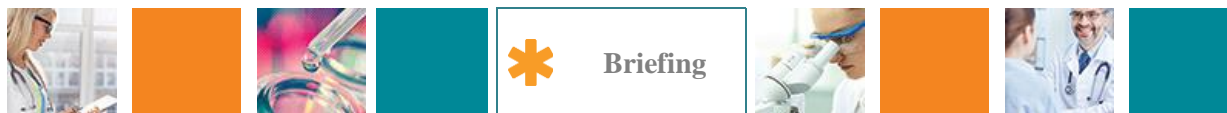




EFPIA-India FTA Negotiations – briefing document 25 November 2021



Introduction

In the context of the renewed FTA negotiations between the EU and India, EFPIA wishes to address its main concerns and seeks the EU support to take advantage of the FTA discussions to create a level playing field for our industry in India, which is currently missing. Our concerns relate to intellectual property rights, the regulatory process, market access and tariffs and customs.

1. Intellectual Property Rights (IPR)

To ensure that the EU remains a leading innovator and exporter of innovative medicines, one of the key achievements for the EU during the FTA negotiations with India should be to advance protection and promotion of scientific innovation in a way that supports the development of cutting-edge medicines and increases patient access to innovative treatments, underpinned by a robust intellectual property (IP) framework. This involves ensuring that India commits to a clear baseline of best practice for IP that reflects current EU standards, so that our innovation is fairly valued. Where markets are open and IP is protected and enforced, pharmaceutical innovators have the predictability and certainty they need to accelerate the launch and export of new, innovative medicines. Future negotiations with India must ensure that European pharmaceutical products are commercialized in India under strong IP standards.

1.1. Patent Protection

A first set of challenges relates to difficulties in securing patents in India. This ranges from the potential threat of patent revocation to the lack of presumption of patent validity, and the narrow patentability criteria under the India Patents Act (1970) which burdens companies across different sectors. Specific examples include:

Restrictive patentability criteria: in contrast to the baseline three-part patentability test (novelty, inventive step, and industrial application), Section 3(d) of India's Patents Act adds an unnecessary fourth substantive criterion of "enhanced efficacy". Application of Section 3(d) has resulted in the denial or revocation of patents for several innovative medicines, even though these same medicines have received patent protection in other countries. Application of these restrictive patentability criteria has upset the level playing field for European companies as Indian companies are likely to



secure patent protection in the EU for inventions that would not be eligible for patent protection in India. Furthermore, this narrow patentability prevents innovators from building on prior knowledge to develop valuable new and improved treatments that can enhance health outcomes. Such improvements also can lead to reduced costs by making it easier for patients to take medicines and improving patient adherence to prescribed therapies. Finally, the provision appears to clearly contravene TRIPS.

In the interim, while Section 3(d) is still in force, as a minimum the Intellectual Property Office (IPO) during the prosecution of patent applications should not apply the provisions of Section 3(d) in a generalized manner without giving any substantial reasons or explanations, even for applications relating to new molecules, which are not based on known substances. Moreover, examiners often raise Section 3(d) objections indiscriminately, without specifying the “known substance” over which there needs to be shown improved efficacy, leaving the onus on the applicant to link the properties related to the efficacy of a new form with enhanced therapeutic efficacy.

EFPIA asks:

- To ensure the Intellectual Property Office (IPO) does not use Section 3 (d) indiscriminately and routinely, i.e. Section 3 (d) should not indiscriminately figure in all First Examination Reports (FERs) during the prosecution, whether the application is for a novel compound or derivative with onus of proof being on the applicant to prove otherwise. This does not require a statutory amendment. Existing guidelines should be revised to allow for a higher standard of clarity while referring to the recommendations of the Parliamentary committee.
- Overall and at the same time, the EU should negotiate for India to abolish Section 3(d).

Pre-Grant Patent Opposition System: under Section 25 of the India Patents Act, a patent may be opposed by third parties before the date of grant (“pre-grant” opposition). Under Section 25 (1) of the India Patents Act, a patent application may be opposed by any person at any time between publication of the patent application and the granting date of the patent.

Recognising the uncertainty of this system, India’s judiciary has taken some steps to standardise pre-grant opposition practice – including extending appeal rights to patent applicants, and elimination of multiple pre-grant opposition petitions related to the same patent application. However, third parties, if they are a person “interested” (includes a person/entity engaged in, or in promoting research in the same field as that to which the invention relates) can even trigger post-grant opposition proceedings under Section 25(2) of the India Patents Act in the event a pre-grant opposition is unsuccessful and the patent is granted.

These procedures create significant uncertainty and delay the introduction of new inventions by undermining patent office efficiency and delaying patent prosecution – exacerbating India’s already significant patent examination backlog of approximately five years. For European life sciences companies, the lack of clear rules and evidentiary standards during the pre-grant opposition process has resulted in substantial delays in the ability to launch new medicines and enforce legitimate patent rights in India. Finally, we are not aware of any other country that has both a pre-and-post grant opposition and so Indian companies do not face these challenges when applying for patents outside of India, however, European companies face this significant challenge when attempting to obtain patents in India. Patent holders have been noticing that in the last few years, certain companies and individual lawyers have been routinely filing pre-grant oppositions in patent applications that cover



successful medicines. The matter is further compounded by the coordinated, sequential and cyclical manner in which the pre-grant opposition applications are filed, thus delaying the grant of the patent.

EFPIA ask:

- To ensure the timely granting of patents and to provide inventors the ability to enjoy and enforce legitimate patent rights, the EU should negotiate for India to eliminate its pre-grant patent opposition system. This requires an amendment of the Indian Statutes.

Excessive reporting requirements: section 8 of India's Patents Act requires patent applicants to keep the patent office "informed in writing of detailed particulars" of all foreign patent applications that claim the "same or substantially the same invention". However, this requirement does not take into account the materiality of the information to whether the patent should be granted, which makes it excessive and burdensome. Failure to disclose information is treated strictly and under Section 64(m) will lead to revocation of the patent even if the information is not material to patentability. India has undertaken some positive steps to reform Section 8 disclosure requirements and should now provide greater clarity on the applicability and scope of Section 8, limiting it to material information only.

In addition, the unique Form 27 'statement of working' requirements, although recently updated, remain unnecessarily onerous and provide yet another pathway by which patentees may lose their rights if not complied with.

These issues must also be seen in the context of a weak system of IP enforcement. This includes delay within the court system, non-specialist judges (especially after the recent abolition of the Intellectual Property Appellate Board), short notice hearings and lack of continuity of judges within a particular case (list of issues not exhaustive). Taken overall, the Indian IP system does not enable innovative European products sufficient access to the Indian market and favors Indian domestic producers.

Additionally, In November 2019, the Indian Patent Office (IPO) in its revised version of Manual of Patent Office Practice and Procedure (MPOPP), introduced amended guidelines for compliance of Section 8. These guidelines appear to have been provided in view of the directions based on various precedents by the Appellate Board and High Court's¹ interpretation of Section 8, namely when the requirement under Section 8 is met or unmet. The guidelines propose that the Examiner/Controller checks and ascertains whether the priority documents and similar documents pertaining to the application being processed in the IPO are available in the WIPO Digital Access Service (DAS). If such documents were available in the WIPO DAS, then further information about the priority may not be sought for, from the applicant, unless such information or document is not available in the WIPO DAS. Likewise, if the priority documents and similar documents being processed by the IPO are available with WIPO DAS, then such information may not be sought by the Examiner/Controller from the applicant. Nevertheless, it appears such practice is still far from implementation and being absolute because an exception to said guidelines allows the Controller to still ask for information under Section 8(2). Likewise, another exception still puts the burden on the applicant at the time of filing the application should provide the information to the IPO, where such relevant documents of the application, pertaining to Section 8 and priority can be found on WIPO Centralized Access to Search and Examination (CASE) and DAS.

It appears that Examiners/Controllers are taking advantage of this exception to still ask for the information from the applicants. The burden is still on the applicant to meet the requirements of



Section 8. The said practice needs to be made absolute and strictly implemented to prevent undue burden on the applicant.

1.2 Patent Enforcement

Generic drugs can be approved in India 4 years after the originator was first approved, as the originator is no longer considered to be “new”. After 4 years, Central Drugs Standard Control Organisation (CDSCO) approval is no longer required and state regulators can issue a manufacturing and marketing license without having to check whether the follow-on product infringes upon a valid patent protecting the originator. Moreover, there is currently no transparency on marketing authorization applications from generic manufacturers and no notification system, which makes it very difficult to successfully enforce patents in India, causing irreparable damage to European innovators. Another obstacle to effective patent enforcement lies with the difficulty in obtaining injunctive relief while patent infringement proceedings can last for years during which the generic copy can be marketed.

EFPIA asks:

- Change in the definition of “new drug” to ensure that a drug is considered new for a period of 10 years after its marketing authorization, as opposed to the current 4 years.
- **Introduction of a database/mechanism allowing patent holders and Indian authorities to have timely notice of any generic/biosimilar marketing approval application or marketing approval.**

1.3. Regulatory Data Protection

Contrary to India’s obligations under Article 39.3 of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), India does not formally provide robust protection against the unfair commercial use of undisclosed test or other data submitted to obtain marketing approval for medicines. This means that regulatory authorities in India allow generic manufacturers to rely on test data submitted by originators to seek approval in India and/or another country when granting marketing approval to generics and biosimilars. This reliance results in unfair commercial use, prohibited by the TRIPS Agreement, and discourages the development and introduction into India of new medicines for unmet medical needs.

From a practical perspective, this lack of protection provides no incentive to conduct clinical trials or launch medicines in India because generic pharmaceutical companies receive a significant competitive advantage over innovative biopharmaceutical companies – stunting innovation and delaying introduction of medicines for Indian patients. Moreover, in light of the restrictive patenting criteria and above-mentioned challenges with patent prosecution and enforcement, RDP becomes an even more important protection as it may well be the form of protection available for certain innovative products.

EFPIA ask:

- The EU to negotiate for India to introduce clear and effective RDP provisions, aligned with the EU system. This will ensure that there is no unfair commercial use of the data submitted by an applicant in securing marketing approval in India or in a third country.

EFPIA wants to reinforce the gravity of concerns linked to the IP environment in India and strongly encourages the EU to engage with life sciences stakeholders to ensure that they are adequately



captured in the EU strategic approach to trade negotiations with India. Failing to do so will set an unhelpful precedent for the future of the EU free trade agreement negotiations with countries that have equally or more severe IP challenges.

2. Regulatory issues

2.1. Clinical Trials

As part of the marketing authorisation process, there is a formal requirement to conduct phase III studies in India. Local studies should not be required for products that have adequate clinical data-based approvals from regulators in major markets, unless there is significant concern of ethnic difference based on International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E5 (E5-Ethnic Factors in the acceptability of foreign clinical data). Legislation requires adequate numbers of Indian patients to be included in clinical trials. This is generally understood to be a minimum of 100 to 200 Indian patients for non-specialty products, but a recent trend – as evident from the minutes of the Subject Expert Committee (SEC) and Technical Review Committee meetings – suggests that this can vary. This means that lower patient numbers may be accepted, or higher patient numbers imposed.

A Drug Technical Advisory Board (DTAB) recommendation (3 July 2014) states that products that have adequate data-based approvals from regulators in major markets, such as the US Food and Drug Administration or European Medicines Agency (EMA), need not be evaluated in local phase III trials. The same recommendation has been reflected in Apex (committee within CDSCO, Central Drugs Standard Control Organization meeting minutes. The decision of the Apex Committee meeting held in the first week of July 2016, which states “the drugs (including Cosmetics and Medical Devices) approved by ICH regulators, with no adverse events, did not require Phase III”, may be implemented. Any formal implementation, however, requires an official notice signed by the DCGI.

As per New Drug and Clinical Trial (NDCT) Rule 2019, a waiver from the requirement to conduct local clinical trials in India is acceptable, in cases of “national emergency, extreme urgency, epidemic, orphan drug for rare disease and conditions/diseases for which there is no therapy”.

Industry experience over the last two years since the issuance of NCDT Rules, 2019 in March 2019, has indicated that the provisions for grant of local Phase III clinical trial waiver is being inconsistently applied in most cases and not being applied at all for grant of marketing authorization of vaccines in India. The provisions in respect of local Phase III clinical trial waiver can be availed only when the drugs are approved in countries specified in the list of countries notified under Rule 101 and are not likely to be ethnically sensitive, however in over two years since issuance of the NDCT Rules, Rule 101 with list of countries has not yet been notified by the Ministry of Health.

EFPIA believes that enabling provisions under NDCT 2019 go a long way in making the drug registration pathway predictable and are a huge step forward towards facilitating ease of doing business in India. On the other hand, in the absence of the list of countries that is to be specified under Rule 101 of the NDCT Rules 2019, implementation of the above provisions continues to remain inconsistent and open to subjective interpretation. Although in some cases, a local Phase III clinical trial waiver is granted for rare and life threatening serious diseases, a local Phase IV clinical trial is directed as a post approval condition.



In addition, conducting a separate clinical development program in India puts unnecessary burden on the patients and delays regulatory submission and approval thus delaying and preventing patient access to life saving medicines.

EFPIA asks:

- Products that have adequate data-based approvals from regulators in major markets, 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).
- In case of rare diseases/orphan drugs or unmet medical need, while a Phase III waiver may be granted, invariably a Phase IV study commitment is being imposed despite existing regulations permitting a Phase IV waiver.
- Some sponsors have also experienced Indian Health Authority requesting additional local phase 3 or phase 4 trials to be conducted despite the sponsor submitting Indian sub-set data from global phase 3 trials and meeting ICH E5 requirements. In this case as the ICH E5 requirements are met, we believe the request for additional local phase 3 or phase 4 trials are unnecessary burden on the patients and hinders patient access to medicinal products.

2.2. Accelerated regulatory pathways

Patients are demanding faster access to new medicines and industry is encouraging regulators to offer incentives to develop medicines for small patient segments.

Although the NDCT Rule 2019 mentions about accelerated review pathway for Orphan indications or Rare Diseases, no process has been defined clarifying how the review follows an accelerated or expedited pathway. It seems both products (orphan and non-orphan) go through the three-step review process.

2.2.1 Expedited review

Whereas it is acknowledged that the Indian NDA approval process is fast compared with other countries in the region, 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 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:

- Adopt abridged review for products approved in reference or major markets countries highlighted in this document. Furthermore, the average time to issue the import license, after the grant of the CT-20 (Step 1 New Drug Approval), is 9-10 months. We recommend CDSCO to consolidate the approval process such that Step 1 (CT 20 – NDA Approval), 2 (Form 41 – Registration Certificate) and 3 (Form 10 – Import License) could run in parallel

2.2.2. Orphan drug (OD)

Increasingly flexible pathways can accelerate patient access to crucial therapies. Commonly-applied criteria are required for expedited review of a serious or life-threatening condition or a product with the potential to address unmet medical needs.

Rare diseases are recognised as an important public health issue and a challenge for medical care. The increasing number of identified rare diseases reveals a need for the development of incentives for pharmaceutical companies to invest in medicines for rare diseases.



The main incentives to include: marketing exclusivity; the setting up of tax credits and financial subsidies for research; and regulatory support for development and marketing approval (e.g. fast-track approval, fee waivers, protocol assistance and market exclusivity).

EFPIA ask:

- We welcome the classification and introduction of orphan drugs in the New Drugs and Clinical Trial Rules. Although the NDCT Rule 2019 provides a provision to grant Orphan Designation (OD), there is no defined process clarifying how to go about applying for OD. Also, the rule mentions about accelerated review pathway for Orphan indications or Rare Diseases, no process has been defined clarifying how the review follows an accelerated or expedited pathway. It seems both products (orphan and non-orphan) go through the three-step review process. We would also like to highlight that there is still a requirement or expectation for sponsors to complete a Phase IV studies incase of rare diseases/orphan drugs, this requirement should be waived.

3. Market Access

3.1. Local content requirements and government procurement

EFPIA members are concerned about the recent adoption of measures that upset the level playing field between foreign and local companies by de facto restricting access to public procurement for foreign companies under the broader “Self-reliant India” (Atmanirbhar Bharat) policy. Such policies can negatively impact exports of pharmaceuticals to India in the future.

Starting from 2020, several restrictive measures have been enacted. First, in September 2020, the Department for the Promotion of Industry and International Trade (DPIIT) under the Ministry of Commerce and Industry, amended the Public Procurement Order (PPO) mandating a minimum 20% local content as a pre-condition to participate in any government tender, with the exception of international tenders. It also introduced provisions on reciprocity, effectively excluding bidders from countries that do not allow Indian companies to participate in government tenders. Subsequently, in December 2020, the Department of Pharmaceuticals (DoP) issued additional guidance that made restrictions even stronger by raising the bar for local content as follows:

- Class I local supplier – Minimum 80% local content
- Class II local supplier – local content between 50-80% required
- Non-local supplier – 50% or less local content.

According to the DoP guidance, for goods for which there is enough local capacity and sufficient competition, only Class I local suppliers can bid. For goods other than those for which there is enough local capacity and competition and where the value of goods to be purchased is less than INR 200 crores (ca. EUR 23 million), Class I and II local suppliers can bid. Non-local suppliers are only entitled to participate in global tenders. Global tender enquiries can only be issued for goods other than those for which enough local capacity and competition has been notified and with a value over INR 200 crores.

An additional challenge is the lack of clarity on the definition of local content and the type of activities that qualify for the calculation. This results in legal uncertainty for EFPIA members considering that a self-certification or a certification by a statutory auditor (if the value of the tender exceeds INR 10 crores) is required in order to ascertain their local supplier status. The lack of clarity on the local content definition therefore exposes companies to the risk of making false self-certifications.

Last but not least, in 2021, there have been discussions about potentially making the application of the 5-year exemption from price controls for patented medicines (permanent for orphan drugs) under



the DPCO¹ 2013 paragraph 32 (i) conditional on local manufacturing. This would introduce another discriminatory pricing measure, in addition to the restrictive government procurement measures. It would also mark a step back on the 2019 amendment of paragraph 32 of the DPCO which removed the condition of local development and manufacturing to qualify for the 5-year price exemptions for patented medicines.

EFPIA ask:

- The EU should leverage the FTA discussions to promote a level playing field between local Indian and foreign companies in terms of access to government procurement, as well as avoid discriminatory pricing policies which fail to adequately reflect the value of innovation.

3.2. Sustainable pricing and Trade Margins Rationalization Policy

While medicines included in the NLEM (National List of Essential Medicines), also called “scheduled drugs” are subject to price controls, non-scheduled drugs are excluded from such controls and only subject to monitoring with a possibility of a 10% annual increase of the maximum retail price (MRP). To support affordable patient access to medicines, the Trade Margins Rationalization Policy was introduced in 2019 for 42 oncology drugs (with a potential expansion to all non-scheduled medicines in the future), setting a 30% cap for the trade margins (i.e. difference between the price to the stockist/distributor and the retail price).

While the biopharmaceutical industry supports the overall objective of the policy, several EFPIA members have experienced challenges with the interpretation of the NPPA (National Pharmaceutical Pricing Authority) in the application of the policy. In particular, the NPPA is not using the actual price to distributor that is verifiable from government databases and tax invoices, but rather a derived figure using a formula – net sales realization divided by the total quantity for the relevant product during the month of June 2018. EFPIA sees several flaws in this approach. First, for the calculation of the price to stockist, the NPPA includes quantities that are not sold via retail trade channels, including: a) free drugs provided through Patient Assistance Programmes, which are a vital tool for EFPIA members to provide access to medicines for patients who are not covered by any government program and would otherwise not afford to pay out of pocket, and b) quantities sold to the government through tenders and price-volume agreements at significantly lower prices than the retail price. This leads to an artificially low price to stockist with a difference of up to 70% between the MRP calculated under this formula and the actual MRP of the company. On this basis the NPPA, claims that companies overcharge, which bears the risk of hefty paybacks, which in some cases may even threaten the financial viability of EFPIA member companies’ operations in India. Another issue relates to the arbitrary selection of the June 2018 timeframe for the calculation of the price to stockist, which results in differentiated treatment between companies, depending on whether and the actual quantities they provided through Patient Assistance Programs and government tenders.

More recently, in July 2021, a new Trade Margins Rationalization Notice covering 5 medical devices showed some positive evolutions, with the reference period changed from a specific month to the total quantity over an entire year, while also excluding quantities not connected to sales (e.g. provided as part of CSR activities, free samples for regulatory approval purposes, HCP education etc.). While this is a positive signal, a more sustainable solution is required to ensure that the TMR policy is applied according to its initial spirit, avoiding any disguised price controls which go beyond the provisions of

¹ Drug Price Controls Order, 2013



the DPCO or the NPPP². This will help provide more predictability and legal certainty, while also ensuring adequate recognition for the value of innovation delivered by the European research-based pharmaceutical industry. Based on latest intelligence, an extension of the TMR system to the entire non-scheduled market (medicines and medical devices alike) together with a revised formula is being considered. While no draft has been published yet, the NPPA is exploring a phased expansion of the policy based on therapeutic categories and/or product price ranges. The policy is likely to be incorporated into the DPCO.

EFPIA asks:

- Any EU-India FTA should include provisions requiring the parties to provide for transparent and predictable pricing policies, that adequately reward the value of innovation.
- India should refrain from imposing price controls that are not foreseen in its pricing policies (DPCO 2013 and the NPPP 2012) and rather apply the TMR policy in a fair and proportional manner in light of its main objective and avoiding unintended negative effects (i.e. limiting the ability of companies to provide patient access through Patient Assistance Programmes). In particular, the TMR policy should only apply to commercial sales, excluding any quantities provided through Patient Assistance Programmes, government procurement and samples from any calculations.

4. Customs-related concerns

4.1. Tariffs and Quotas

Tariffs, other levies and quotas increase the cost of medicines, reduce patient access to medicines made in the EU and therefore drive the health costs in India to higher level. Therefore, the elimination of such costs for finished pharmaceuticals, active pharmaceutical ingredients (APIs), intermediates and starting material and research products that are used in the early stages of the R&D chain (phases I and II of the drug development process, and exceptions that currently apply to phase III) leads to a win-win-situation for both trade partners.

This will enable pharmaceutical companies to avoid unnecessary costs when moving goods across borders and to develop medicines in the most efficient way, delivering the best possible value to health systems.

Furthermore, pharmaceuticals are one of the few categories of goods with their own liberalisation agreement at the World Trade Organization (WTO) level. The 1995 WTO Pharmaceuticals Tariff Elimination Agreement eliminated tariffs on all finished medicines and some APIs for signatory countries. India is considered one of the most contentious non-signatories (along with China) to the Agreement. WTO members often cite India as an example of a “free-rider” to this Agreement (benefitting from the Agreement without sharing the burden) and many WTO members have expressed their unwillingness to progress an update to the Agreement until India (and others) sign up.

EFPIA asks:

- Eliminate all customs tariffs and quotas for products classified in the HS chapters 28 to 39. 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.

² National Pharmaceutical Pricing Policy, 2012



- Eliminate all specific levies on products.

4.2. Preferential Rules of Origin

With the increasing number of regional and bilateral FTAs, the variety and complexity of the rules of origin have also grown, sometimes with rules as detailed as per customs tariff line. Handling these differences of rules in a worldwide supply chain setup has become a tremendous administrative burden to internationally operating companies, and for small and medium-sized enterprises (SMEs) it is essential that rules are easy to implement so that the administrative cost of exporting does not outweigh the benefit of qualifying for preferential tariffs.

Rules of origin are a key element in determining the magnitude of the economic benefits that accrue from preferential trade agreements.

The rules should include the concept of choosing the alternative, change of tariff heading and/or added value rule. In HS chapters 28 and 29 the change of the CAS number could be an additional concept. In HS chapter 30 unequal rules of origin have to be avoided (e.g. 3002 and 3004).

EFPIA asks:

- Rules of Origin (RoO) should be simplified and based on common, defined chemical and pharmaceutical processing activities that make commercial sense and are easy for customs administrations to verify.
- 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 every FTA 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

Note: EFPIA published a position paper which proposes modern, easy to handle rules of origin which shall be the standard rules for new Free Trade Agreements as well as for Free Trade Agreements which need to be modernized. (see attached, EFPIA position paper "Rules of Origin in Free Trade Agreements (FTAs) and Economic Partnership Agreements (EPAs)").

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. The presence of a representative of the importing Party as an observer during the verification process has to be avoided due to the handling of sensitive data (name of suppliers, prices, calculations, proprietary production processes etc.). Negotiations should be lead in a manner which enables the partners to build up confidence and trust in the verification activities of each other.

India introduced new preferential trade rules last year which place greater onus on the importer to prove the authenticity of the Certificate of Origin (CoO). In summary, the importer is now fully responsible for the accuracy of information on the CoO, compliance with the RoO, and access to the manufacturer's cost and import data. More specifically, in addition to producing the CoO, the importer needs to make a declaration on details relating to the CoO (including details that are not in the CoO itself, such as whether the goods are transported directly from the country of origin) at the time of filing an import declaration. The importer is also expected to possess and furnish information to demonstrate that the rules are satisfied (including the manufacturing process, documentary proof of origin where the exporter is not the manufacturer etc.), if requested by authorities during customs clearance. This is challenging as the exporters/manufacturers may be concerned with exposing business sensitive information.



Additionally, from an export perspective, the issuing authorities in some Indian states do not issue CoO when there is more than one middleman in the trade route because the transaction between the two middlemen is outside of their jurisdiction and the rules did not provide for four-party invoicing. We would suggest a principal trading partner arrangement to be accepted with multiple intermediaries.

4.3. Direct Shipment Rule

The challenge when maximizing distribution routes and optimizing the supply chain are the markets with low import volumes. The additional task of artwork preparation for cartons and leaflets, which indicate use, in a specific language, is often performed in warehouse facilities outside of an FTA territory before importing to the targeted countries of destination. None of these tasks alter the medicinal product and therefore its origin

Rules requiring direct shipments between FTA partners increase the administrative burden and sometimes, the prove of "non-manipulation" from the third-party customs authorities of the territory where such a warehouse is located, the so-called "non-manipulation" certificate, is not possible. As a consequence, the advantages of an FTA cannot be used.

EFPIA asks:

- 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.).

4.4. Customs Procedures/Trade Facilitation

According to the WTO Trade Facilitation Agreement 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.

As India lacks an ecosystem to prevent the illegal import of drugs to India, there are cases of illegal imports of patented drugs which are coming across from the neighboring countries (particularly Bangladesh) being sold on the Indian market. The power to stop patent infringing products from entering India and reaching Indian patients is an important tool for customs to have to protect public health. India should be encouraged to reinstate that power.

EFPIA asks:

- 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.



5. Falsified Medicines

The World Health Organization (WHO) estimates that 1 out of 10 medicines sold worldwide are falsified or substandard, a number which significantly increases in low- and middle-income countries. Globally, the Pharmaceutical Security Institute (PSI) reported a 38% increase of incidents of falsified medicines from 2016 to 2020- a trend exacerbated by the Covid-19 pandemic.

India is one of the largest exporters of pharmaceuticals, however, India is also known as one of the world's leading producers of falsified medicines. According to research by the OECD and the EU Intellectual Property Office (EU IPO), India remains the main source economy for counterfeit pharmaceuticals, accounting for 53% of the total seized value of medicines worldwide. The latter is followed by China (30%), Hong Kong (China) (4%) and the United Arab Emirates (4%). In addition, 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. Similarly to the worldwide trend, it is followed by China (37%) and Hong Kong (China) (8%). The PSI also cited India as one of the top three source countries for falsified medicines since 2018.

Since the outbreak of the COVID-19 pandemic, Interpol reported an increase in the seizure of illicit medicines (4.4M doses seized during operation Pangea) including key COVID-19 medical products (Interpol, 2020). A trend they foresee continuing. Similarly, in India during the peak of the pandemic authorities 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.

The societal impact of falsified medicines is multiple. For patients they lead to therapeutic failure, serious harm or death, since they are often not properly formulated and may contain no or dangerous active pharmaceutical ingredients. For the public health and private sectors, falsified medicines undermine patients and society's trust in genuine and effective medicines. It also results in significant financial (i.e. counterfeit market estimated to be valued at 4.4 Bn by the OECD) and reputational damage. Often leading to the loss of confidence in healthcare professionals, health programmes and the overall health systems.

EFPIA ask:

- Encourage the Indian government to join the MEDICRIME Convention^[1] that aims to safeguard protect public health through penal measures against criminal behaviors, protection of victims, promotion of cooperation at national and international levels
- The existing copyright/trademark laws play a pivotal role in combating falsified medicines, and the following measures would help enforce these laws with greater efficiency:
 - o Enhanced coordination between the various agencies and providing direction and guidance on strengthening enforcement measures;
 - o Intelligence sharing and best practices at the national and international level;
 - o Undertake stringent measures to curb the manufacture and sale of falsified medicines;
 - o Enhance the penal provisions related to falsified medicines/counterfeiting for better deterrence;
 - o Crimes related to falsified medicines to be prioritized by enforcement and judicial authorities;
 - o Regulate the sale of pharmaceuticals on Online marketplaces, websites, and e-pharmacies.



Thus, there is an impending requirement for 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 in India which works closely with MEDICRIME convention.

6. Non-prescription medicines

India's healthcare ecosystem is changing from in-person consultations to digital consultations and services, including e-consultations, e-pharmacies and e-diagnostics. However, there is no legal recognition of 'non-prescription' medicine (also called, Over-The-Counter) in the Indian Regulatory Framework. Medicine regulations describe 'prescription medicine' (Schedules H, H1, X of Drugs and Cosmetics Rules), and any medicine which is not a prescription one is then considered as non-prescription. By providing a legal definition of non-prescription medicine and clearly defining the processes of non-prescription drugs approval, it would bring clear structure and standards on the approval, marketing and distribution of these medicines for business, empower the consumer on available and safe options for self-care and assist the pharmacist to identify the correct medication.

EFPIA ask:

- The EU to ask for adoption and implementation of a well-defined 'non-prescription' medicine regulation framework that includes:
 - o a clear and distinct regulations for import, manufacture, distribution, sale and labelling requirements for non-prescription medicines, including the product definition;
 - o a well-defined regulatory pathway, for "prescription medicine to non-prescription switch" and for "new" non-prescription medicines.



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