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WTO Dispute Settlement: The Turkish Pharmaceutical Sector

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ABSTRACT

Free international trade has been the main concept for decades for economic growth globally and locally. It is expected that the only barrier for international trade should be tariffs, each nation should treat others equally and all the imported products should be treated same as domestic products when the importation requirements are fulfilled. However, the nature and extend of the goods traded affect the process of international trade, as well as the treatment of recipient countries. The developing countries that generally have balance of payment problems treat especially pharmaceutical products differently as the demand for those have been increasing steadily and the main producers are developed countries. Turkey with its growing population above 80 million has initiated a localization policy since 2016 in order to transfer the substantial part of pharmaceutical production into Turkey. However, the EU made a formal complaint against Turkey to the WTO in April 2019 by referring to national treatment rule mainly. Under localization policy, Turkey was accused to apply prioritization measure and also technology transfer requirement. The main exception accepted by the WTO for disputes about the deviations from national treatment rule is governmental procurement. Referring to the Turkish pharmaceutical sector, the procurement of imported drugs has been realized for the final use of Turkish patients and the resale pricing procedure is also fixed by regulations so it can be concluded that the resale pricing is not competitive and not creating a profit for the government itself and hence it seems there is not a violation of the national treatment rule

INTRODUCTION

The global pharmaceuticals sector has reached a size of 1,3 trillion USD in 2019. The sector has been led by the developed countries financially as well as technologically. It is expected that the size of the sector will increase to a level of 1,57 trillion USD till 2023[1]. In 1975, World Health Organization (the WHO) announced a resolution with the aim of assisting member countries to develop their national drug policies (the WTO, 2001). Since that time member countries, especially developing ones, followed the relevant recommendations of the WTO in order to improve access to "essential drugs" as listed in *Essential Medicines List* of the WTO (WTO, 2013). This list reports the most efficacious, safe and cost-effective medicines with high priority. In the list there exist patented drugs, as well as off-patent cost effective generic products, which are often offered at lower prices than the innovator branded product (Alfonso-Cristancho, et al. 2015). The use of generic pharmaceutical products has been promoted by many means globally in order to reduce costs and increase access to healthcare. As of 2015, the generic pharmaceutical products represent over half of the total volume of pharmaceutical products used worldwide but only 18 % of the total value of the pharmaceutical market (Sheppard,A. 2010).

WHO defines a generic medicine as "a pharmaceutical product, usually intended to be interchangeable with an innovator product, that is manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights"[2]. The two leaders of the global pharmaceutical sector are the USA and Europe. The Food and Drug Administration (FDA) of USA defines a generic pharmaceutical as "A generic drug is identical—or bioequivalent—to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use"[3]. Similarly, the European Medicines Agency (EMA) of the EU, defines a generic pharmaceutical product as a "product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference

medicinal product has been demonstrated by appropriate bioavailability studies in Art 10(2b) of Reg. 726/2004[4].

In such a framework, under the dispute settlement process, European Union requested consultations with Turkey regarding various measures concerning the production, importation and marketing of pharmaceutical products on 2 April 2019. The major concern of the EU is related with the measures of Turkey with regards to localization requirement, a technology transfer requirement, an import ban on localized products, and a prioritization measures of Turkey for the pharmaceutical products. Not surprisingly, the other leader of the sector USA requested to join the consultations on 18 April 2019.

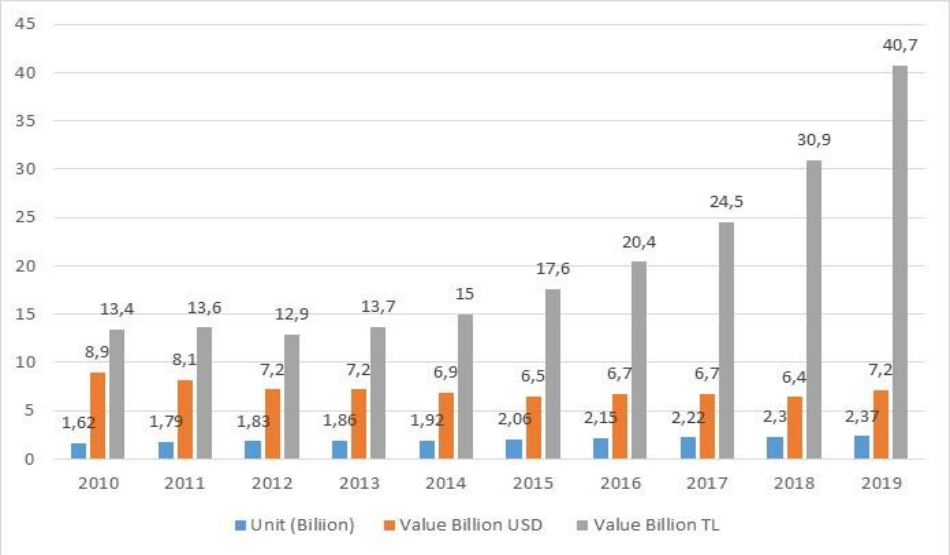
The aim of this paper is to present the international trade issues under the GATT 1994 that the EU has referred in relation with the consultation request about the measures of Turkey in pharmaceutical sector[5]. It is also aimed to provide the possible explanations that may justify the applications of Turkey in the pharmaceutical sector. In the first section Turkish pharmaceutical sector will be elaborated in terms of size, as well as prevailing regulations applied. In the second section, the consultation request issues together with the possible explanations of Turkey will be explained. In the last section the concluding remarks will be reported.

[1] https://home.kpmg/tr/tr/home/gorusler/2020/03/sektorel-bakis-2020-ilac.html
[2] https://www.who.int/medicines/areas/access/NPrices_Glossary.pdf
[3]Shah US. Regulatory strategies and lessons in the development of biosimilars. In: Pharmaceutical sciences encyclopedia. Wiley; 2010. doi:10.1002/9780470571224.pse511.
[4]https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2004_726/reg_2004_726_en.pdf
[5] The EU complaint also refers to Trade Related Investment Measures ('TRIMs Agreement'), the Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS Agreement') and the Agreement on Subsidies and Countervailing Measures ('ASCM'), but those are not the subject to elaborate in this paper.

1. The Turkish Pharmaceutical Sector

Turkey has a population of nearly 82 million as of 2019[6]. As illustrated in Figure 1, the size of Turkish pharmaceutical market is 40,7 billion TL (7,2 billion USD) in terms of ex-factory prices in 2019. During the same period unit sales reached 2,37 billion units.

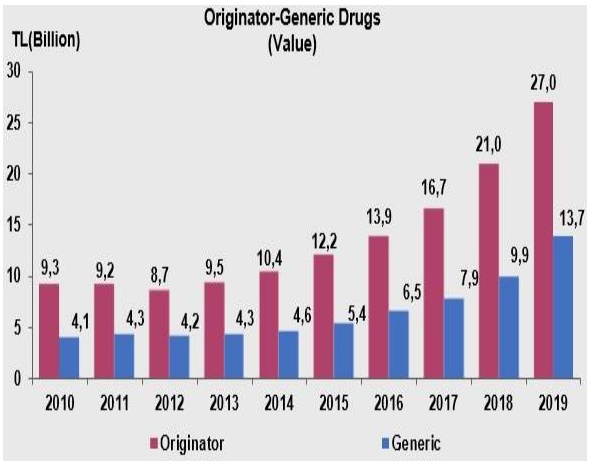
Figure 1: The Turkish Pharmaceutical Sector

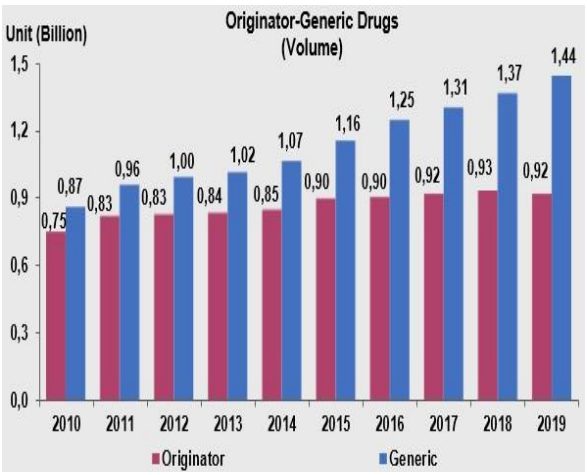


Source: IQVIA, IEIS

Referring to the Figure 2, while in terms of value the Turkish pharmaceutical market is dominated by originator drugs (66%), in terms of unit the generic drugs dominate (61%). The cost advantage of generic medicine comes from both the production and marketing attributes. The generic medicines are produced without license especially after the expiry of patent or other rights. They are generally marketed under a non-proprietary brand names or specially defined names called “branded generics”. In these circumstances, at a point in time both the original and generic equivalent of the medicine can be in the market for sale. It is accepted that substantial savings could be achieved by switching from original medicines to generic equivalents in emerging market countries which are generally represented by generally both trade and budget deficits (Alexandra et al. 2012).

Figure 2: Generic vs. Originator Drugs – Turkish Market





Source: IQVIA,IEIS

[6] https://data.worldbank.org/indicator/SP.POP.TOTL?locations=TR

As illustrated in Figure 3, the share of locally produced drugs in total volume of market has been consistently increasing since 2014 and the first time it exceeded the imported drugs value in 2019. In fact, the value share of local drugs increased to 52,1% in 2019. The similar developments are realized in terms of volume. The share of local production in total market volume has consistently increased since 2014 to a level of nearly 88% in 2019. Those developments are results of the policies applied since 2014 in relation with the aim of localization of the pharmaceutical products.

Figure 3: Imported vs. Local Drugs – Turkish Market

Source: *IQVIA,IEIS*

Health Transformation Program (HTP) has altered Turkish healthcare system. HTP was designed to improve the quality and efficiency of Turkish health system. The major aim is to ease the access of all citizens to health services enabling equality in health services and achieve universal coverage with financial sustainability (MOH, 2003; Rockefeller Foundation, 2010). Another important application was the announcement of a notification about the pricing of medicinal products in 2004 that changed the cost-based pricing system to external reference pricing system. Under this new system, the reference price of an originator product is determined according to the lowest ex-factory price among 5 European Union member countries, namely France, Spain, Italy, Portugal, and Greece. Additionally, it is determined that for originator products, reference price is 100% of the price in the lowest ex-factory price and the generics are priced as 60% of the price of the originator product. A reimbursement commission for issuing the positive list of drugs was firstly established (MOH, 2012).

In 2005, positive lists for three social security organizations were integrated under a unique list and the equivalent groups of drugs were introduced depending on the active molecule. The reimbursement was capped at 30% above the cheapest brand in each group. The institutionalization of three security organization under the same root was realized in 2006, namely the SSI.

In 2007, the SSI announced Health Implementation Practice in order to harmonize and equalize the benefits offered and set rules for reimbursement, invoicing, and copayments for drugs. Then a new copayment regime was introduced whereby there exist full reimbursement in case of the patient has a chronic disease certified by a physician, in other cases contributors and their dependents pay a 20% and beneficiaries pay 10% coinsurance. In 2008, Medical and Economic Appraisal Commission was established to provide the required technical expertise especially in order to appraise the applications for inclusion into reimbursements list. The evaluation process is based on economic analysis mostly and focus on budgetary concerns. Meanwhile, external reference pricing of generics was reduced to 66%.

In 2014, a more structural reform was made in the form of *Localization Policy* for the production of a substantial amount of pharmaceutical items as announced in 64th Government Action Plan- action item No:46. Under this policy, the Turkish General Directorate of Medicines and Pharmacy and Social Security Institution (SSI) jointly announced a localization process which initiates the requirement of the localization of drug production formally introduced with the aim of lowering the burden of importation of drugs on current account deficit. Under the localization policy, drugs that can be manufactured in Turkey are determined and it is stated that for the selected drugs if production is not begun by February 2018 they will be removed from the repayment scheme. In order to be in the list, many pharmaceutical have companies realized the production of imported drugs in Turkey since 2016. In order for the smooth operation of the localization policy, the Ministry of Health (MOH) applied a proactive approach to inform the pharmaceutical companies in relation with the proposed process and schedule. Although it is also criticized by some stakeholders MOH individually negotiate with the pharmaceutical companies about their plans of local manufacturing of already imported products which are required to be produced domestically.

Under the localization policy, the major aim of Turkish authorities to transfer the substantial part of pharmaceutical production into Turkey and they required the international pharmaceutical producers to commit a plan to such a transfer gradually. In the cases that such a domestic production commitment has not been given or has not been realized, pharmaceutical products concerned are to be excluded from the scheme prepared for the reimbursement of the pharmaceutical products sold by pharmacies to patients operated by Turkey's social security system which is named as "reimbursement scheme by Turkish authorities. When a pharmaceutical has been excluded from the reimbursement scheme, they lost their competitive advantages as compared to domestic like products. The duration of the localization policy has not been clearly defined but it is accepted that it will be applied on an ongoing basis. In order not to be excluded from the reimbursement list, many pharmaceutical producers either committed or realized the domestic production of certain pharmaceutical products. As can be seen from Figure 3, in 2019 for the first time the value of the imported drugs was lower than the domestic ones. The policy has been criticized that specific commitments have been negotiated with different pharmaceutical producers individually in somehow non-transparent circumstances.

It is also proposed that the localization policy also constitutes technology transfer requirement implicitly. The foreign pharmaceutical producers may be required to bring their technological know-how together with the patent rights in order to realize domestic production. It is criticized that such a technology transfer requirement which is not applicable to Turkish pharmaceutical producers may also be applied selectively in a non-transparent manner. However, there does not exist any formal statement in relation with the technology transfer requirement in any of the policy documents.

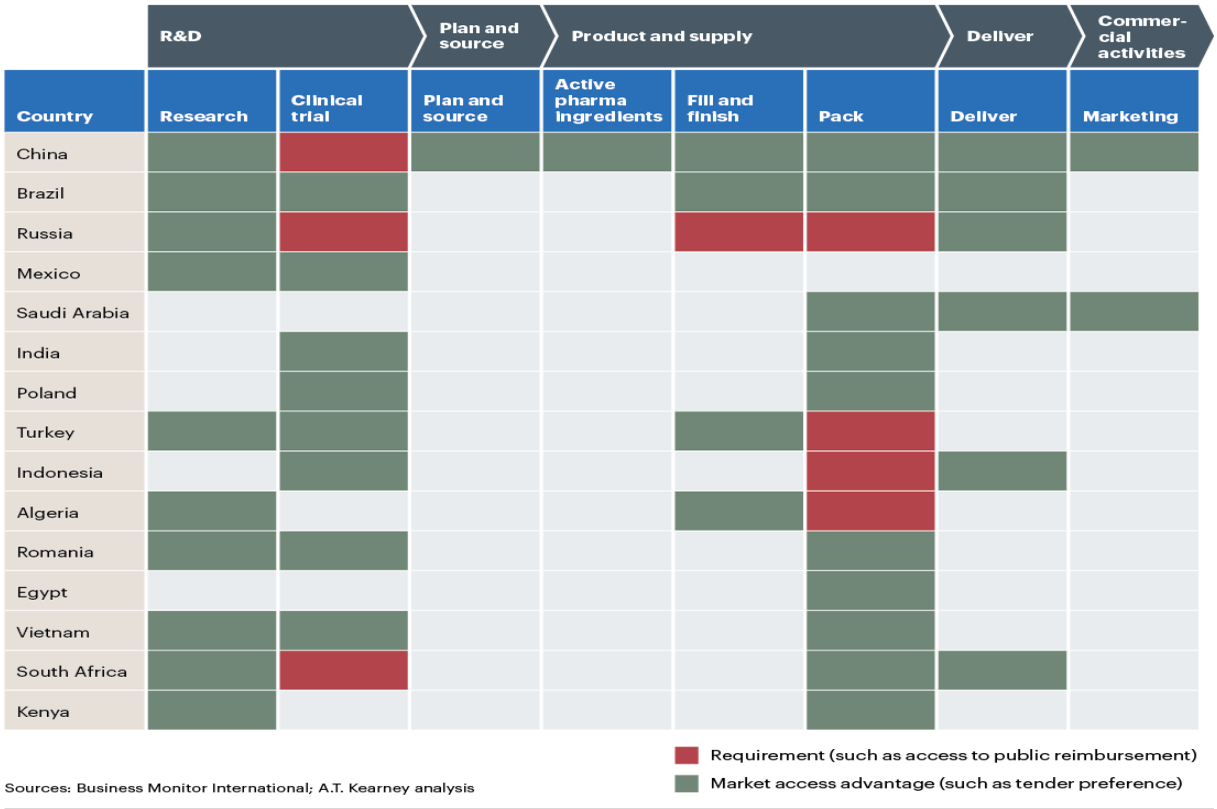
Another criticism about localization policy is the implicit ban on importation of already localized products. Although some of the imported medicine has not been removed from the reimbursement list, Turkish authorities are charged with their policies to give priority only for reviewing the applications of medicine produced domestically against the imported ones. They are also accused to give priority to domestic products with respect to any pricing and licensing policies and processes. However, to prove the application of such a policy is not that easy and only some of the complaints of the companies are accepted as ground for this treatment.

In fact, Turkey is not the only country applying localization policy in pharmaceutical sector. As it is stipulated in Figure 4, several emerging market countries have applied localization policies in pharmaceutical sectors by many means[7]. While Indonesia and China require some of the production process to be realized domestically for at least one product by using a

[7] https://www.es.kearney.com/health/article/?/a/localization-an-emerging-requirement-of-a-global-pharma-strategy

portfolio approach, China also requires R&D investments to be realized domestically in order to create know-how in the field. Brazil treats the localization on the production on product basis on a stricter approach. Saudi Arabia and Russia are increasing the product specificity of localization benefits. Recently, Russia, also requires a high propensity of the production process to be realized domestically. These strategies do not only create benefits for the domestic country, but also for the pharmaceutical producers as well. The low labor costs prevailing in the emerging market countries help to reduce the cost of production, also gains from the logistics costs and avoiding import tariffs are amongst the achievements of the domestic production of pharmaceuticals.

Figure 4 - Localization Policies in Emerging Market Cou ntries



3. Complaint of the EU Regarding the Turkish Pharmaceutical Sector - National Treatment

In relation with Turkish pharmaceutical sector developments, the EU made a formal complaint against Turkey to the WTO in April 2019 referring to the obligations of Turkey as expressed by the provisions of Article III, X and XI of the General Agreement on Tariffs and Trade 1994 ('GATT 1994')[8].

3.1. Complaint of EU Regarding National Treatment of Pharmaceuticals and Relevant Exception(s) – Article III

Under the heading of "Certain measures concerning production, importation and marketing of pharmaceutical products," the EU proposed that the localization policy implemented by

[8]The complaint also refers to the Trade Related Investment Measures ('TRIMs Agreement'), the Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS Agreement') and the Agreement on Subsidies and Countervailing Measures ('ASCM'), but those are not the subject to elaborate in this paper.

Turkey in pharmaceutical sector since 2016 is inconsistent with the GATT 1994 Article III[9].The policy has been implemented together with the technology transfer requirement and the import ban on localized products which lead treatment of imported drugs less favorably than products of national origin[10].

The GATT Article III:1, under the heading of "national treatment", requires that as a general principle "Members must not apply internal taxes or other internal charges, laws, regulations, and requirements affecting imported or domestic products so as to afford protection to domestic production." Article III:2 stipulates that "Members shall not apply standards higher than those imposed on domestic products between imported goods and like domestic goods, or between imported goods and a directly competitive or substitutable product." With regard to internal regulations and laws, Article III:4 provides that Members shall accord imported products treatment no less favorable than that accorded to "like products" of national origin. In determining the similarity of "like products," the GATT panel reports have relied on a number of criteria including tariff classifications, the product's end uses in a given market, consumer tastes and habits, and the product's properties, nature, and quality[11].

EU initiated its compliant by referring to Article III:4 and proposed that:

- by according priority to the review of applications for inclusion in the reimbursement scheme, as well as with respect to any other pricing and licensing policies and processes of pharmaceutical products of national origin, the prioritization measure applied by Turkey creates a more favorable situation than to similar imported products[8].
- by excluding imported pharmaceutical products for which localization commitments have not been given have not been accepted or have not been fulfilled from the reimbursement scheme, the localization requirement accords to imported pharmaceutical products being treated less favorably than similar products of national origin covered by that scheme in respect of laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use[8].

3.2. Exception to National Treatment Rule

The main exception that can be used in order to clarify the positioning of localization policy applied in the Turkish pharmaceutical sector is thought to be stipulated in Article VIII: 8 (a). In this sub-article, it is defined that provisions of Article III:4 shall not apply to "...laws, regulations or requirements governing the procurement by governmental agencies of products purchased for governmental purposes and not with a view to commercial resale or with a view to use in the production of goods for commercial sale."

At this point, some form of interpretation is required in order to determine whether this exception applies to the policies implemented in Turkish pharmaceutical sector. It is accepted that "procurement by governmental agencies" is realized in order to perform mainly the public service of the government. However, the goods should not be offered as "commercial resale" and "to be used in the production of goods for commercial sale" both of which defines sales with an implicit purpose of profit.

The legal definition of commercial sale is ".. any sale which transfers physical possession and title to any licensed product to a third party in exchange for value and after which transfer the seller has no right or power to determine the third party's resale price." Referring to the Turkish pharmaceutical sector, the procurement of imported drugs has been realized for the final use of Turkish patients and the resale pricing procedure is also fixed by regulations so it

[9] https://trade.ec.europa.eu/doclib/docs/2019/april/tradoc_157821.pdf
[10]The consultations were joined by the United States, and a panel was established in September 2019 involving Brazil, Canada, China, India, Indonesia, Japan, the Russian Federation, Switzerland and Ukraine as third parties.
[11] https://www.meti.go.jp/english/report/downloadfiles/gCT0322e.pdf

can be concluded that the resale pricing is not competitive and not creating a profit for the government itself. The resale pricing of pharmaceuticals is a complex procedure and set in 2004 by MOH as an external reference pricing system under the decree on the pricing of medicinal products for human use:

- the reference price of an originator product is determined according to the lowest ex-factory price among 5 European Union member countries, namely France, Spain, Italy, Portugal, and Greece.
- For originator products, reference price is 100% of the price in the lowest ex-factory price. For generics, prices are determined as 60% of the price of the originator product. The prices of generics cannot be higher than the originators' reference prices and the highest price of the equivalent generic in the market.
- A molecule-based equivalent grouping policy is applied by including roughly 1,500 equivalent groups. For each equivalent group, the base price is calculated and up to 10% over the base price is reimbursed by the SSI and the remaining is financed out-of-pocket (the SSI, 2014).

All of these procedures indicate the non-profit orientation of governmental procurement activities of pharmaceuticals of Turkey. A similar dispute was handled whereby Canada was complained about the feed-in tariff programme which requires the use of domestic materials in the construction of the green energy facilities by Japan and EU (Çalışkan Y. and Sarıbeyoğlu, M. 2016). The panel decided that the Ontario state sells the electricity by profit and the exception was not accepted (Panel Report, 2013).

Considering the governmental procurement which serves the pharmaceutical needs of the population, Turkish state has two alternative means; the procurements of public hospitals and the reimbursements made for the individual pharmaceutical purchases of the patients. In the latter case, the procedures for those procurements of pharmaceuticals are transparently announced in the application communiqué of the SSI and the protocol signed by the SSI and the Turkish Pharmacist Association about the procurement of pharmaceuticals by individuals. In each of the documents such procurements are regarded as governmental procurement without the profit orientation. This also confirmed by some Supreme Court decisions such as the Decision of Council of State dated May 13, 2011.

CONCLUSION

The global pharmaceutical sector is expected to grow further due to the factors of growing and aging population, rising income levels, emerging medical conditions and emergence of new diseases. Additionally, improvements in the purchasing power and efforts for increasing the access to quality health care of the poor and middle-class families worldwide will contribute to this growth. The global pharmaceutical market is expected to reach a size of USD 1.57 trillion by 2023. By that time, it is also expected that the market share of North America will increase to 45%, Asia Pacific pharmaceuticals market is expected to retain the second position with a market share of 24% whereas the share of Europe is expected to decline to nearly 20%. Latin America and Middle East and Africa (MEA) are expected to retain 7.5% and 3% market share of global pharmaceuticals market in 2023[12].

Emerging market countries represent an exceptional opportunity for the pharmaceutical industry because of their large population, growing prosperity, and increasing life expectancy. The growth in the developed countries has been flattened mainly due to spread of use of less expensive generic drugs and tight regulations. However, in the last decade emerging market countries have begun to develop domestic production ability mainly in order to overcome the balance of payment problems. United Nations also provide support to the emerging market countries in the form of technical cooperation and advisory services to

[12] https://www.globenewswire.com/news-release/2020/01/17/1972092/0/en/Global-Pharmaceuticals-Industry-Analysis-and-Trends-2023.html

advance local pharmaceutical production (LPP) in developing countries with a wide range of public and private sector partners under a programme named the UNIDO since 2006.

In these circumstances, Turkey, referring to her growing population, increasing pharmaceutical spending financed by governmental sources and enduring balance of payment problems, designed a localisation policy in 2016. Under the localization policy, the major aim of Turkish authorities to transfer the substantial part of pharmaceutical production into Turkey and they required the international pharmaceutical producers to commit a plan to such a transfer gradually. In the cases that such a domestic production commitment has not been given or has not been realized, pharmaceutical products concerned are to be excluded from the scheme prepared for the reimbursement of the pharmaceutical products sold by pharmacies to patients operated by Turkey's social security system which is named as "reimbursement scheme" by Turkish authorities. When a pharmaceutical has been excluded from the reimbursement scheme, they lost their competitive advantages as compared to domestic like products. The outcomes of the policy emerged and in 2019 for the first time the value of the imported drugs was lower than the domestic ones. This policy was complaint by the EU to the WTO mainly by the means of violating the national treatment rule, as well as violating the requirements of the GATT about the publication and administration of trade regulations. In its complaint, the EU proposed that the localisation policy applied by Turkey in pharmaceutical sector also constitutes technology transfer requirement implicitly, as well as an import band in the form of prioritisation.

The possible explanation of Turkey to this compliant is thought to be built on the exemption of governmental procurement of the GATT. It is accepted that "procurement by governmental agencies" is realized in order to realize mainly the public service of the government. However, the goods should not be offered as "commercial resale" and "to be used in the production of goods for commercial sale" both of which defines sales with an implicit purpose of profit.

The legal definition of commercial sale is ".. any sale which transfers physical possession and title to any licensed product to a third party in exchange for value and after which transfer the seller has no right or power to determine the third party's resale price." Referring to the Turkish pharmaceutical sector, the procurement of imported drugs has been realized for the final use of Turkish patients and the resale pricing procedure is also fixed by regulations so it can be concluded that the resale pricing is not competitive and not creating a profit for the government itself, thus it appears there is not a violation of the national treatment rule.

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