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EU-India FTA Negotiations: EFPIA Input



Presentations
2 February 2022



Content

1. Intellectual Property Rights
2. Regulatory
3. Market Access
4. Customs-related
5. Falsified medicines
6. Non-prescription medicines





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Intellectual Property Rights



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Roche



IPR Issues in India

- Restrictive Patentability Criterion (Section 3d)

- EFPIA Ask

- Non-Discriminative use of Section 3(d)

- Need of higher standard of clarity. Revision of Existing Guidelines and implementation recommendation of Parliamentary committee.

- Pre-Grant Opposition

- EFPIA ask

- 1st Preference: Elimination of Pre-Grant Opposition

- 2nd Preference: Provision to introduce limitation period (1yr) for filing pre-grant oppositions as in the case of post-grant opposition



India IP Issues (Contd.)

➤ Patent Enforcement

➤ EFPIA Ask

- Introduction of Specialized IP Courts.
- Increase New Drugs definition from 4 yrs to 10 yrs from time of authorization.
- Public Notification system by Indian authorities on marketing & manufacturing approvals of generic/biosimilar drugs.

➤ Regulatory Data Protection (RDP)

➤ EFPIA Ask

- Introduction of RDP provisions





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Regulatory



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Jazz Pharmaceuticals



Regulatory: Waiver of local Clinical Trials (CTs) requirement

Although New Drugs and CT rules 2019 mentions the possibility of Phase III/local CT waiver, it is our understanding that this is not fully implemented consistently.

It is our understanding that barriers for consistent implementation is due to non-publication of Rule 101. *(Name of countries for purpose of new drug approval- The Central Licensing Authority, with the approval of the Central Government , may specify, by an order, the name of the countries , from time to time, for considering waiver of local clinical trial for approval of new drugs under Chapter X and for grant of permission for conduct of clinical trial under Chapter V.)*

New Drugs and CT rule 2019 (New Drugs and Clinical Trial Rule) also says “waiver of Phase IV study commitment” in certain cases, this is not being implemented citing the absence of Rule 101.

➤ EFPIA Ask

- EU to request that products that have been approved by countries such as US, EU, UK, Japan, Canada and Australia do not need to be evaluated in local phase III trials and should be confirmed by an official notice publishing of Rule 101 (Rule 101 forms the basis for local clinical trial waiver under the NCDT rules).
- EU to suggest a joint forum between the Indian regulator and the industry to review the implementation of any new rules or guidance's.

Regulatory: Accelerated Regulatory Pathways

Expedited Review: The Indian regulatory process for imported products consists of three sequential phases: 1) NDA approval; 2) manufacturing site approval; 3) import license. This is time-consuming (9-10 after the NDA approval) and delays patient access to medicines.

A trend has arisen, whereby health authorities in developing countries are implementing the recognition of approvals from reference countries through the use of reliance pathways and implementing an abridged review process. The same approach is recommended for India HAs.

➤ EFPIA Ask

- EU to request India to adopt abridged review for products approved in reference or major countries such as US, EU, UK, Japan, Canada and Australia.
- EU to request India to consolidate the process to obtain the import license after the NDA approval.



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Market Access



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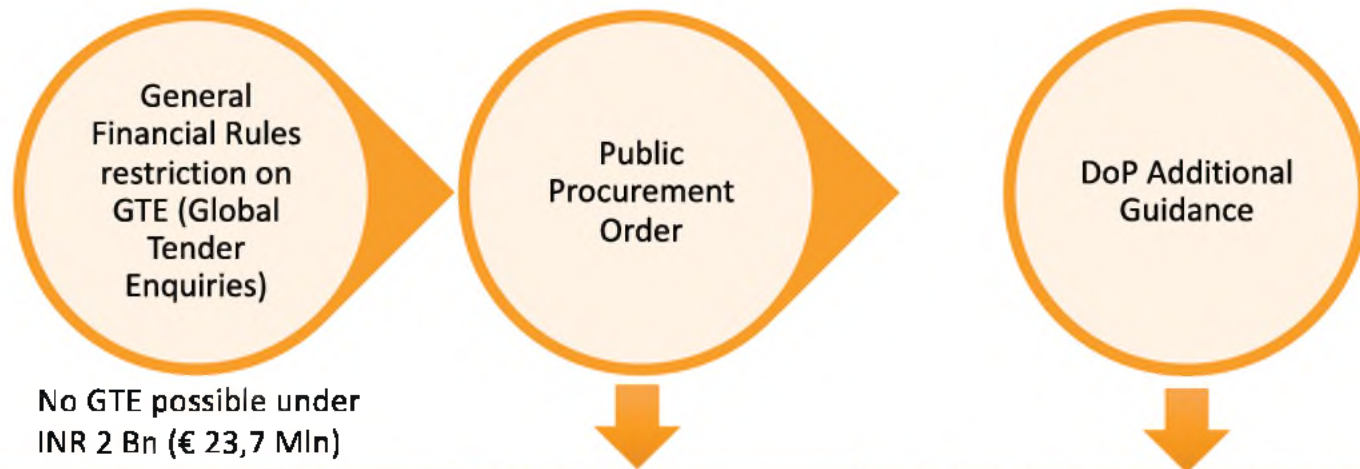
Bristol Myers Squibb



European industry faces increased barriers in access to public tenders due to discriminatory local content requirements



Self-reliant India (Atmanirbhar Bharat)



	DPIIT PPO dated September 16, 2020	DoP Guidelines for Pharmaceutical formulations
Class - I Local Supplier	Minimum 50%	Equal to or more than 80%
Class - II Local Supplier	Minimum 20%	More than 50% but less than 80%
Non-Local Supplier	Local Content less than that prescribed for Class II	Less than or equal to 50%

Local content requirements – implications for the European industry

Companies with less than 50% local content can only participate in global tenders (above INR 2 Bn) for goods other than those for which the relevant department notified that there is enough local capacity and competition → companies may therefore be excluded from procurement, affecting EU exports

Case by case exemptions possible but cumbersome (no blanket exemption)

- Has to be requested by the procuring authority after seeking to run a local tender and engaging with DPIIT to identify local suppliers
- Requires detailed argumentation for the exemption,
- Requires involvement of multiple authorities

Blanket exemption from GTE restrictions granted on Jan. 6, 2022 for 128 medical devices with no alternative available in India (valid until 2023).

Open-ended definition of “local content” requires clarifications

- “local content/manufacturing” not defined in PPO or DoP guidelines
- Refrigeration, (re-)packaging, labelling are included under “manufacturing” as per Foreign Trade Policy 2015-2020 and Drugs & Cosmetics Act
- Risks of unintentional incorrect certifications submitted by companies; exposure to corresponding penalties

Industry view

- Ensure level playing field and avoid discriminatory provisions
- Blanket exemptions should be given for products with no local alternative available/when a products gets an exemption upon request of a procuring entity, it should be valid across entities
- Broad definition of local content including packaging, labelling, marketing.

Overview of the pharmaceutical pricing policy in India



Pricing of pharmaceuticals in India (DPCO*, 2013)

Scheduled (National List of Essential Medicines, NLEM)

- Subject to price controls – i.e. max. price fixed by the NPPA
 - *Patented drugs exempted from price controls for 5 years; orphans exempted permanently*

Non - Scheduled (National List of Essential Medicines, NLEM)

- Price monitoring applicable (max. 10% annual price increase)



Implementation of Trade Margins Rationalization (TMR) to support affordability

- Introduced in February 2019 as a pilot for 42 oncology treatments
- 30% cap on the trade margin (i.e. difference between retail price and price at first point of sale/Price to stockist)
- Based on the following formula:
Retail price of the product = Price to Stockist (PTS) x {1+(TM/100-TM)}
PTS = Price to stockist → not actual but derived figure (total sales realization in June 2018/total quantity sold in June 2018)

*Drug Price Control Order

TMR became a disguised price control mechanism leading to challenges of sustainability and predictability of the pricing system

Flaws in the TMR policy

- PTS not defined based on government databases but through a formula set by the NPPA which includes supplies without any trade margin
 - Free products supplied via Patient Assistance Programmes (PAP)
 - Quantities supplied to government through public tenders at discounted prices (usually below PTS)
- Arbitrary selection of the 42 oncology drugs
- Arbitrary choice of the period (June 2018) considered



TMR becomes a price control tool going beyond the DPCO & NPPP**

- Several companies received “show cause notices” – 1 pending court case
- Formula artificially drives the PTS down leading to up to 70% retail price reductions
- Retroactive paybacks undermines the financial sustainability of our affiliates
- Lack of predictability – calculation depending on the NPPA interpretation

**National Pharmaceutical Pricing Policy, 2012

Latest developments

- **Potential reform** of the TMR policy based on a new formula → open question on institutional sales & free of charge/discounted supplied through PAP
- **Extension of the system** to the entire non-scheduled sector in phases (products priorities based on average mark-up and price band)

Industry view:

- Transparent, predictable and fit for purpose TMR system and broader pricing policy
- Limit TMR to supplies through trade channels and preserve ability to support affordability and access through Patient Assistance Programmes.



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Customs



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Boehringer Ingelheim



Customs-related concerns – our asks related to...

a. Tariffs and Quotas

Eliminate all customs tariffs and quotas for products classified in the **HS chapters 28 to 39 (no exclusion list)**. If an **immediate elimination of all tariffs is not feasible**, adequate **transition periods** should be defined.

Ensure that agreement to an FTA includes a commitment from **India** to become a **signatory to the WTO Pharmaceuticals Tariff Elimination Agreement** as a minimum requirement.

Eliminate all specific levies on products. (such as: Goods and services tax + Social Welfare Surcharge: 28%)

b. Preferential Rules of Origin

Modern, easy to handle Rules of Origin (RoO), including **origin conferring manufacturing processes** which are **easy for customs administration to verify** (see EFPIA position paper "Rules of Origin in Free Trade Agreements (FTAs) and Economic Partnership Agreements (EPAs)")

The EU to provide within the FTA for a **mechanism to adapt rules of origin later**.

Exemptions from the Principle of Territoriality to be included in order to account for modern supply chains. The permitted **added-value of outward-processing shall be harmonized** in all FTAs at a **level of 20% of the ex-works price** of the final product for which originating status is claimed

The **verification of the applied proof of origin** shall be conducted by the customs authority or the designated responsible authority of the **exporting Party only**. (**safeguarding confidential business information**)





Customs-related concerns – our asks related to...

c. Direct Shipment Rule

The EU to refer in the FTA to **relevant international standards**.

Avoid rules requiring direct shipments between FTA partners as a prerequisite to get preferential treatment. Storage and shipment of goods of preferential origin is to be **allowed from any country** in the world, as long as these activities do not change the preferential origin of the goods. The **origin of the goods** has to be accessible for checks (e.g. through a declaration of origin at the time the goods have been imported into the country from which they are shipped; the unique requirements should be the identity (e.g. Batch-#) and traceability of goods.).

d. Customs Procedures/Trade Facilitation

Make **customs procedures more efficient**. E.g. **facilitate documentation requirements** by using internationally recognized documentation sets. **Ease customs procedures** by the introduction of government approved authorized traders. **Increase transparency and efficiency** by the use of modern information technologies.

India needs to introduce a system for **stronger border enforcement and vigilance** within the country against **illegal imports of medicines**. There is a need for a **strong policy framework for enforcement and prosecution** to prevent these illegal products from reaching Indian patients, comprising coordinated efforts of the border enforcement authorities, police, CDSCO and judiciary to stop illegal and counterfeit trade in India.



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Falsified Medicines



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Novartis



India is one of the largest exporters of pharmaceuticals, and one of the world's leading producers of falsified medicines

- India remains the main source economy for counterfeit pharmaceuticals, accounting for 53% of the total seized value of medicines worldwide
- India is also the main source country for counterfeit pharmaceuticals shipped to the EU, making up to 47% of the total value of medicines seized by EU customs authorities.
- During the peak of the pandemic, authorities in India seized large quantities of falsified COVID 19 related medical products ranging from oxygen to Remdesivir (antiviral used to treat COVID 19)
- In Aug 2021, the WHO issued multiple product alerts related to falsified COVISHIELD vaccine which been reported at patient level in multiple counties including India.
- **India needs a strong policy framework to prevent counterfeits/parallel imports of patented drugs** comprising coordinated efforts of the border enforcement authorities, police, CDSCO and judiciary **to stop illegal and counterfeit trade.**

EFPIA asks to the EU Commission: Encourage Indian government to take steps to combat production and distribution of falsified medicines

- Encourage the Indian government to join the MEDICRIME Convention that aims to safeguard protect of cooperation at national and international levels, and/or to follow UNODC Guide on Combatting falsified medical product related crime
- Copyright/trademark law plays a pivotal role in combating falsified medicines, and the following measures would help enforce these laws with greater efficiency:
 - a. Enhanced coordination between the various agencies and providing direction and guidance on strengthening enforcement measures
 - b. Intelligence sharing and best practices at the national and international level
 - c. Undertake stringent measures to curb the manufacture and sale of falsified medicines
 - d. Enhance the penal provisions related to falsified medicines/counterfeiting for better deterrence
 - e. Crimes related to falsified medicines to be prioritized by enforcement and judicial authorities
 - f. Regulate the sale of pharmaceuticals on Online marketplaces, websites, and e-pharmacies

Backup: MEDICRIME Convention and UNODC Guide aim to improve national and international cooperation to combat counterfeiting of medicines

MEDICRIME Convention

- Adopted by the Committee of Ministers of the Council of Europe in Dec 2010, entered into force on 1 Jan 2016
- To date, 19 member and non-member states of the Council of Europe have signed, and five have ratified it.
- Introduction of standards on substantive and procedural criminal law

<https://www.coe.int/en/web/medicrime/the-medicrime-convention>

UNODC Guide

- UN launched 'Guide to Good Legislative Practices on Combating Falsified Medical Product-Related Crime' in 2019
- Advice on prevention, investigation, prosecution, etc.
- Be used as a practical tool for drafting, amending or reviewing relevant national legislation



https://www.unodc.org/documents/treaties/publications/19-00741_Guide_Falsified_Medical_Products_ebook.pdf

Ultimate Purpose

Protection of public health systems and individuals' health



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Non-Prescription Medicines



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GSK



6. NON-PRESCRIPTION MEDICINES

THE ISSUE

India's healthcare ecosystem is changing:

- **Increasing use of digital consultations and services** (e-consultations, e-pharmacies and e-diagnostics).

But still...

- **No legal recognition of 'non-prescription' medicine** (Over-The-Counter) in the Indian Regulatory Framework.
 - 1.No legal definition; and
 - 2.No clear regulatory approval process

THE ASK:

To seek the **adoption and implementation of a well-defined 'non-prescription' medicine regulation framework** that includes:

- a clear and distinct **regulation for import, manufacture, distribution, sale and labelling requirements** for non-prescription medicines, including the product definition;
- a **well-defined regulatory pathway**, for "prescription medicine to non-prescription switch" and for "new" non-prescription medicines.

BENEFIT

Having a dedicated framework for non-prescription medicines would bring: 1) **clear structure and standards on the approval, marketing and distribution** of these medicines for business; 2) **empower the consumer** on available and safe options for self-care; and 3) **assist pharmacists** to identify the correct medication.

How the system works today

* There is **no definition of non-prescription drug**. All drugs listed in Schedule H, H1, G, X of the Drugs and Cosmetics Act are considered prescription drugs because of labelling requirements attached to these drugs.



* **All drugs enter market as new drugs** first and remain as new drugs for a period of **4 years** from the date of first approval. After 4 years, a company can ask for permission to switch from prescription drug to OTC drug, if the drug does not contain any 'scheduled' ingredient.



* All drugs continue to be sold. However, unless a **formal switch** has been obtained by a company for a drug, the labels would need to continue to reflect Rx symbol to indicate them as 'prescription drug', requiring a prescription for purchasing these drugs



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Thank you

