Pharmexcil’s efforts to bolster the pharmaceutical sector. Currently, we are analyzing demand-side data for APIs in regulated and Row markets. This supports India's aim to strengthen domestic API production while minimizing reliance on neighboring nations for essential raw materials and KSMs.

USP’s advanced expertise in data analytics and risk-based frameworks can contribute significantly. We welcome collaboration with USP in demand forecasting, identifying high-risk API’s prone to shortages and developing strategic plans. Such efforts would not only aid manufacturers but also influence future policy-making and investment strategies. Pharmexcil and its member companies stand to gain immensely from such a partnership.

Resolution VII: Enhancing Regulatory Systems Worldwide

India is undergoing a significant regulatory transformation, including the nationwide rollout of revised Schedule M to improve GMP compliance across all pharmaceutical manufacturers. This resolution offers an excellent opportunity to support these efforts through USP’s global scientific and regulatory strengthening initiatives.

While Pharmexcil is not a regulatory authority, we actively contribute to industry preparedness and quality advancement. USP’s technical expertise, capacity-building tools and tailored dissemination of global best practices can make a substantial impact. We remain committed to supporting collaborative initiatives that enhance regulatory systems and ensure the sustainability of pharmaceutical quality systems.

Key Outcomes:

Election of Leadership: USP announced the newly elected members of its Council of Experts and Board of Trustees for the 2025–2030 cycle, who will play pivotal roles in setting standards and guiding USP's mission.

- Adoption of Resolutions: Delegates reviewed and adopted several proposed resolutions that will influence USP's focus areas, including enhancing global health through quality standards and strengthening the supply chain for medicines.
- Stakeholder Engagement: The Convention facilitated input from members on critical areas of USP governance, ensuring that diverse perspectives inform the organization's strategies and initiatives.

Meeting with Dr. Ajay Kumar, Minister (Commerce), Embassy of India, USA in the Embassy 09 May 2025

Mr. Raja Bhanu, Director General, engaged in discussions with Dr.Ajay Kumar, Minister (Commerce) Indian Embassy, USA to address key issues related to pharmaceutical exports. As part of the preparatory meeting held at the Embassy of India (EOI), USA, the dialogue focused on strengthening trade facilitation, regulatory alignment, and market access for Indian pharmaceutical products.

The discussions aimed to enhance bilateral cooperation, streamline export processes, and address challenges faced by Indian exporters in the evolving global pharmaceutical landscape. This engagement underscores India's commitment to ensuring compliance with international standards while reinforcing its position as a reliable supplier of high-quality pharmaceutical products worldwide.

Meeting with DCGI held on 08 May 2025 on the New Export NoC System:

CDSCO:

- Dr Rajeev Singh Raghuvanshi, DCGI, CDSCO

PHARMEXCIL:

- Mr Namit Joshi, Chairman
- Mr Bhavin Mehta, Vice Chairman
- Mr Rollins John, Director

Officials from the Pharmaceuticals Export Promotion Council of India (Pharmexcil) extended sincere thanks to the Drugs Controller General of India (DCGI) for the release of the new Guidance Document for Export No Objection Certificates (NOCs).

The document provides a clear and structured framework outlining the procedures for obtaining NOCs for the export of approved and unapproved new drugs, excluding narcotic drugs and psychotropic substances (NDPS) as well as drugs classified as banned in India.

Clarifications Sought by Pharmexcil on Export NOC Guidance Document:

During the meeting with the Drugs Controller General of India (DCGI), Pharmexcil officials raised specific points requiring clarification to ensure smooth implementation and understanding of the recently released Guidance Document for Export No Objection Certificates (NOCs). The clarifications sought and the responses received from the DCGI are summarized below:

1. Requirement of COPP/FSC in Absence of Registration Certificate: Pharmexcil sought clarity on the situation where Certificate of Pharmaceutical Product (COPP) or Free Sale Certificate (FSC) is typically required for registering an Active Pharmaceutical Ingredient (API) or Formulation in the importing country.

The DCGI responded by referring to Clause 5(c) of the Guidance Document, which includes provisions for R&D purpose as under.

c) R & D Batches: API: The API / Bulk drug's Pharmacopeial status in IP/USP/BP/JP/EP may be submitted.

Page 2 of 6 guidance document & (or) Importing. Further, if formulation of the said API is approved in SRA country (United States/European Union Member States/ Canada/ Japan/Australia/Switzerland) country & (or) India may be submitted.

Formulation: Approval status of any SRA Country (United States/ European Union Member States/ Canada/ Japan/Australia/Switzerland) & (or) Importing country may be submitted.

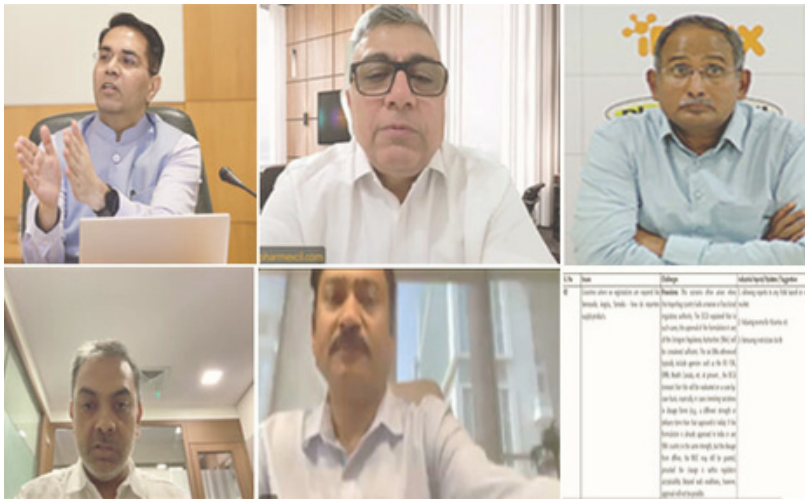
2. Recognition of Registration Certificate in Case of Third-Party Exports: A clarification was also sought under Clause 5, particularly regarding third-party exports. In scenarios where the destination country is Senegal, but the goods are routed through France (a transition country), there was ambiguity about whether the registration certificate from Burkina Faso would be considered valid by ADC at Port/Airport. The DCGI clarified that in such cases, the registration certificate of the final destination country (i.e., Burkina Faso) will be accepted for the purpose clearance at Port/Airport. The transition through another country (such as France) does not affect the validity of the destination country's regulatory approval for export purposes.

3. Unapproved Formulations in India and SRA Substitutes: Under Clause 5 pertaining to Finished Formulations, a new provision has been introduced to address situations where the formulation intended for export is not approved in India. This scenario often arises when the importing country lacks a mature or functional regulatory authority. The DCGI explained that in such cases, the approval of the formulation in any of the Stringent Regulatory Authorities (SRAs) will be considered sufficient. The six SRAs referenced typically include agencies such as the US FDA, EMA, Health Canada, etc.

4. **Use of Existing Approvals by Other Applicants:** The final point of clarification was regarding the transferability of product approvals across different applicants. Specifically, Pharmexcil inquired whether an existing approval for an API or formulation obtained by one company could be used by another company to support its NOC application.

The DCGI affirmed that the approval is considered to be product-specific and granted by the agency, rather than being restricted to the original applicant. For example, if Amoxicillin+Clavunate 1125 mg sachet has already been registered by another manufacturer in the importing country, any other company can submit this registration certificate (obtained directly from the agency) as part of their export application. This certificate will be reviewed by Indian regulators for NOC issuance, provided the product remains the same.

VC chaired by Mr. Nitin Kumar Yadav, IAS, JS, DoC, to review the trade performance of the Pharmaceutical and Medical Devices sectors. 13 May 2025



The meeting, chaired by Mr. Nitin Kumar Yadav, IAS, Joint Secretary, EP (Pharma), addressed challenges and opportunities in export growth, market competitiveness and regulatory support. While exports are generally increasing, some product categories are seeing declines, prompting the need for targeted interventions. Rising imports from key countries are creating competitive pressures, leading to potential market share losses. Key issues discussed:

- Regulatory Support: Essential for exporters to navigate evolving international standards.
- Geopolitical Shifts: Affecting bulk drug exports due to increasing localization efforts.
- Policy Implementation: Disparities between central policies and state-level execution impact licensing and export procedures.
- Trade Data Concerns: Discrepancies in export-import figures, particularly with the Netherlands, raise concerns over trade deficits.
- Market Stability: The low-cost generic drug market remains stable, but high-value exports face uncertainties.

Meetings with Embassy of India in Austria, & Austrian Pharmaceutical Industry Association held on 13 May 2025

The discussion focused on enhancing bilateral trade between India and Austria, recognizing Austria as a key European market with high potential for cooperation.

Austria as an Importing Partner: The Austrian Association expressed strong interest in Indian pharmaceutical products, acknowledging India's global presence and supply capabilities.

Opportunities for Collaboration: a. Indian companies can play a role in addressing medicine shortages in Austria and the EU, and explore partnerships in CMO/CDMO. b. Austria can serve as a hub for Indian pharmaceutical companies to expand into Europe.

Indian Pharmacopoeia: The association suggested discussing its integration at the EMEA level in the Netherlands.

IPHEX Participation: Austrian companies will be identified for participation and encouraged to join Expos in Europe.

Market Overview: Austria is a fast-growing market and ranks third in EU GDP, with healthcare spending at 11.2% of GDP and medicinal product expenditures at €3.6 billion.

Actionable:

1. We need to invite PHARMIG to IPHEX
2. Identify the members of Austria for IPHEX
3. See potential for Austria as Hub

Meetings with Embassy of India in Croatia and HALMED (Croatian agency for Medicinal Products & Medicinal Devices) held on 19 & 20 May 2025

India ranks third globally in pharmaceutical production by volume, with a vast network of manufacturers. PHARMEXCIL serves as the apex export council, supporting a large member base.

India exports 30 million USD worth of pharmaceuticals to Croatia, while the total market size stands at 2 billion USD.

HALMED inspectors may visit plants or importers in Croatia, but inspections only occur if a product is filed for registration.

HALMED oversees only pharmaceutical authorization, ensuring compliance with regulations.

The EU and Croatian pharmacopoeias are connected, while Indian Pharmacopoeia is relatively new and recently formalized.

Croatia follows EU decisions on pharmaceutical shortages, importing only EU-compliant or parallel market products.

Ireland, unlike Croatia, has independent pharmaceutical import regulations.

Dr. Rajgarhia invited HALMED to participate in IPHEX/Bharat Health, where representatives from 60 countries are expected. HALMED suggested routing the invite through its ministry director.

HALMED's Adrijana Ilić Martinac stated that Indian Pharmacopoeia can gain recognition faster if a product is filed using IP standards, ensuring automatic recognition upon registration.

"iPHEX-2025 will serve as a global platform to showcase India's pharmaceutical capabilities, fostering innovation and international partnerships." – Pharmexcil Official"

Mr. Raja Bhanu, Director General met Dr Win Kyaing, Chairman MCCPMD.MCCPMD expressed its consent to sign the MoU at Bharat Health

Meeting with Dr Win Kyaing, Chairman of the Myanmar Chamber of Commerce for Pharmaceutical and Medical Device (MCCPMD) 14 May 2025

Dr Win Kyaing, Chairman of the Myanmar Chamber of Commerce for Pharmaceutical and Medical Device (MCCPMD) met Mr.Raja Bhanu, Director General and discussed the possibilities of trade cooperation in fast-track approval for pharmaceutical products and possibilities of signing an MoU with MCCPMD. Invited Myanmar industry participation in Bharat Health scheduled from 04-07.Sep.2025 at Bharat Mandapam, New Delhi .MCCPMD expressed its consent to sign the MoU at Bharat Health. Joined by Mr.Murali Krishna S,Director,Pharmexcil

Meeting chaired by Mr. Nitin Kumar Yadav, IAS, JS, DoC with CDSCO, DoHFW, Pharmexcil, Ayushexcil, and EPCMD to discuss the issues of Pharma Industry Exporters in Room No. 441, Vanijya Bhawan, Delhi 16 May 2025

The meeting, chaired by Mr. Nitin Kumar Yadav, IAS, Joint Secretary, EP (Pharma), with CDSCO officials Mr. B K Samantaray, Deputy Drugs Controller and Mr. Naveen Mehta, Assistant Drugs Controller deliberated on the regulatory challenges in pharmaceutical exports with the New Export NoC, including regulatory approvals, documentation complexities, and international compliance. Discussions focused on streamlining approval processes, easing export restrictions, and establishing a uniform policy for deemed exports. Significant proposals included allowing alternative documentation for countries without formal drug registration systems, improving shelf-life compliance to prevent delays, and introducing a ticket-based /responsive system for faster regulatory resolutions. Industry representatives also highlighted the need for certified translation alternatives, clearer guidance on banned API exports, and conditional NOCs to minimize disruptions during manufacturing site transitions. It was emphasized to have better dissemination of export guidelines, removal of redundant NDPS permissions, broader acceptance of foreign API registrations, and formalized policies for export sample approvals. The meeting underscored the importance of structured collaboration between regulatory bodies and industry stakeholders, aiming for more predictable and transparent export operations.

First Meeting of the CII Telangana Pharma & Life Sciences Panel 2025–2026 in CII-Sohrabji Godrej Green Business Centre, Hyderabad 21 May 2025

Mr. Raja Bhanu, Director General of Pharmexcil, participated in the CII Telangana Pharma & Life Sciences event & highlighted Telangana's significant role in the pharmaceutical sector. As the second-largest contributor to pharmaceutical exports, Telangana continues to strengthen its presence in global markets through innovation and regulatory excellence. His address emphasized the need to enhance industry collaboration, streamline regulatory frameworks and drive sustainable growth to further solidify India's leadership in pharmaceutical exports. Mr.AVPS Chakravarthy, Convenor-CII,Telangana Pharma & Life Sciences Committee lead the discussions of Life Sciences Panel.

Annual General Body Meeting of FOPE at Roseate House, Aerocity, Delhi 24 May 2025

Mr. Raja Bhanu, Director General, attended as the Guest of Honour at the 18th FOPE Annual General Meeting (AGM), where he commended FOPE's proactive role in strengthening the pharmaceutical MSME sector. His address emphasized the importance of innovation, regulatory compliance, and international market access, providing meaningful direction for industry stakeholders.

Highlighted the critical need for MSMEs to adopt advanced technologies, streamline regulatory processes, and enhance global competitiveness, vision for India's expanding pharmaceutical footprint underscored the country's commitment to quality, sustainability, and strategic collaborations in the global market.

Applauded FOPE's proactive role in strengthening the pharmaceutical MSME sector and shared his vision for enhancing India's global pharma footprint. His valuable suggestions on innovation, compliance, and international market access provided meaningful direction for industry stakeholders.

Hon'ble CIM meeting with EPC's 27 May 2025

Meeting convened under the Chairmanship of Hon'ble Commerce & Industries Minister Mr.Piyush Goyal on the Centralised Export Trade Portal, to bridge the gap in Trade Information. Dignitaries include Mr.Jitin Prasada, Hon'ble State Minister for Commerce & Industries Minister, Mr. Sunil Barathwal, Commerce Secretary, Mr.Ajay Badoo, DGFT, Mr.L S Srinivas, Additional Secretary, DoC.

The HCIM advised that portal should incorporate intuitive and interactive features such as live chat, AI-driven query resolution, and matchmaking tools to facilitate real-time engagement between global importers and Indian exporters. A verified, searchable database of Indian exporters, including product profiles, certifications, and capacity details, should be integrated to help importers identify suitable suppliers efficiently.

The portal should serve as a one-stop destination for all trade-related information-market insights, regulatory guidelines, incentive schemes, logistics facilitation, and contact points in Indian Missions and EPCs-to bridge the existing information gap

Mr.Raja Bhanu, Director General ,Pharmexcil joined the meeting virtually and informed that Council is preparing a web portal incorporating the B2B platform with real time product showcasing and services and communication with overseas buyers. Mr.Kamal ,Director joined the meeting in person

Meeting with Pharmaceutical Development Agency, Uzbekistan

Participants:

Director of the Pharmaceutical Development Agency, Uzbekist

1.Mr. Oybek Elmuratov, First Deputy Chairman
2.Mr. Sagdullaev Nodirbek, Chief specialist
3.Mr. Qahramon Karimbaev, Chief specialist

Embassy of Uzbekistan, Inda:

1.Mr. Khurshdibek Samiev Trade Counsellor

Pharmexcil:

1.Mr. Raja Bhanu, Director General
2.Mr. Vishal Rajgarhia (Finecure Pharmaceuticals Limited), COA Member
3.Mr. Murali Krishna, Director
4.Mr. Rollins John, Director

A VC meeting was held on 29 May 2025 between representatives of the Embassy of the Republic of Uzbekistan in India and the Director of the Pharmaceutical Development Agency, Uzbekistan to explore avenues of bilateral cooperation in the pharmaceutical and healthcare sectors between Uzbekistan and India.

During the meeting, several key points were discussed:

The participants explored potential collaborations between pharmaceutical companies in India and Uzbekistan, with a focus on fostering mutually beneficial partnerships. Discussions were held on attracting investments from Indian pharmaceutical companies into Uzbekistan to support the development of the sector and strengthen economic ties between the two countries.

An invitation was extended to Pharmexcil and its member companies to participate in upcoming business and investment forums in Tashkent, aimed at promoting greater engagement and collaboration. Pharmexcil raised issues pertaining to registration of products and clarity regarding entry into Uzbek market. The meeting also focused on facilitating B2B partnerships at iPHEX 2025 .

"The "India-UK Free Trade Agreement" (FTA)marks a milestone in economic cooperation, particularly in the field of pharmaceuticals, stronger supply chains, & improved access to affordable medicines & in fostering Foreign Direct Investment (FDI), encouraging collaborations"

"The UK-India collaboration event was a fantastic showcase of industry dialogue and its impact. The recent UK-India FTA announcement highlights the UK's commitment to free and fair trade. We look forward to deeper engagement with India's life sciences sector, particularly at the upcoming Bharat Health 2025, organized by Pharmexcil, to further strengthen the UK-India relationship ." **Gareth Wynn Owen**
British Deputy High Commissioner

Exclusive event co-hosted by Mr. Gareth Wynn Owen- British Deputy High Commissioner- Andhra Pradesh, Telangana and Rephine UK in Deputy High Commissioner's Residence, Banjara Hills, Hyderabad

An exclusive event, co-hosted by Mr. Gareth Wynn Owen, British Deputy High Commissioner for Andhra Pradesh, Telangana and Rephine UK, was held at the Deputy High Commissioner's Residence in Banjara Hills, Hyderabad. The gathering brought together industry leaders to discuss critical advancements in pharmaceutical manufacturing, digital transformation and global trade opportunities.

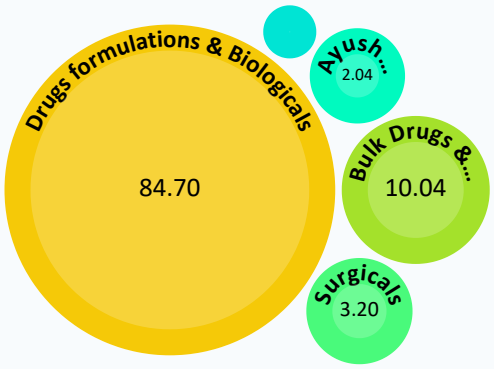
Mr. Murali Krishna S, Director, participated in the event and shared key insights on the evolving trade relationship between India and the UK in the backdrop of India-UK Free Trade Agreement. His remarks emphasized the importance of fostering stronger partnerships, regulatory alignment, and sustainable growth in pharmaceutical exports. The highlight of the evening was a powerful panel discussion, moderated by Dr. Eduard Cayón, Rephine, featuring:

- Mr. Krishna Venkatesh, Dr. Reddy's Laboratories
- Mr. Prabhakar Duwuri, Sri Krishna Pharmaceuticals
- Mr. Ashutosh K Sinha, Neuland Laboratories

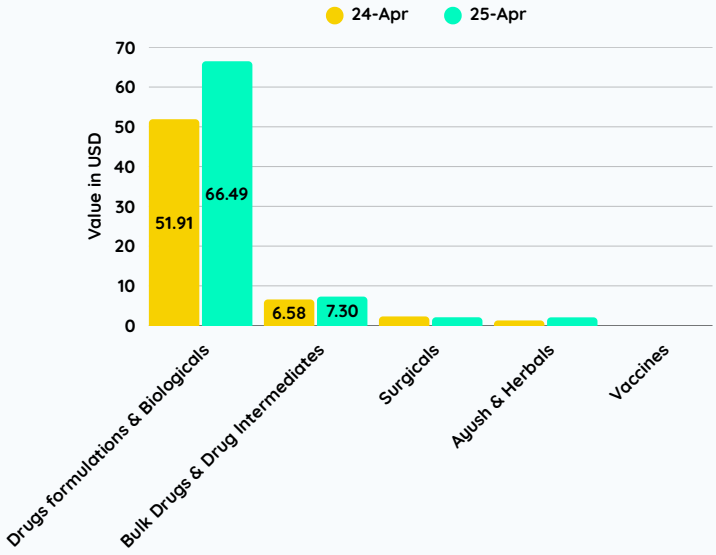
The event facilitated high-impact discussions on driving excellence in pharma manufacturing through quality, innovation using technology. Strengthening international collaboration, offering valuable perspectives for industry stakeholders.

UK -INDIA EXIM DATA(Link)

Category wise India Exports Pharmaceutical products to UK (value share in %) - FY 2024-25



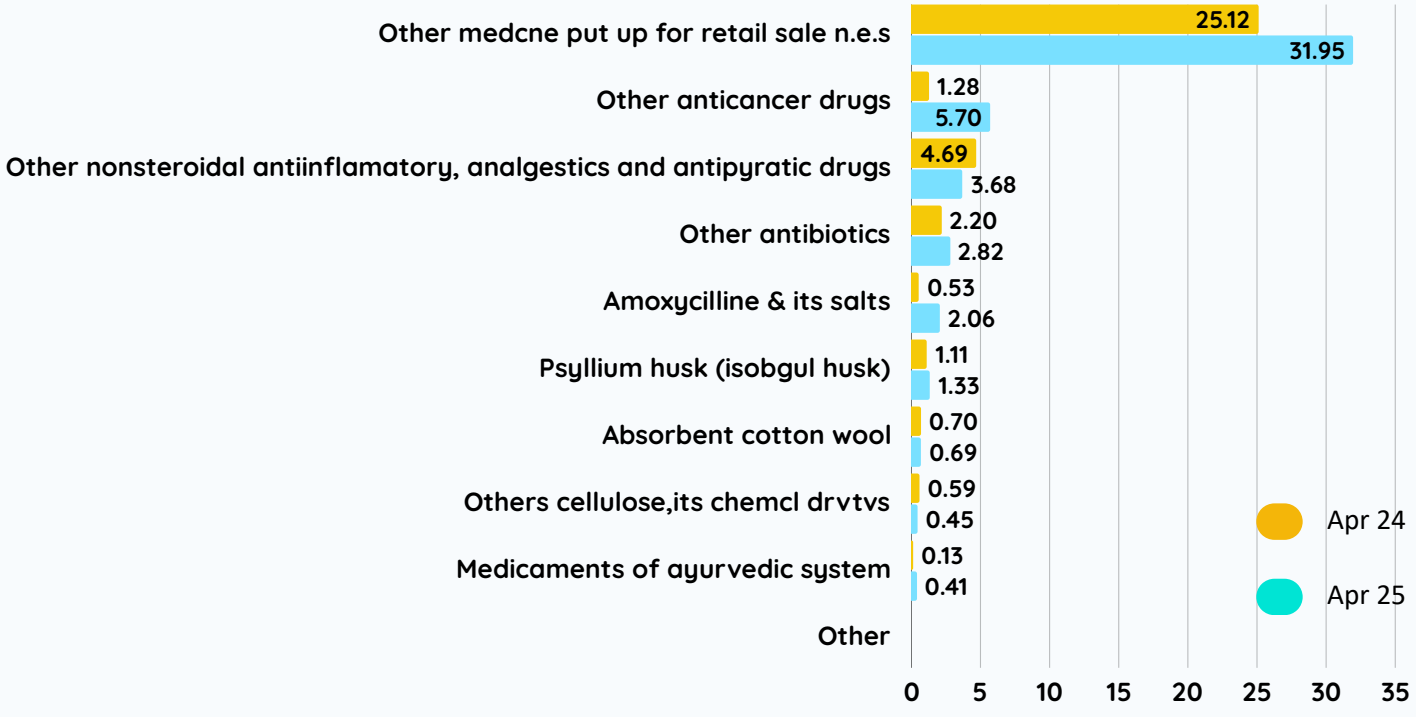
Comparative Analysis of April 24 vs. April 25 Exports (Value in USD Mn)



India's pharmaceutical exports to the UK in FY 2024-25 are projected at USD 830.18 million, growing 17.74%. Drugs Formulations & Biologicals lead with USD 703.18 million (84.70% share, 15.69% growth), while Bulk Drugs & Intermediates rose 38.88% to USD 83.41 million. Surgicals and Ayush & Herbals expanded, but vaccine exports fell 69.59%, reflecting market shifts.

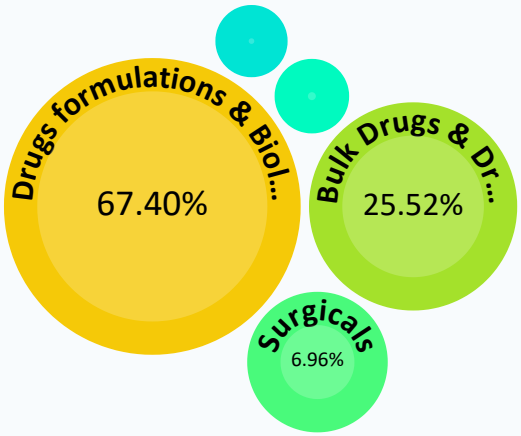
In April 2025 vs April 2024, Drugs Formulations & Biologicals increased 28.10% to USD 66.49 million. Bulk Drugs & Intermediates grew 10.90%, while Ayush & Herbals surged 59.88%. Surgicals declined 9.15%, and vaccines remained stagnant, likely due to reduced approvals.

Top 10 Pharmaceutical Products Exports to UK (April 24 & April 25 in $mn)

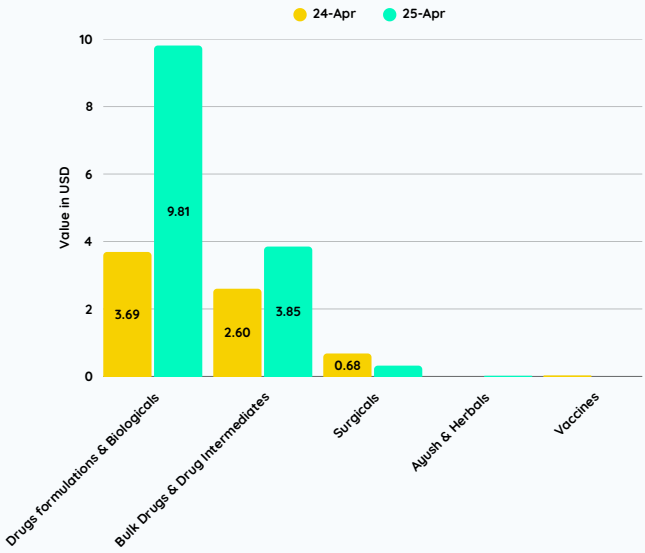


UK -INDIA EXIM DATA (Link)

Category Wise India's imports Pharmaceutical products from UK (value share in %)- FY 2024-25



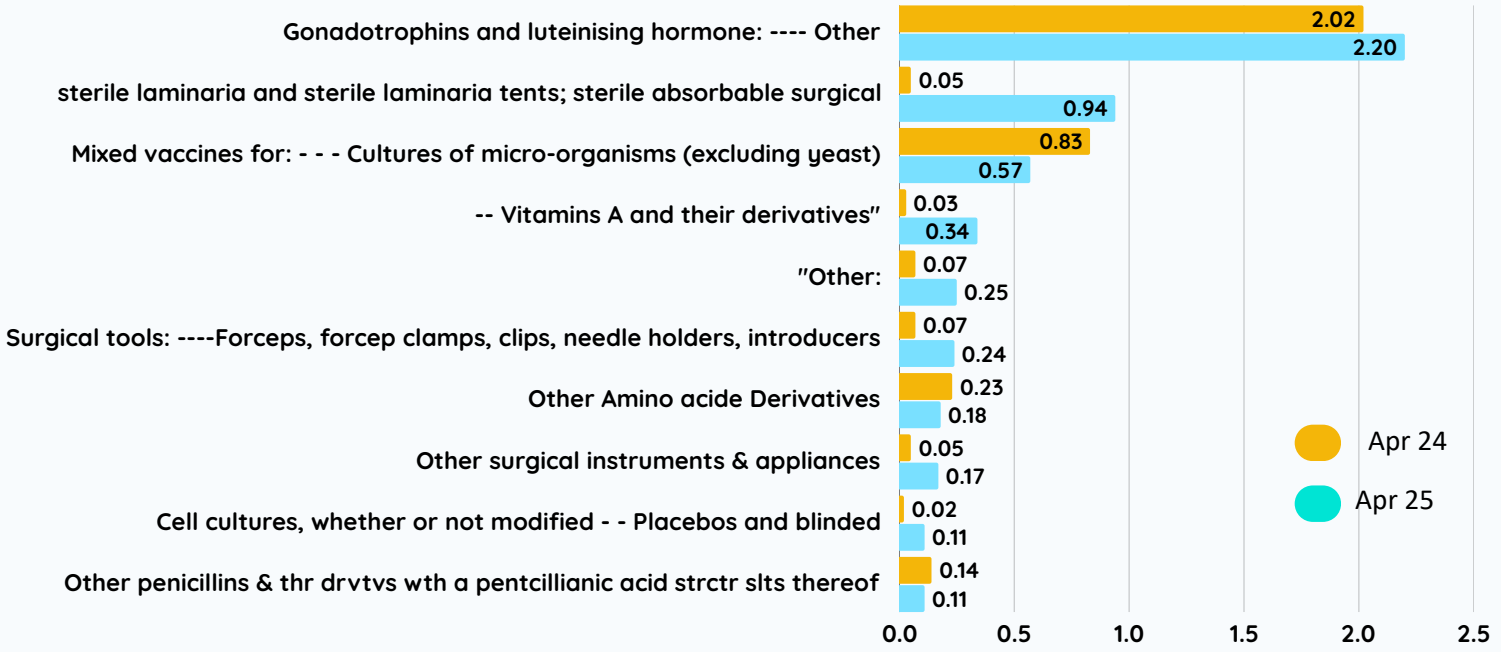
Comparative Analysis of April 24 vs. April 25 Imports (Value in USD Mn)



India's pharmaceutical imports from the UK in FY 2024-25 grew 12.85% to USD 430.15 million, driven by demand for specialized products. Bulk Drugs & Intermediates dominated at USD 290.12 million (67.45% share, 10.47% growth), while Drugs Formulations & Biologicals totaled USD 110.58 million (15.86% growth). Surgicals, Ayush & Herbals saw moderate growth, but vaccines dropped 22.54%, indicating sourcing strategy shifts.

In April 2025 vs April 2024, Bulk Drugs & Intermediates rose 8.62% to USD 25.48 million, while Drugs Formulations & Biologicals grew 11.45% to USD 9.80 million. Surgicals and Ayush & Herbals showed minor increases, but vaccines declined 34.29% to USD 0.38 million, reinforcing reduced annual imports.

Top 10 Pharmaceutical Products Importing from UK (April 24 & April 25 in $mn)



Comprehensive Registration Procedure for Pharmaceutical Products: Navigating UK MHRA Guidelines

Determine the Registration Pathway
- Choose between National, Mutual Recognition, Decentralized, or International Recognition Procedure (IRP)
- IRP applies if the product is already authorized by a trusted regulator

Prepare the Application
- Submit via MHRA Portal (Link)
- Use eCTD (Link)

Include ASMF if applicable (Link)

Conduct Pre-Submission Checks
- Validate eCTD submission using MHRA-approved tools (Link)
- Ensure compliance with UK MDR 2002 and ICH guidelines (Link)

Submit the Application
- Provide product details, manufacturing site information, and supporting documents
- Pay applicable fees based on product type and registration pathway (Link)

MHRA Review & Assessment
- Provide product details, manufacturing site information, and supporting documents
- Pay applicable fees based on product type and registration pathway (Link)

Approval & Post-Market Obligations
- Receive Marketing Authorization (MA) if successful(Link)
- Maintain compliance with post-market surveillance and pharmacovigilance requirements (Link)
- Renew authorization periodically (Link)

Comprehensive GMP Inspection Guidelines for UK MHRA: Ensuring Regulatory Compliance & Pharmaceutical Quality

Manufacturer Applies for GMP Compliance (Link)

MHRA Conducts Risk-Based Inspection (Link)

Findings Categorized (Critical, Major, Minor)(Link)

Compliance Report Submission(Link)

Corrective Actions Implementation

MHRA Issues GMP Certification(Link)

Ongoing Monitoring & Periodic Inspections (Link)

Continuous Compliance & Improvement (Link)

Fee Structure (Link)

Pharma News

Ethiopian FDA's assessment or onsite inspection of medical device manufacturing factories GMP/QMS compliance

PHARMEXCIL DIGEST provides a curated selection of industry news, keeping professionals informed about key developments in pharmaceuticals. Covering regulatory updates, market trends, and global trade insights, this digest ensures timely access to essential information shaping the sector

May Month- 2025

Few Pharma Firms Apply for Schedule M Extension After Seeking More Time; Govt. Urges Urgent Action. (Dt: 01 May 2025)

CDSCO adds tooltips in its online platforms for legal forms to support stakeholders. 01 May 2025

DGFT seeks feedback on major export policy realignment following Finance Act 2025 amendments. 05 May 2025

DTAB ratifies extension of timeline for revised Schedule M implementation for MSMEs. (Dt: 07 May 2025).

Ethiopian Food and Drug Authority revises GMP Rules, mandates re-inspection every 3 years. (Dt:12 May 2025)

India has not accepted 'data exclusivity' demand by UK to protect generic drug firms. (Dt:12 May 2025)

Pharmexcil initiates high-level discussions with key ASEAN nations to strengthen pharma trade.(15 May 2025)

LUB asks Centre to extend deadline till 2026 end for implementing revised Schedule M for cos below Rs. 50 crore turnovers. (Dt: 16 May 2025)

The government invites Pharma firms to submit the data for ceiling price review.(Dt:17 May 2025)

Indian pharma industry feedback sought to explore Kuwaiti pharma market potential. (Dt:13.05.25)

In this newsletter you can expect:

Regulatory Notifications

Call for Comments

Inviting comments on Revised Guidelines on Similar Biologics- Regulatory requirements for Marketing Authorization in India, 2025 drafted by CDSCO. (Dt:06 May 2025)

Revised Export NOC Guidance

Inviting comments on Revised Guidelines on Similar Biologics- Regulatory requirements for Marketing Authorization in India, 2025 drafted by CDSCO. (Dt:06 May 2025)

Import & Transit Ban on Goods from Pakistan

Prohibition on Import or transit of all goods originating in or exported from Pakistan- Insertion of Para 2.20A of Foreign Trade Policy (FTP) 2023. (Dt: 02 May 2025)

Schedule-II (Export Policy) Harmonization – 2025

Harmonization of Schedule-II (Export Policy), ITC (US) 2022 with amendments introduced vide Finance Act, 2025. (Dt: 19 May 2025)

Anti-Dumping Duty on Sodium Citrate

Seeks to continue imposition of Anti-Dumping Duty on imports of "Sodium Citrate" originating in or exported from China PR. (Dt: 08 May 2025)

Raxaul Land Customs Station Amendment

Amendment in the Notification No. 63-1994-Customs (N.T) dated 21.11.1994 in respect of Land Customs Station, Raxaul. (Dt: 23 May 2025)

Rule 104A: Import Permission Clarification

Clarification on Comprehensive Permission for Imported Products under Rule 104A, Drugs & Cosmetics Rules 1945. (Dt:26.05.25)

Restoration of RoDTEP for AAs, SEZs & EOUs from 01ST June 2025. (Dt: 26.05.25)

RoDTEP Schedule Alignment with Customs Tariff Act Changes from 01.05.2025 (Dt: 26.05.25)

Flowing Towards Sustainability: Role of Flow Chemistry & Continuous Manufacturing in Strengthening Indian Pharma Ecosystem

How flow chemistry, continuous manufacturing and deployable digital instrumentation will strengthen leadership of Indian pharmaceutical manufacturing, and sustain its momentum through innovation and supply chain security.

Securing India's Pharma Backbone

Indian pharmaceutical industry has rightfully earned its reputation as the 'Pharmacy of the World'. Its formulation capabilities, cost-effective scalability, and regulatory credibility have positioned it as a global supplier of essential medicines. The pharmaceutical manufacturing ecosystem has catered affordable and accessible quality medicines to multiple geographies across the world.

Yet, behind this success lies a critical vulnerability. Presently a significant portion of the chemical building blocks required for pharmaceuticals manufactured in India is imported.
This does create a concern for supply chain security and potential price fluctuations, which can affect India's commitment to quality and affordable medicines. This import dependence creates structural exposure to global supply shocks, pricing instability, and geopolitical risk.

The need for newer regulatory norms, commitment to sustainability and modernization of current manufacturing capabilities is also being increasingly recognized.

Emerging technologies like flow chemistry, process intensification platforms, and real-time monitoring systems are defining how chemical and pharmaceutical manufacturing can be reimagined for the future. Against this background, there is certainly a need to reposition the pharmaceutical manufacturing landscape. Typically, the lifecycle of a novel drug from its invention to clinical trials to approval requires the identification of the right routes for synthesis. Similarly, bringing an active pharmaceutical ingredient (API) to market as a generic drug involves neither just copying nor mere demonstration of the innovator's route of synthesis. Innovation in chemical process development plays a pivotal role in the development of any generic API and offers a strategic vantage point to any pharmaceutical company in its efforts to carve out a niche for itself in the ever-challenging generic drug market. It is, however, important to recognize that on the wide and holistic canvas of a generic API development, an innovative and sustainable chemical process is rarely the one that requires a global restructuring of the known synthetic route or a brute-force inclusion of an exotic chemical transformation. Indeed, an efficient synthetic route to an API evolves through a continuous process of incremental improvement and gradual simplification of the existing chemical processes to the API and related intermediates.

Molecular complexity of an API is often derived from its key starting materials (KSMs). The latter could be oxygen- and nitrogen-rich heterocycles, contain fluorine and other halogens, or have a single or multiple chiral centres.

Dr.Srinivas Oruganti, Ph.D, FRSC
Director, Dr. Reddy's Institute of Life Sciences

A notable step in this direction was the DRILS – Pharmexcil Flow Chemistry workshop, supported under Pharmexcil's CSR grant. The workshop trained several students from engineering, chemistry and pharmacy disciplines. The curriculum was designed to emphasize not only the fundamentals of flow chemistry, but also its application in promoting environmentally sustainable manufacturing practices. The impact of this initiative was two – fold: building a technically capable workforce and instilling a strong ethos of sustainability in early career professionals

★★★★★

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Molecular complexity of an API is often derived from its key starting materials (KSMs). The latter could be oxygen- and nitrogen-rich heterocycles, contain fluorine and other halogens, or have a single or multiple chiral centres. An ideal route to an API or its KSMs places emphasis on satisfying seven key concepts:
i.The need for the route to be convergent,
ii.Having as many chemo-/biocatalytic steps in the reaction sequence as possible,
iii.An overall reduction in the number of steps compared to the existing synthetic routes,
iv.Ensuring that the chemical transformations envisaged are robust and scalable,
v.Making a conscious effort to avoid using reagents, solvents, and reaction conditions that are known to be hazardous,
vi.Patentability,
vii.Adherence to the twelve principles of green chemistry in general.
A strong integration of process engineering modernization with good route design often becomes the right recipe for efficient, sustainable, safe, and cost-competitive manufacturing of any API or its KSM.

Flow chemistry is being increasingly recognized as a key enabler of this transformation. It provides exceptional control over reaction parameters, enables safer execution of hazardous transformations, and supports real-time process adaptability. The compact nature, modular footprint, customizability and inherent safety characteristics of continuous flow reactors make them ideal for localized, high-performance manufacturing environments.
Further they allow better thermal and mass transfer efficiency, which minimizes impurity formation and facilitates higher consistency in product quality from one batch to another.
Flow chemistry is particularly suited for novel reaction pathways involving photochemical, electrochemical, and microwave-driven systems. This expands the synthetic toolbox available for complex APIs and naturally aligns with the principles of green chemistry by lowering environmental impact through reduction of solvent usage, reaction volumes, and waste generation...

Flow Chemistry and Continuous Processes: From Legacy to Leadership

While batch manufacturing has long been the industry standard, its inherent limitations are at odds with the demands of modern pharma that demand greater flexibility, safety, and scalability. Traditional batch processes, while familiar, are inherently segmented, slow, and scale-dependant. Materials move from reactor to crystallizer to formulation units with manual interventions and risk of downtime at every stage. This introduces risk, inefficiency, and variability.
Flow chemistry emerges as a transformative alternative. By executing reactions in compact closed-loop reactors, flow chemistry redefines how hazardous or complex chemical transformations can be handled. Chemistries (such as halogenation, cyanation, and diazotization), which were previously outsourced due to risk or inefficiency, can now be handled safely and efficiently in-house. Continuous microreactors offer tighter control, faster kinetics, and higher reproducibility, all while minimizing energy use, waste generation and physical footprint.

The transition does not stop at safer reactions. When coupled with continuous manufacturing, flow chemistry unlocks a new paradigm of integrated operations. Rather than handling synthesis, purification, and formulation in disconnected stages, continuous systems link

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link these operations into a single, streamlined process. This not only reduces human intervention but also embeds real-time quality control into the very fabric of production.
For India, this shift from batch to continuous manufacturing is no longer just a technological advancement – it is a strategic requirement. In a nation tasked with balancing domestic therapeutic needs and international supply commitments, continuous infrastructure enables a form of responsive manufacturing that adjusts to demand, instead of merely forecasting it. It transforms pharmaceutical output from static capacity to dynamic capability.

This paradigm also finds real-world resonance in advanced biologics and mRNA manufacturing, where uninterrupted synthesis and purification workflows have delivered new levels of agility, consistency, and regulatory compliance. In India, such capability will be foundational to future-readiness.
Building Capability for India's Future
No transformation in pharmaceutical manufacturing, however advanced its technology may be, can sustain itself without a parallel transformation in human capital. Successful adoption of flow chemistry and continuous manufacturing does not depend merely on infrastructure and equipment. It requires a new generation of chemists, engineers, and process scientists who are trained to navigate the convergence of chemistry, digital systems, and process intensification.

Recognizing this imperative, the Flow Chemistry Technology Hub at Dr. Reddy's Institute of Life Sciences (DRILS) was established with support from the Government of Telangana, Dr. Reddy's Laboratories, and Laurus Labs. The Hub serves as a neutral, cross-industry platform to accelerate knowledge transfer, provide access to industrial-grade equipment, and foster real-world problem-solving skills in a controlled, innovation-focused environment.
This effort complements DRILS' larger capacity building ecosystem. Through structured initiatives like the Fundamentum course, DRILS has trained over 200 students from academia and more than 80 industry scientists in the principles and application of flow chemistry and continuous processing. The tutorials blend theory with hands-on reactor training and cover various aspects of safety mapping, instrument calibration and reaction optimization in order to ensure that the trainees graduate with both conceptual clarity and operational readiness.
This quiet but deliberate investment in capability development reflects a shift in outlook. India is not merely preparing to adopt global technologies - it is moving ahead to master, modify, and lead them. As the pharmaceutical sector embraces modern manufacturing, institutions like DRILS are laying the foundation for self-sustaining, deeply skilled innovation pipelines that will underpin India's industrial competitiveness for decades to come.

Digital Instrumentation and Process Control

At the heart of every reliable continuous manufacturing system lies a robust network of advanced instrumentation and process analytical technology (PAT) tools. These systems are not just supplementary in nature - they are foundational in ensuring consistent quality, operational stability, and regulatory compliance. Whether it is maintaining precise control over temperature gradients, optimizing flow rates for complex multiphase reactions, or monitoring impurity profiles in real time, digital instrumentation serves to transform subjective oversight into measurable, traceable control.

In flow and continuous setups, every second of operation counts, and every fluctuation, if unchecked, can cascade into deviations, batch failures, or compliance breaches. Hence, the importance of inline sensors, digital flow meters, thermal probes, pH monitors, turbidity detectors, and spectroscopy-based analysers cannot be overstated. These instruments, when integrated with distributed control systems (DCS) or supervisory control and data acquisition (SCADA) frameworks, enable continuous visibility and oversight of key process parameters.

Critically, the focus in regulated pharmaceutical environments is not on speculative artificial intelligence or opaque algorithmic systems. Instead, the emphasis is on deployable digital systems, technologies that are validated, explainable, and aligned with good manufacturing practices (GMP). These systems are

engineered to function reliably within the constraints of GxP environments and offer not just data, but actionable insights with audit-ready traceability.

When paired with carefully calibrated feedback loops, such systems allow manufacturing plants to operate in a state of predictive control. Instead of waiting for deviations to trigger alarms ex post facto, these platforms enable real-time corrections, adjusting flow rates, reagent concentrations, or reaction times dynamically. This significantly reduces waste, minimizes risk, and ensures that quality is not inspected into the product after-the-fact, but built into the process from the start.

Furthermore, digital instrumentation supports advanced capabilities such as digital twins, historical trend analysis and multivariate process control (MVPC). It empowers process engineers and quality control teams to run simulations, validate changes virtually, and implement continuous improvements with minimal disruption.

As Indian pharma moves toward globally harmonized quality standards, the integration of smart instrumentation and reliable digital control layers will define the readiness of our manufacturing systems, not just for today's production goals, but for the complexity, scale, and speed that the future will demand

Redefining SCM through Sustainable Chemistry

Flow chemistry and continuous manufacturing are not incremental improvements. They represent a paradigm shift in how pharmaceutical production systems are conceived, operated, and scaled. Unlike traditional upgrades that address only individual bottlenecks, these technologies rewire the manufacturing architecture itself, creating an ecosystem that is inherently modular, safer to operate, and capable of embedding quality directly into the process.

In the context of today's globalized markets and volatile geopolitical landscape, the resilience of India's pharmaceutical supply chain is not merely a logistics challenge, it is a technological imperative. With increasing expectations for sustainability, traceability, and compliance from global regulatory agencies and customers alike, India must look beyond volume-driven strategies and build systems that are intelligent, adaptive, and self-correcting.

Flow chemistry enables safe and localized execution of high-risk or resource-sensitive chemistries that were earlier either outsourced or considered unviable. Continuous manufacturing, in turn, integrates these chemistries into uninterrupted production pipelines that respond in real time to both quality feedback and market dynamics. Together, they allow companies to move from reactive capacity planning to proactive, demand-aligned supply execution.

The result is a redefined vision of supply chain management (SCM), one no longer cantered around warehousing, scale economies, or low-cost labour, but on sustainable chemistry as the strategic backbone.

In this framework, flow and continuous systems do not merely support SCM; they transform it into a chemistry-driven value chain characterized by minimal waste, minimal downtime, and maximum responsiveness.

India's opportunity is to lead this redefinition, not just as a manufacturing destination, but as a knowledge powerhouse that fuses scientific innovation with operational agility. Flow can be an enabler to redefine supply chain management as a sustainable chemistry movement, one that prioritizes both innovation and resilience at its core.

The views or the opinions expressed in this article are solely of the author's; and do not necessarily represent those of Dr. Reddy's Institute of Life Sciences

Regulatory Updates

Kenya's Pharmacy and Poisons Board (PPB) Reaffirms commitment to Safe, Quality Health Products

The Pharmacy and Poisons Board (PPB) faces Challenges like informal distribution, falsified products, industry resistance, and digitization barriers, threatening public health and Kenya's WHO Maturity Level 3 (ML.3) status. To address this, PPB is strengthening regulations, enhancing surveillance, and improving inter-agency coordination. Expanding public awareness, accelerating digital transformation, and incentivizing compliance will support enforcement. These efforts aim to protect health, streamline oversight, and advance Kenya's pharmaceutical regulation. (Link)

May 13 2025| Nisticò (AIFA): "High drug prices in the US are the result of a completely privatized healthcare system"

Robert Nisticò highlights that the U.S. drug pricing system drives up healthcare costs, while Italy's National Health Service, supported by AIFA, secures some of the lowest prices in the OECD. However, rising pharmaceutical expenditures in Italy necessitate governance reforms to prioritize genuine innovation that delivers measurable therapeutic benefits. (Link)

May 14 2025| Summary table of new drugs and extension of indications

The summary table lists newly approved drugs and extensions of indications from the Italian Medicines Agency's latest negotiations. It includes orphan drugs like Hyptacopan for paroxysmal nocturnal haemoglobinuria and new chemical entities like Tenecteplase for acute ischemic stroke. Generic drugs and parallel imports, such as Ramucirumab for gastric carcinoma, are also included. Some drugs, like Vydura for migraine, were classified as innovative. The document highlights Italy's evolving pharmaceutical landscape and pricing strategies.(Link)

May 14 2025| AIFA Board of Directors approves reimbursement of 11 drugs

The Italian Medicines Agency approved reimbursement for 11 drugs, including the orphan drug Fabhalta for paroxysmal nocturnal hemoglobinuria, four new chemical entities like Fruzaqla for metastatic colorectal cancer, and Vydura for migraines. Two generics, Alfacalcidolo Doc and Beclometasone e Formoterol Doc Generici, along with the parallel import drug Cyramza for gastric cancer, were also included. Three drugs—Cosentyx, Pirfenidone Teva, and Xtandi—received expanded therapeutic indications.(Link)

Members ACHIVEMENTS

01

SMS Pharma's Vizag plant receives WHO prequalification 03.05.25

02

Shilpa Biologics Dharwad site gets European GMP certificate 06.05.25

03

Shilpa Medicare Unit VI gets GMP approval from EMA 08.05.25

04

Aurobindo Pharma arm's biosimilar gets marketing nod from U.K.'s MHRA 14.05.25

05

Sun Pharma gets FDA approval for new device to treat skin disease 19 05 2025

"""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."."

WELCOME NEW MEMBERS

Drugs formulations & Biologicals

IGNATURE PHYTOCHEMICAL INDUSTRIES PVT LTD
SARV PHARM
KBM PHARMACEUTICAL
GVB LIFE SCIENCES PVT LTD
YANASHA PHARMA PVT LTD
CSBS HEALTHCARE PVT LTD
NEWPHARMA ORIGIN PVT LTD
ASIEL CHEM PHARMA
PADMASHREE ENTERPRISE
SAMARPIT GROUP
SAMARPIT GROUP
SIMILIS PHARMA INDIA LLP
TRESINDE BIOTECH
SUNNYCO
COCREATE GLOBAL TECHNOLOGIES PVT LTD
PRIVET PHARMA
ARUSK PHARMA PVT LTD
PAC HEALTHCARE LLP
WESTPOLE IMPEX
AUREOSTEM RESEARCH PVT LTD
FORTUNE HEALTHCARE PRODUCT PVT LTD
BIOVONIC HEALTHCARE PVT LTD
CENT CURE PVT LTD
AQUA CHARGE LIFESCIENCE LLP
KUREASIA PHARMA PVT LTD
HERBS NUTRIPRODUCTS PRIVATE LIMITED
BIORA GLOBAL LLP
HEALTHSPARK PHARMA PVT LTD
P K PHARMA VENTURES
VAKRATUNDA INTERNATIONAL PVT LTD
MATRIX UNIVERSAL PVT LTD
THE MOLECULEZ
CHOUDHARI IMPEX
APOLLO INGREDIENTS LIMITED
SWERINE HEALTHCARE
MEDNEX PHARMA LLP
MEDILATINA FARMA PVT LTD
GANA SREE SAI PHARMACEUTICALS & DISTRIBUTORS
EXYLONE LIFESCIENCE PVT LTD
MEDVIXX PHARMACEUTICALS
BRISKINN SOLUTIONS PRIVATE LIMITED
GENAIDE PHARMACEUTICAL PVT LTD
M S SURGICALS
NOVASIS HEALTHCARE PVT LTD
SAVIOUR CAPS PRIVATE LIMITED
NYSA BIOMED PRIVATE LIMITED
VIBCARE HEALTHCARE PRIVATE LIMITED
UNIGROW PHARMACEUTICALS
ERIS BIONXT PRIVATE LIMITED
MEDIBLUE LIFESCIENCES
YOGI MEDICAL AGENCY

51

WELCOME NEW MEMBERS

Bulk Drugs & Drug Intermediates

11

BHAVNA LABORATORIES PVT LTD

RADISON LABS PRIVATE LIMITED

INDIA PHOSPHATE AND ALLIED INDUSTRIES PRIVATE LIMITED

KHODIYAR CHEMICALS

BRUNDAVAN LABORATORIES PRIVATE LIMITED

ELIXIR PHARMA

SVR DRUGS AND INTERMEDIATES

GOLD PHARMA PRIVATE LIMITED

SVR DRUGS AND INTERMEDIATES

3XPER INNOVENTURE LABS LIMITED

DIVYAKSHAR INTERCHEM PRIVATE LIMITED

Nutraceutical Products

02

TIHORA HEALTHCARE

ZOIC LIFE SCIENCES

NECON SOFTGEL LLP

NB HEALTHCARE

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

Online Services

RCMC MEMBERSHIP Registration/Renewal
RCMC's issued month of May : 70 Companies
Click here to Apply for New Membership/Renewal

Certificate of Origin COO-(Non Preferential):
Members can obtain COO online
Time for Issuance (same day)
No.of COO's issued : 176 (Month of May)

Market Access Initiative:
Product Registration
Plant inspection
Patent filing
BA/BE Studies
Clinical Trials
MAI Applications Recommended -May Month
Recommended to DoC-19
Returned-13

Pharmexcil Help Desk

11.07.2024

The Pharmexcil Helpdesk WhatsApp service, launched on July 11, 2024, enhancing 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

+91 8977024106 – Handles queries related to the Market Access Initiative (MAI).

+91 8977025106 – Covers Certificate of Origin (CoO), RCMC, Events & Regulatory Guidance. tes on Government Schemes and policies.

NEW

Appointments of Advisors

Pharmexcil has appointed Advisors for addressing the matters relating to DGFT, Customs & GST.

Member companies facing issues/requiring advise on DGFT, Customs & GST can now avail the services by sending request to the following email ids

- **Customs and GST**

advisor-gstcustoms@pharmexcil.com

- DGFT Matters

Advisor-dgftmatters@pharmexcil.com

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

SUBMIT YOUR
FEEDBACK

Dear Members, Greetings from Pharmexcil!

Subject: Request for Data Submission – Trillion-Dollar Trade Target for Pharma Sector- Submit inputs by 07 June 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 Mr.Nitin Kumar Yadav,IAS, 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 June 7th 2025, to enable us to consolidate and submit the data within the stipulated timeline. Questionnaire for Pharma 2025

iPHEX

4 - 6 SEPTEMBER 2025
NEW DELHI
Bharat Mandapam, New Delhi

11th EDITION INTERNATIONAL PHARMACEUTICAL EXHIBITION

IPHEX IS AN INITIATIVE OF MINISTRY OF COMMERCE & INDUSTRY, GOVERNMENT OF INDIA | ORGANIZED BY PHARMEXCIL

IT IS THE LARGEST EVENT TO SHOWCASE THE ENTIRE INDIAN SPECTRUM OF DRUGS & PHARMACEUTICAL SECTOR TO THE WORLD

OVER 600+ PROMINENT OVERSEAS BUSINESS DELEGATES ACROSS THE GLOBE WILL BE SPONSORED

- THREE DAYS EVENT
- BUSINESS SESSIONS
- CONFERENCE SESSIONS

FOCUS SECTORS

- Formulations
- APIs
- AYUSH
- Nutraceuticals
- Health Services
- Vaccines / Biosimilars
- Biotechnology Products
- R&D Services
- Technologies & Consultancy
- Diagnostics/Surgical Dressings
- Medical Devices
- Contract manufacturing and more…

HIGHLIGHTS

→ More than 700+ Exhibitors
→ Over 600+ Invited Business Visitors from across the Globe
→ Seminars / Workshops on pharma exports related technical & commercial topics
→ Over 25,000+ Business Visitors are expected

OVERSEAS BUSINESS VISITORS PROFILE

- Manufacturers
- Distributors
- Importers
- Govt. Procurement Agencies
- Pharma Associations / Chambers

www.iphex-india.com
www.pharmexcil.com

COMPLIMENTARY VISITOR REGISTRATIONS ARE OPEN NOW

General Enquiries:
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BLOCK YOUR DATES