

To: Art.4.1.b (TAXUD); Art.4.1.b (TRADE); Art.4.1.b
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Subject: EFPIA meeting on EU-India FTA talks - 02 February 2022
Attachments: EU-India FTA Negotiations - meeting 2feb22-participants list EFPIA.docx; EU-
 India FTA talks-EFPIA briefing paper-25nov21-FINAL.docx; EFPIA Position on
 Customs and Rules of Origin-December 2019-Final.pdf; EU-India FTA-meeting
 2feb22-Final-1feb22.pdf

On 2 February 2022, the Commission met virtually with a delegation of the European Federation of Pharmaceutical Industries and Associations (EFPIA) led by Art.4.1.b, and with participants from the following companies: Roche, Jazz Pharmaceuticals, BMS, Boehringer Ingelheim, Novartis, GSK, Pfizer, Scienceindustries, Servier and GSK (see detail in annex).

Commission participants were: Art.4.1.b (DG TRADE C2), Art.4.1.b (DG TAXUD), Art.4.1.b (DG TRADE E3), Art.4.1.b (DG TRADE E3), Art.4.1.b (DG GROW), Art.4.1.b (DG TRADE E3), Art.4.1.b (DG TRADE E4), Art.4.1.b (DG TRADE B3), Art.4.1.b (DG TRADE B3), Art.4.1.b (DG TAXUD), Art.4.1.b (DG TRADE E3) and Art.4.1.b (DG TRADE C2). The EU Delegation in India was represented by Art.4.1.b, Art.4.1.b and Art.4.1.b.

Based upon its Briefing Document of 25 November 2021, EFPIA addressed their main concerns in view of the resumption of the FTA negotiations between the EU and India. Their concerns related to: (1) the regulatory process, (2) market access, (3) intellectual property rights, (4) tariff and customs, (5) falsified medicines and (6) non-prescription medicines.

(1) Concerning the regulatory process, EFPIA raised the issue of the waiver of local Clinical Trials (CT) requirement. Although included in the New Drugs and CT rules 2019, Phase III/ local CT waiver is not fully implemented consistently, due to the non-publication of Rule 101. EFPIA asked the EU to request that products that have been approved by countries such as the 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. Against this background, EFPIA asked the EU to suggest a joint forum between the Indian regulator and the industry to review the implementation of any rules. EFPIA would also like India to adopt accelerated regulatory pathways, notably for products approved in reference or major countries such as the US, EU, UK, Japan, Canada and Australia. EFPIA suggested that India consolidates the process to obtain the import license after the new drug approval (NDA).

(2) On market access, EFPIA observed that European industry faces increased barriers in access to public tenders due to discriminatory local content requirements, notably due to the 'Self-Reliant India' policy.

Case by case exemptions are possible but require a cumbersome procedure (detailed argumentation, involvement of multiple authorities) which does not allow for blanket exemption. Also, since “local content” is not defined in Public Procurement Order (PPO) guidelines, there is a risk of unintentional incorrect certifications submitted by companies and consequential exposure to corresponding penalties. Against this background, EFPIA asked that blanket exemptions should be given for products with no local alternative available. EFPIA will come back to the EU on the actual cost of local content requirement measures on the European pharmaceutical industry. EFPIA also added that Trade Margins Rationalization (TMR) in India has become a disguised price control mechanism leading to challenges of sustainability and predictability of the pricing system. TMR system should be more transparent, predictable and limited to supplies through trade channels while preserving the ability to support affordability and access.

(3) On intellectual property rights, EFPIA called for the non-discriminative use of the Restrictive Patentability Criterion (Section 3d) and the elimination or a limitation period for filing pre-grant oppositions. EFPIA also suggested the EU asked India for the introduction of Specialized IP Courts and a Public Notification system by Indian authorities on marketing & manufacturing approvals of generic/biosimilar drugs, as well as increasing the New Drugs definition from 4 to 10 years from the time of authorization. Finally, EFPIA asked for the introduction of regulatory data protection (RDP) provisions in the FTA.

(4) On customs, EFPIA said the FTA is a good opportunity for India to eliminate (immediately or gradually) all customs tariffs and quotas for products classified in the HS chapters 28 to 39 and ensure that India becomes a signatory to the WTO Pharmaceuticals Tariff Elimination Agreement as a minimum requirement. EFPIA added that the FTA should provide for Rules of Origin (RoO), including origin conferring manufacturing processes that are easy for customs administration to verify. Concerning product specific rules (PSR), EFPIA seemed satisfied with the PSR included in UK and revised PEM (processing rules) and would like the same in India. Exemptions from the Principle of Territoriality are 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. EFPIA illustrated this request with the example of the secondary packaging and drafting of leaflets that are more and more carried out in third countries. This is not done in particular by EU exporters or Indian exporters. They explained that in the RCEP, packaging can be carried out in any party of the RCEP (medicines produced in VN can be packed in CH and exported to JP with preference). The Commission explained that secondary packaging cannot be solved with outward processing but non-alteration clause. On the verification procedure, EFPIA insisted that the importer should not be required to demonstrate himself the origin of the goods because it would oblige the exporter to provide confidential information to the importer. EFPIA also insisted that the verification should only be performed by the competent authorities in the exporting Party and not by the competent authorities of the importing Party. The Commission explained that in the Agreements with JP and UK, the importer is not required to provide more than the statement on origin if the claim for preference is made on the basis of a statement on origin and the verification is done, through administrative cooperation, by the competent authorities in the exporting Party. The Commission does not intend to deviate from these principles for the negotiations with India. EFPIA expressed interest in discussions with Commission customs experts and will follow-up on this.

(5) EFPIA observed that India needs a strong policy framework to prevent counterfeits and parallel imports of patented drugs, underpinned by coordinated efforts of the border enforcement authorities, police and the Central Drugs Standard Control Organisation (CDSCO), notably in the context of Covid-19.

EFPIA asked the Commission to encourage the Indian government to take steps to combat the production and distribution of falsified medicines.

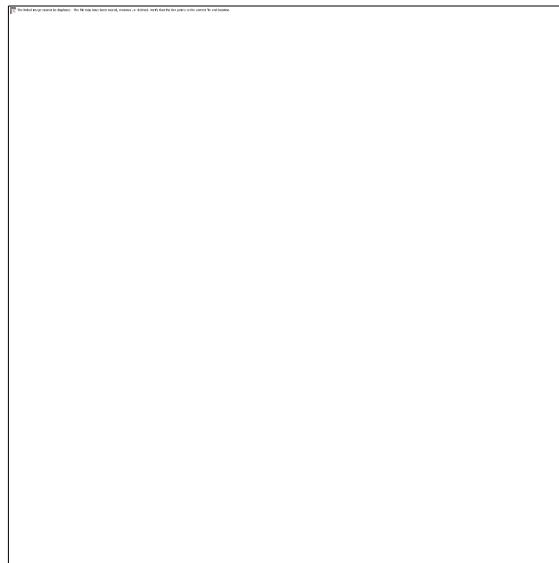
(6) Since there is still no legal recognition of 'non-prescription' medicine in the Indian Regulatory Framework, EFPIA would like India to adopt a well-defined 'non-prescription' medicine regulation framework.

EFPIA took note with interest of the possibility to establish an EU Chamber of Commerce in India.

Enclosures:

- List of EFPIA participants
- EFPIA presentation
- EFPIA position paper on FTA negotiations
- EFPIA position paper on rules of origin

Art.4.1.b



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