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What does European business expect from the EU-India Trade and Investment Protection Agreements

The announcements made during the EU-India Summit of 8 May to resume negotiations for a trade agreement, launch negotiations on a stand-alone investment protection agreement and start negotiations on a separate agreement on geographical indications were very well received by European business.

BusinessEurope supports in particular the aim to have a "balanced, ambitious, comprehensive and mutually beneficial" trade agreement which would respond to the current challenges. We hope that a high level of ambition will be maintained during the whole negotiation process and the final agreement will be comprehensive.

To achieve this, it will be necessary to find solutions to long-standing market access issues. While this is an exercise which proved to be difficult during previous negotiations, we consider that the economic and geostrategic importance of India as well as the huge potential of its market are worth the effort.

The EU and India share important principles and values of democracy, freedom, rule of law and respect for human rights as well as common interests in ensuring security, sustainable development and commitment to rules-based multilateralism in a multi-polar world.

With over 1.3 billion inhabitants, almost 18% of the world population in 2019, India is the second most populous country after China, the 5th biggest global economy (in nominal GDP in 2019) and one of the fastest growing emerging markets. Nevertheless, India is the EU's 10th largest trading partner, accounting for only 1.8 % of EU total trade in goods in 2020, while the EU is India's third largest trading partner and the first foreign investor in India. This shows that the Indian market has a huge untapped potential.

Besides the potentially huge consumer market for European goods, India presents a number of challenges that can also be future opportunities for European companies. The 700 million people living in urban areas pose important challenges that involve the improvement of certain areas such as strategic and transport infrastructures, urban planning development, smart cities (sustainable cities), water and waste treatment, telecommunications and a transition towards a renewable energy system. The trade agreement could be a catalyst to enable and stir cooperation and partnerships in all these areas that are key for the green and digital transitions.

Moreover, India could play an important role in the EU's supply chain diversification strategy post-COVID-19. With European companies looking to diversify their supply chains and reduce their dependencies away from dominant sources, India is well positioned to be an important player in this strategy.

All of the above shows the importance to maintain the momentum generated by the EU-India Summit for bilateral trade relations. Below we present the priorities of European business for an EU-India trade agreement and investment protection agreement.

1. Tariffs, quotas additional duties and levies / lack of transparency in additional taxation

Regarding **tariffs and quotas**, the central offensive interest for European business is the **comprehensive elimination of tariffs and quotas on a reciprocal basis, while sensitive products should be excluded.**

Indian import duties are very high as compared to other countries and it also imposes many quantitative import restrictions. While India has an average duty of 15%[1], there are enormous differences between sectors and products with tariffs sub-heading duties ranging from 0.5% to prohibiting duties of 150%. It is also concerning that there have been some tariff increases in recent years. In many cases, these increases are not previously notified to the WTO and can be approved or modified through internal circulars of the Ministry of Finance. The following are some examples (it is not an exhaustive list) of high duties we would like to see removed:

Agri-food products:
- Almost all tariffs for food products range between 30% and 40%, with very significant peaks reaching up to 150% in the case of alcoholic beverages, which prevents the European sector from doing business in India. In the case of raisins, coffee, tea, wheat, rice, garlic, peanut oil, food preparations and concentrates, wine, alcohols and cigars, tariffs are equal to or greater than 100%.
- Since 2018 there has been a tax increase in extra virgin olive oil from 12.5% to 38.5%, in refined olive oil from 20% to 44% and in pomace oil which has increased from 20% to 49.5%.

IT products:
- Despite being bound by ITA I, India has increased in recent years tariffs on mobile phones, cameras and several other electronic products and components from 0% to between 7.5% and 20%. Furthermore, India did not join the ITA II Expansion Agreement. India should join ITA II as a priority of the agreement, while compliance with ITA commitments should be settled before entering into any free trade agreement.

Polished diamonds:
- Since January 2012, India has imposed a 2% import duty on polished diamond imports. India has been increasing this duty over the years to 2.5% in 2014, to 5% in February 2018 and 7.5% in September 2018. These increases were allegedly imposed by the Indian Government to prevent "round tripping", the virtual import and export of diamonds by Indian companies in order to boost their business figures and get more financing from the banks, in the form of export credits. Nevertheless, the import tarriff applies to all imports and therefore also to the bona fide traders.

Vehicles:
- Vehicles and vehicles parts (HS 87) are charged with duties between 10% and 100% when imported into India. This, combined with country-specific measures prevents European manufacturers to compete with local manufacturers on a level-playing field.
- Tariffs for passenger vehicles are extremely high: 100% for vehicles with a CIF value of more than 40.000 USD or an engine displacement > 3.000 ccm (petrol) or 2.500 ccm (diesel); 60%

[1] According to WTO's website: http://tao.wto.org/report/TariffAverages.aspx

for all other imports of finished vehicles; 30% for CKD with pre-assembled transmission, gearbox or engine; 15% for other CKD. With other national duties on top, the maximum burden for imports can be 125%. This duty structure discriminates against imports of finished vehicles and enforces local content.
- The ultimate objective should be to eliminate completely tariffs on vehicles and vehicles components.
- Although recently a specific HS code for electric vehicles was created (8703 80), India has not lowered the duty for electric vehicles so far. Lower import tariffs for electric vehicles would however help to reach the climate targets. To be effective, such a move would also require the building-up of the necessary charging infrastructure.

Toys:
- India has imposed very high import duties on toy products. HS code 95 attracts duties between 10% and 60%, with HS code 9503 attracting a duty of 60%. This is the highest duty on toy products in the world and clearly represents a trade barrier impeding European toy manufacturers from exporting to India.

Other examples of high tariffs include: duties on medical devices and diagnostic products (varying between 5 % to 28 %, leading to higher prices for life saving tests and treatments); cosmetics (between 10-20%); canned fish-tuna (products with HS code 16041410 tuna and HS code 16041310 sardines are subject to 2 taxes which cumulatively amount to 45,6% making it very difficult to export this product to India); chemicals with a high average tariff close to 40%; and ceramics with an average of 10% duty in contrast to the 1.5% duty the EU applies as part of the GSP.

In addition to import duties, India applies **indirect and additional taxes** to some imported products, which are not charged to local producers. **It is of utmost importance that negotiations focus on the sum of the different import duties and taxes charged on imports (but not on local products), and not only on the Basic Customs Duties. Parties[2] should commit to grant tariff liberalization in good faith and to ensure that the reduction will not be compensated by an increase of other taxes and levies on imported products in a different form, including at state level. If this is the case, the other party reserves the right to revisit its schedule of commitments and to reduce benefits granted proportionally.** Here are some examples:

Social Welfare Surcharge:
- In addition to the corresponding tariffs for each product, a new tax has been introduced by the Indian Government in the General Budget for the fiscal year 2018-19, known as Social Welfare Surcharge, which replaces the "education fee" in customs and has a maximum limit of 10% on the importation of goods.

Agricultural Infrastructural Development Cess:
- On 1 February 2021, India announced, through the Union Budget for the Financial Year 2021-22, a number of changes to customs duties for several products, including alcoholic beverages. Through this measure, India has included an Agricultural Infrastructural Development Cess (AIDC) on import of certain items (20 items). To ensure that the imposition of this cess does

[2] « Parties » should be understood as both the Federal Government and individual states.

not increase the overall tax burden on these imports, the basic customs duty (BCD) rates has been lowered. Yet, in practice, the overall import tariff on several products remains the same (e.g. for spirits would be 150% with the basic customs duty brought down to 50% and the introduction a fresh levy of 100% with the AIDC).

Automotive:

- In the automotive sector, additional and indirect local taxes have to be added to the basic customs duty and lead to a much higher burden of up to 125%.
- As these additional taxes are calculated based on the import price plus the import duty, importers are seeing a so-called 'cascading effect', meaning that these local duties, although valid also for local producers, do have a much higher effect on imported goods.
- Simplifying the current GST Tax structure for automobiles by reducing GST Compensation Cess would be very helpful. This would increase India's manufacturing competitiveness and help India to compete on the global stage.

Health Cess on Medical Devices:

- With the Indian Union Budget 2020, an additional 5 % health cess was levied on the import of many categories of medical devices. It directly impacts the cost to patients and challenges the industry with additional costs. Much of the complex and high-risk medical devices are still imported into the country and therefore, any hike in custom duty – especially on those devices not sufficiently manufactured in India – will only increase the burden on patients and the health economy of the country. This is a worrisome move and is contrary to the government's vision to provide affordable healthcare to Indian patients, which depends largely on imported technologies. The removal of the additional 5 % Health Cess would much better enable medical device companies to continue bringing innovative medical devices to India.

It is worth noting that India's state tax system is hugely complex with multiple fees and charges that varies from State to State, leading to some products facing discrimination in certain Indian States. There is no single periodical publication that includes all the information on the tariffs applicable to imports and changes arbitrarily over time. In May 2017, India introduced a Goods and Service Tax (GST) which unified the previous complex system of multiple indirect taxes into a single federally controlled tax. While this has helped, some products such as the ones defined as 'alcoholic liquor for human consumption' are excluded from the scope of goods that fall under jurisdiction of the Federal Government, and so are not included in the scope of GST.

India is also increasingly applying **anti-dumping duties** to limit market access and protect local, dominant producers at the expense of broader downstream industries. Anti-dumping actions should only be pursued in exceptional circumstances and only be imposed in strict compliance with WTO rules. We value efforts to ensure that anti-dumping actions are pursued on a fair, efficient, and legal basis with appropriate consideration of the negative effects on long-standing business partnerships and strategic bilateral relationships.

On Trade Defence Instruments, we would suggest similar provisions to the EU-Mercosur Trade Agreement. For trade remedies it includes existing WTO trade defence instruments (anti-dumping, anti-subsidy and global safeguards), and also bilateral measures on safeguards more specifically. The last one allows both parties to remove preferential tariffs to protect their domestic industry from bilateral imports which could cause severe damage to domestic producers.

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2. Export duties

The trade agreement should remove all export duties on raw materials (including minerals and metals).

3. Customs and Trade Facilitation

Customs issues remain problematic and should be addressed through the trade agreement. customs procedures and controls are not transparent, burdensome, heterogeneous and unpredictable. Industry recommends a comprehensive electronic, single-window certification process.

Indian customs are "invariably rejecting" on a sectorial basis a number of European companies' transfer prices when transactions are made between related parties, citing differences between the declared customs value and prices extended to duty-free operators. It is inappropriate to use the value extended to duty-free operators as the basis for determining whether the relatedness of the parties affect the transaction value for sales to the domestic market; or, as "identical goods" or "similar goods" under the WTO Customs Valuation Agreement (CVA).

India has implemented new customs clearance requirements at the beginning of the year (DGoS, ICES advisory No 06/2021), with the launching of the E-Sanchit ICEGATE portal. Unfortunately, the portal has shown some technical limitation, since it does not support the size of the document uploaded for the release of the product at customs. While the platform has slightly improved, another concern is that the new custom clearance requirements have impacted the ease of business in India, slowing down access to the market. Indeed, companies exporting to India have to upload documentation specific to the products contained in the shipment (e.g. for the cosmetic sector: batch release certificates, or products certificates of analysis), while this information is already provided for the registration of the product in land. The preparation and upload of the corresponding documentation depending on the composition of the shipment immobilizes the products at the storage facility, increasing exporters' burden and considerably impacting the whole supply network of companies.

Industry would recommend an **in-market control** (instead of a pre-market approval) with notification to authorities inspired from what is done in the European Union. This might be a long term goal and a transitional measure could be to reduce the non-tariff barrier of registration requirements.

Chip Import Monitoring System (CHIMS) in India: by October 1st, 2021 importers of all kinds of Integrated circuits including MCP and MCO (HS 8542XXX) into India will be required to apply online for a CHIP Import registration between 60 days to 15 days prior of expected date of arrival of the consignment. This will heavily restrict freedom and flexibility of short-term deliveries and changes. Further it will create considerable administrative burden and cost. A long list of items should be submitted[3]. There is also a risk that data involving sensitive or confidential information will be requested. It seems that this requirement is part of India's Central Government policy to curtail imports of chips and promote domestic manufacturing, thus imported goods are monitored.

[3] https://imports.gov.in/MEITY/public/home

4. Sanitary and Phytosanitary Measures (SPS)

In the case of **fruits and vegetables**, India applies a positive list system for the authorization of imports of plant products. Only about 40 products (fruits and vegetables) are authorized, of which only five species of fresh fruits are of commercial relevance and the process for approval of new products is highly restrictive. For those products that are authorized, India requires two systems for imports. The first one requires fumigation with methyl bromide and cold treatment. This treatment is banned throughout Europe and the use at destination is only an exceptional and temporary measure that implies certain penalties that increase customs clearance fees fivefold. This is considered, not only disproportionate, but also arbitrary and discriminatory. The second requirement is cold treatment prior to shipment. The problem with this treatment is that the requirement has to be prior to shipment, (to which refrigerated transit must be added). This lengthens the export operation and reduces storage time upon arrival. The Indian government now allows cold treatment in transit for some types of fruits which alleviates the burden on imports.

5. Technical barriers to trade

On technical barriers to trade, the agreement should ensure **compliance with international standards and go beyond the WTO Technical Barriers to Trade (TBT) Agreement, including its principles for the development of international standards[4]. The agreement should aim at eliminating burdensome technical requirements.** Some of these requirements in India put unequal burden on foreign companies when it comes to compliance as shown below.

India has adopted regulations with specific national requirements for products to enter its market, without considering international recognised standards such as UN or ISO standards. These regulations create significant barriers to trade sometimes even impeding European manufacturers from entering the Indian market. Below are some examples of the numerous outstanding technical and administrative barriers to trade:

Quality Control Orders, BIS registration and other technical regulations specific for sectors:

Automotive Sector:

- India, which is not a member of the relevant international agreement - the so-called UNECE Agreement of 1958, has adopted regulations to protect its market. It requires specific certification and marking, resulting in double testing, additional costs and cumbersome administrative procedures.
- India has put several auto components like safety glass, wheel rims, electronic components (camera) including tires, under Quality Control Orders (QCOs)/ Compulsory Registration Order (CROs). Meeting QCO requirements for niche small volume vehicles increases the administrative requirements for manufacturing these vehicles in India, although the vehicles and their components globally meet the most stringent quality and safety requirements. Consequently, we ask for exemption from requirements of Quality Control Orders (QCOs)/ CROs to OEMs having established local manufacturing / assembly operations.
- Also concerning the tire sector, India published on May 17, 2021 a new AIS 142 regulation on thresholds for the three performances (rolling resistance, wet grip and noise) applicable for the original equipment market. This regulation will be implemented on all types of tires with

[4] https://www.wto.org/english/tratop_e/tbt_e/principles_standards_tbt_e.htm

a different schedule (October 2021 for new designs, October 2022 for existing ones). While the thresholds proposed by this regulation are very close to the thresholds of the UNECE regulation, which is positive, the implementation of the text raises a number of questions, in particular: the lack of WTO notification and the short deadline of implementation, the unique recognition of only four test centers in India and the non-recognition of international laboratories. Finally, while the regulations are slightly less restrictive than the UNECE regulations, no device for recognizing tires in accordance with UNECE regulations is planned.

- Need for a Nodal Ministry for Automotive regulations: different Ministries of Government are issuing different regulations for Automotive Sector. This results in uncertainty and potential risk for compliance in shorter time and prioritisation. It is recommended that the Government of India can appoint a nodal Ministry for formulating and issuing regulations for automotive sector.
- India shall consider the harmonisation of regulation with the UN Regulations and shall accept the UN R test report/ certificates. Accordingly, India can consider signing UN 1958 agreement. This would avoid duplication of tests and faster introduction of globally available vehicles in India.

Toys:

- On 1 January 2021, India imposed a new Quality Control Order (QCO) for imports of toys. This is currently one of the biggest challenges for European toy producers exporting to India. The QCO mandates that all toys sold in India require licensing from the Bureau of International Standards (BIS). The issuance of licenses is based on applications made by toy manufacturers, followed by an audit of the manufacturing facilities by BIS. Domestic facilities have already been audited while overseas manufacturing plants are facing delays because of travel restrictions due to the pandemic. This is currently, practically shutting out companies from the market. While since May 2021, the Indian government has agreed to temporarily allow for virtual inspections, the legislation is nowhere in sight.

Cosmetics:

- The registration process for imported cosmetic products is burdensome. Inspection of foreign manufacturing sites including subcontractors should be performed every 3 years or more and only in cases of serious safety concerns, as prescribed in Cosmetic Rules 2020. ISO and GMP certificates could be accepted to alleviate the process.
- India imposes obligations to manufacturers and primary importers with regards to products that could be imported by third economic operators, and over which they have no control. India also imposes prescriptive and rigid mandatory vertical performance (BIS) standards, that are difficult to comply with for products manufactured globally in different countries. It limits innovation and discourages investment in research. The industry highly recommends the use of harmonized safety/horizontal standards and voluntary performance standards for the sake of innovation and international convergence of cosmetic regulations.

Steel:

- Steel-related products cannot be produced, sold, imported or traded in India unless they are certified under the BIS mark. Foreign companies that want to sell their products in India have to obtain the BIS registration, which can take up to 6 months.

Medical Devices:

- The Medical device's regulation is based on conformity with global consensus standards, clinical proof of conformity with essential principles of safety and performance, and materiovigilance. Compliance with BIS (Bureau of Indian Standards) requires additional regulatory hurdles without any additional value in terms of added safety or scientific scrutiny. A regulatory clearance from CDSCO or State regulators should also be enough for products to qualify for the Public Procurement Order.

Chemicals:

- The Chemical sector faces a number of regulatory challenges when importing into India e.g. the India's Chemicals Management and Safety Rules (ICMSR), the Bureau of Indian Standards (BIS, national Indian certification body), Maximum residue levels (MRL) in food and nutrition, the food safety standards authority (FSSAI) newly introduced certificate for incoming food products (currently discussed at WTO level).

Labelling and marking requirements:

- Several imported commodities including tiles and cosmetics have to apply specific labelling requirements considerably increases the importers' burdens. MRP (Maximum Retail Price), generic name of product, month and year of entry in trade channel, importer name and address and quantity in standard units must be displayed prominently on the "principal display panel" and apply to the import of pre-packaged commodities. This requirement considerably increases the importers' burdens, as calculations are normally based on several factors including freight, insurance and internal taxes.

- The Food Safety and Standards Authority of India (FSSAI) has developed labelling regulations that deviate from international practice and requires some information that is not common in other markets. This deviation from international practice, the uncertainty created by the changes and adjustments that occurred and the short period of adaptation have been the main problems.

- Medical devices should be exempted from Legal Metrology (LM) as it was done in the past. All medical devices comply with the principal Act (D & C Act 1940). Having another parallel Act of LM will complicate the labelling & create confusion. Further, LM should not disregard the globally acceptable symbols/visuals of the "Date of expiration" (DOE) or "Date of manufacture" (DOM).

In the area of **cyber security certification for ICT products,** both sides should seek to enhance cybersecurity through risk-based approaches grounded in global, industry driven, voluntary-consensus standards and best practices, refraining from country specific approaches that fragments markets. Implementing "security by design" through evolving industry best practices tend to be the most efficient way to reduce security vulnerabilities. Hence, we encourage EU-India cooperation with industry to ensure vendors shall use secure coding practices and those practices are audited (GSMA-NESAS or future CSA-NESAS). Both sides should also ensure coordinated input to advance future CSA-NESAS certification hereby avoiding additional national schemes.

In addition, India is currently considering **source code review** to comply with additional security measures for 5G. This would require vendors of critical infrastructure/public communication networks to deposit their source code with a 3rd party for review hereby vendors losing control over their IPR. This is a worrying development in India. Not only is the measure inappropriate to increase the level of security, but the consequences of requiring transfer and access to source code outside a secure environment of the vendor exposes the source code to uncontrolled leaking. This introduces a new threat to the security of critical infrastructures. The agreement should address this issue stating that the evolution of 5G must be done without any technological mandates imposed by governments. Government entities should avoid state-led approaches to mandate technology or require companies to transfer or subvert technologies such as forced disclosure of source code, algorithms, encryption keys, or other sensitive information as a condition of doing business.

6. Import and export licensing procedures

Non-automatic import or export licenses should be prohibited, except in justified exceptions, in a future trade agreement with India.

- This requirement is specifically important for European tire manufacturers. On June 12, 2020, India issued new regulations establishing non-automatic import licenses for tires. Implemented immediately without WTO notification and without guidelines, this legal regime introduces quantitative restrictions on trade of a discriminatory nature. Companies have thus obtained import licenses corresponding to a small percentage of the volume of their imports per year (e.g. 40%). It is important to note that the Indian authorities have indicated orally that the authorized volume of imports would be reduced according to the following formula: 40% year N, then 20% year +1, and finally 10% year N + 2. In other words, the Indian tire market is closing gradually but inevitably.

- Regarding export licensing and controls, India is lagging behind in the implementation of its regime (especially regarding EU, US and some Asian countries) concerning timelines and flexibility. Currently decisions on export licenses are taken on a monthly or bi-monthly basis, instead of on a continuous basis, which is the standard set up in countries that implement national export controls. This in combination with a fairly rigid and inflexible approach to the implementation of the respective legislation means practical hurdles for exports of controlled items. This should not be underestimated as a requisite for industry to decides whether to base production and/or logistic hubs in India aimed to service also markets outside of India. Being flexible should of course not be interpreted as being light on national export controls. India should be encouraged to introduce a process whereby decisions on export licenses are taken on a continuous basis, to introduce Global and General Export Authorizations, to simplify exports to certain countries/regions and end users and of certain controlled items, and to fully introduce the Wassenaar Arrangement also on Export Control Classification Numbers (ECCN) where India currently differs from the other member countries.

7. Services and Establishment

The agreement should remove unnecessary discriminatory obstacles and provide new opportunities to invest through establishment in both services and manufacturing sectors. It should also ensure a level-playing field between EU service providers and their Indian competitors.

- India prohibits the majority foreign direct investment in single brand e-commerce unless the company wholly owns at least one branded store. India also only permits investment in single brand retail stores if 30% of product/goods components are sourced locally over the value of a 5 year period.

On **Data Flows,** it would be desirable to ensure the availability of multiple legal mechanisms for the cross-border transfer of personal and non-personal data which are interoperable across EU-India jurisdictions, while ensuring high level of privacy.

International standards like the OECD guidelines on Intercompany **Transfer Pricing** should be agreed upon to facilitate a deeper integration also in services.

The importance of schemes such as the Production Linked Incentive Scheme launched by the Indian government in 2020 are well-documented. We believe new opportunities can be developed by taking a holistic approach to value chains e.g. expanding the scheme to essential manufactured inputs will promote mutually beneficial opportunities. In particular, extended support for preservation capacity by including food packaging will help reduce food waste.

8. Public Procurement

Liberalisation at national, federal and local levels should be a top priority, given that India is not a party to the WTO Agreement on Government Procurement (GPA). Thereby it is crucial to enforce the principles of **transparency and non-discrimination in public procurement**. It is key that the agreement will contain a **comprehensive chapter on public procurement** as it is the case in other important trade agreements the EU has concluded with third countries like Canada and Japan in recent years. Besides the above-mentioned principles as well as rules on important aspects of the procurement procedure, the chapter should also contain at least basic guarantees and **effective legal remedies procedures for cases of complaints regarding infringements of procurement rules**.

Currently, when submitting bids and public offers in India, the following aspects should be taken into account:

- It is common practice the need to participate jointly with a local partner and even bring the production to India in order to be able to participate (Make in India).

- Public companies are obliged to buy a minimum of 20% of the value of their purchases from small and medium businesses. Of that 20%, 4% must be purchased from caste entrepreneurs and catalogued tribes.

- Disputes are usually resolved by the body responsible for the adjudication itself, rather than by an independent authority.

- If there is only one company left in a tender, the tender is cancelled and re-tender by adapting the conditions to increase the number of offers.

- The price is the fundamental criterion in the award. In May 2020, the public procurement regulation was modified: foreign companies will not be able to participate in public tenders of the Government when these have a value below 200 crore rupees (€ 25 million).

Apart from negotiating a comprehensive chapter on public procurement, the EU should also call on India to **join the GPA**, as now India has only observer status. In addition, the following sector-specific comments seem important:

- India has favoured domestic IT companies over European companies for the deployment of **5G**. The agreement should ensure that neutrality is safeguarded in this area and governments do not favour certain local companies.

- It has been reported that the canteens of the Ministry of Defence have prohibited the purchase of certain imported products such as **spirits**. While the procurement of such goods does obviously not belong to the category of specific defence-related products which may follow specific rules, prohibiting the procurement of imported goods such as spirits does not seem adequate.

- The promotion of local content and calls for "Buying National" are common in India – de iure or at least de facto – counter the principles of market openness and non-discrimination in public procurement. This basically applies for all business sectors, among them for instance sectors like **solar power** and **medical devices**.

- The Public Procurement Order on **Medical Devices** dated May 2018, calls for certain percentage of local contents (e.g. Medical disposables/ consumables 50%, Medical equipment, Surgical instruments 25%, Implants 40%, Diagnostic Regents 25%). The guidelines also state that the local content requirements would be increased in a phased manner over the course of the next three years, and preference will be given to local suppliers in terms of procurement. However, in practice 85% of critical Medical Devices of Class C & Class D are imported, with only one or two local manufacturers. Therefore, a neutral agency should judge the present status of local capacity in each category and redefine local content.

9. Intellectual Property Rights

India needs to significantly **<u>step-up efforts to enforce international standards on IPR.</u>** Guarantees in this regard should be a fundamental part of a future EU-India agreement.

- The **Trademark System** in India is extremely slow. Severe backlogs with trademark applications at the Indian trademark office remain an obstacle. To date, numerous applications to get trademarks registered as 'well-known trademark' are pending, despite several follow ups. This problem is also applicable to other areas of India's intellectual property rights system.

- **Regulatory Data Protection:** India continues to fail to ensure that there is no unfair commercial use of the regulatory data submitted by another party in securing marketing approval in India or in a third country. Rather, when a pharmaceutical product has been previously approved by a Regulatory Authority in India or another country, India requires only limited clinical data (in some cases involving as few as 16 Indian patients), instead of requiring submission of the entire dossier for review by India's Regulatory Authority. In addition, data for generics/biosimilars are considered to be confidential. The unfortunate effect of lack of such provisions is that biosimilars and generics flood the Indian market and blatantly violate the IP rights of the Innovators.

- **Restrictive patentability criteria:** the pharmaceutical industry continues to face considerable barriers at every step of the patent application process, including restrictive patentability criteria posed by Section 3(d) of India's Patents Act, outdated patent application disclosure

requirements, and narrow patentability standards applied during pre- and post- grant opposition proceedings.
Under this provision, several chemical and pharmaceutical substancse are presumed to be the same substance as the original chemical entity and thus not patentable, unless it can be shown that they differ significantly in properties with regard to efficacy. In addition, additional substantive requirements for patentability beyond those enumerated in the TRIPS Agreement are inconsistent with India's international obligations.

- **Patent enforcement:** Indian law permits the Central Drugs Standard Control Organization (CDSCO) to approve third-party manufacturers to commercialize copies of innovator products, regardless of whether those products infringe on an innovator's patent(s). Therefore, an infringer can obtain marketing/ manufacturing authorization from the state government for a generic version of an on-patent drug, forcing the patent holder to seek redress in India's court system, which often results in irreparable harm to the patent holder.

10. Investment protection

India **unilaterally scrapped the existent Bilateral Investment Treaties** that it had with several EU states in 2016. One of the major concerns of businesses following this, has been the text of India's proposed model Bilateral Investment Treaty blueprint. Especially the clause establishing a five-year time period before international arbitration could be sought in case of disputes is quite concerning. Any willingness to eliminate this clause or at least flexibility in reducing the time frame from five years to lesser- ideally 1-2 years on part of the Indian government would help build investor confidence. Overall, the investment protection provisions included in the EU-Canada agreement (CETA) would be a good basis for an agreement with India.

11. Chapter on Trade and Sustainable Development

The agreement should include a Trade and Sustainable Development chapter that lives up to the highest standards for chapters in other modern agreements of the EU. Both sides should agree that increased trade should not come at the expense of the environment or labour conditions. On the contrary, it should promote sustainable development. Labour or environmental standards should not be lowered in order to attract trade and investment. The trade agreement should not constrain both sides' right to regulate on environmental or labour matters.