TURKEY
PHARMA MARKET
&
REGULATORY REPORT

Pharmaceuticals Export Promotion Council of India

(Set up by Ministry of Commerce & Industry, Government of India)

CONTENTS

DEMOGRAPHY

SL. No	Parameter	Description
1	Region	South Eastern Europe
2	Country	Republic of Turkey
3	Capital	Ankara
4	Population	82,017,514 (July 2020 est.)
5	Population growth rate (%)	0.45% (2020 est.)
6	GDP (purchasing power parity)	$ 2.186 trillion (2017 est.)
7	GDP - real growth rate (%)	7.4% (2017 est.)
8	GDP - per capita (PPP)	$27,000(2017 est.)
9	Exchange rates	1 US dollar = 3.53 Turkish lira on 28th July 2017
10	Population below poverty line	21.9%
11	Age structure (%)	0-14 years: 23.41%
		15-24 years: 15.67%
		25-54 years: 43.31%
		55-64 years: 9.25%
		65 years $ above:8.35%
Source: CIA World Fact Book updated to July 2020		

MARKET REPORT

INTRODUCTION:

Turkey presents significant growth opportunities for multinational pharmaceutical firms, on account of its large, ageing population with a high and rapidly growing prevalence of non-communicable diseases. However, the country's regulatory environment and government's pharmaceutical policies will deter innovative drug makers, while the weakness of the lira will erode revenues. Nevertheless, the country remains a key market in the region.

Market was around $ 7.7bn in 2019. It has negatively grown continuously during the last three years. However the forecast for 2020 is a growth by 5.43% and market is expected to reach $ 8.12bn.

Updates

- On April 30, Turkey's Industry and Technology Ministry announced that a private-public venture for nationally-produced ventilators had delivered its first batch of 100 ventilators to the Basaksehir City Hospital, and another 5,000 to be delivered in May.
- In January 2020, the WHO announced the deployment of emergency medical assistance in Elazig and Malatya provinces in the aftermath of the 6.8-magnitude earthquake in eastern Turkey.
- In January 2020, Turkey announced it will open hospitals in Libya, Palestine, and Kyrgyzstan in 2020 as part of humanitarian efforts to share its health expertise with regional countries and beyond.

Economic View

Growth rates over the coming years in Turkey will remain well below averages recorded between 2008-15, in part due to a precarious business environment and a lack of structural reforms. Broader concerns regarding the country's political outlook and various macroeconomic imbalances will persist, undermining capital expenditure and business activity.

Strengths:

- The third-largest pharmaceutical market in Central and Eastern Europe.
- Strong domestic production capacity.
- The availability of a skilled workforce.
- Large, growing and ageing population with a growing disease burden.
- International investment activity continues to increase.

Weaknesses

- Relatively low per-capita drug spending compared with other European markets.
- Fiscal conservatism in public pharmaceutical expenditure due to government attempts to control spending.
- Turkish legislation does not provide effective protection for intellectual property holders in resolving patent disputes.
- Long regulatory delays in receiving marketing authorization for innovative and newly registered drugs.

- Lira weakness will continue to limit revenue-earning opportunities for multinational drug makers.

Opportunities

- Harmonization with the EU and sector modernization holding considerable potential for the Turkish market.
- Significant scope for growth, given the size of the population, the current low consumption rate and the expansion of insurance coverage.
- Potential for generic sector growth, with market demand patterns structured by a cost-conscious government and a low-income population.
- Export trade to benefit from closer links with the EU, an improvement in local industry standards and an increase in international investment.

Market Highlights

Turkey's pharmaceutical market is the third largest in the CEE region owing to its considerable population size. Turkey's pharmaceutical expenditure per capita, at USD92.1 in 2019, is considerably lower than any EU member state. It ranks just 22nd out of the 32 countries in the CEE region, trailing most markets aside from the Commonwealth of Independent States markets. Turkey's pharmaceutical expenditure has fallen significantly in US dollar terms in 2018 & 2019 because of the depreciation of the lira.

Total pharmaceutical sales in 2019 amounted to USD7.7bn. Opportunities for multinational pharmaceutical firms will be restricted by Turkey's highly challenging operating environment despite considerable growth opportunities. Forecasts say that the Turkish drug market is likely to grow at a cagr of 1.8% in the next five years and touch $10.34 billion in 2024.

As part of the Turkish government's Vision 2023, it has begun to impose an aggressive localisation policy in order to achieve its aims of developing the domestic pharmaceutical industry as a means of economic diversification. As outlined in the initial plan, Turkey hopes to increase the manufacturing capacity of its domestic pharmaceutical industry, to increase pharmaceutical exports and to become a net exporter of medicines.

The government began notifying pharmaceutical firms with products at risk of delisting (for reimbursement) in February 2017, with the warning that these products would be delisted unless the drug makers submitted plans to localise the products in Turkey. The policy was separated into a number of 'waves' of delisting:

The First Wave: 71 foreign-made medicines with 50% market share and with three approved domestically-manufactured generic alternatives were delisted in February 2018.

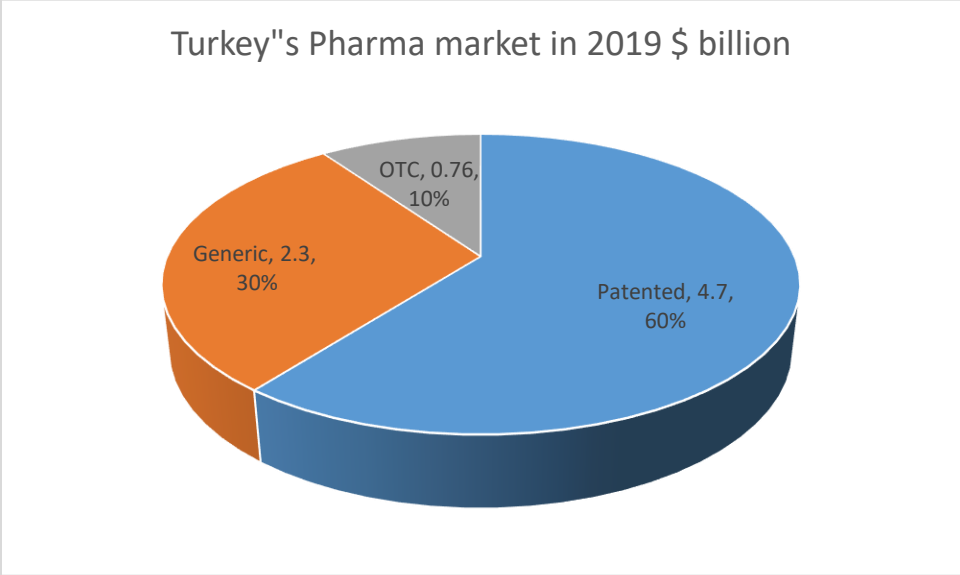
The Second Wave: 119 foreign-made products with 10% market share and with two approved domestically-manufactured generic alternatives were delisted in July 2018.

Pharmaceutical Research and Manufacturers of America (PhRMA), pointed that, the specific definition of localisation - be it complete full-cycle production or limited to packaging, or somewhere in between - remains undefined. Furthermore, this policy approach is reportedly not legally enforceable under the country's current regulations; the Social Security Institute (SGK) may remove products from reimbursement on the basis of a product's budget impact, cost-

effectiveness and/or clinical outcomes, however, it is not permitted to delist products based on the country of manufacture. As a result, this policy directly contradicts the country's trade obligations with the WTO as well as the EU-Turkey Customs Union Declaration.

Turkey's epidemiological profile resembles that of other CEE states, like non-communicable diseases such as heart disease, cancer and strokes the leading causes of mortality and morbidity in the country. The biggest single contributor to disability-adjusted life years (DALYs) lost was cardiovascular diseases, followed by neuropsychiatric conditions and cancer.

Market composition of Turkey:



Generic Market

Due to state cost containment measures, the country's historically poor regulatory environment and intellectual property regime, the generic sector will outpace the patented segment, driving sales growth in the wider pharmaceutical market. Downside risks are posed by the increasingly competitive environment due to accelerating investment in the country's domestic pharmaceutical industry.

Generic segment was valued at $ 2.3bn in 2019 after a negative growth of 3.13%. It is forecasted to grow to $ 3.2bn by 2024 at a cAGR of 7%.

The Turkish market is broadly more attractive for pharmaceutical firms' generic medicine portfolios over innovative medicines due to the severe mandatory discounts for SGK reimbursement for higher-valued products.

However, this forced localisation policy significantly reduces the opportunities for multinational pharmaceutical firms selling generic drugs in Turkey too. At present, the government's localisation policy has targeted the generic market in order to increase the volume of domestically-produced products on the market. Generic drugs are inherently low-value/high-

volume products, and as such pharmaceutical firms have to resort to revenue from economies of scale from large regional manufacturing plants. As a result, it is inefficient for drug makers to localise the production of these products in every market in which they operate. The recent investment within the domestic industry - boosted by the country's Vision 2023 of localising the complete requirement of generics.

Consequently, there is limited interest from innovative drug makers to launch their products in Turkey given the significant regulatory issues, ranging from weak patent enforcement, preferential reimbursement policies, the state's aggressive pricing policies and regulatory approval delays.

Pharmaceutical trade

Turkey's Vision 2023, which aims to boost local pharmaceutical production, will reduce the trade deficit significantly; however, the country will remain reliant on imports. Continued lira weakness will place downward pressure on pharmaceutical export revenues as well as increasing the cost of active pharmaceutical ingredients required to produce medicines. Nevertheless, the domestic industry will grow considerably in the coming years.

In 2019, pharmaceutical exports from Turkey amounted to USD992mn. This is forecast to decrease by 2.6% in USD in 2020 to USD966mn. By 2024, forecast of exports points to USD1.3bn at a compound annual growth rate (CAGR) of 9.0% 4.8%. Pharmaceutical imports in2019 were worth USD3.9bn. This is forecast to increase in local currency terms by 0.3%in 2020 to USD4.1bn. By 2024, projections show imports to increase to USD4.8bn at a CAGR of 4.2%.

Turkey's Vision 2023 aims to boost Turkey's domestic pharmaceutical industry, with the intention to become a net exporter of medicines to the surrounding Europe, Commonwealth of Independent States (CIS), Central Asia and Middle East and North Africa regions. The need to become less reliant on pharmaceutical imports has increased in recent years due to the weakness of the lira due to the increasing cost of imported medicines at a time when demand for drugs is increasing. However, despite this initiative, the country will remain heavily reliant on imports. The domestic industry is heavily affected by the weak lira for two reasons: local firms are dependent on imported active pharmaceutical ingredients (APIs) and export revenues are highly sensitive to currency exchange rates.

Pricing

Prices of pharmaceuticals in Turkey are determined by the lowest price of the same product (at manufacture selling price) in a basket of five countries namely, Greece, Italy and Spain, France and Portugal.The reference price (now termed the real source price) is set as the lowest ex-factory price (excluding VAT and wholesale/retail margins) in these markets; or if the product is not sold in these five 'source' countries, the lowest ex-factory selling price among EU countries is used.

The calculation of the 'source price' - the price of the product in Turkey - from the real source price remains the same; for an original product where there is no generic entry, the source price is set at 100% of the real source price. When a generic medicine is launched on to the market, the source price will be set at 60% of the real source price

The most significant change in the new Communiqué is that drug prices will be set once a year (rather than twice) according to a prescribed process between August and December each year:

• **August 15-September 1:** Application for the reference ex-factory price (the real source price) of the product.

• **September 2-30:** Evaluation period for medicine price applications and publication of price onto the intermediary list of prices.

• **October 1-7:** Admission period for objections to the intermediary list.

• **October 8-21:** Evaluation period for objections to the intermediary list.

• **October 21:** Publication of the amended intermediary list of medicine prices.

• **October 22-30:** Application period of equivalent (generic) products.

• **October 31-November 21:** Evaluation period for medicine price applications and publication of the second intermediary list.

• **November 22-28:** Admission period for objections to the intermediary list.

•**November 29-December 15:** Evaluation period for objections to the intermediary list and publication of final list of medicine

Another notable change is that if a 'similar equivalent' product is introduced to the market (same active ingredient and pharmaceutical form but with a different dosage of the active ingredient), the price of the original product will fall by 40%, essentially pricing both products as generics.

Market Access Issues

Currently in Turkey, the procedure for registering a pharmaceutical product with the Ministry of Health requires a GMP certificate to be submitted alongside the license application. The requirement is in line with most European and US procedures, which demand that drug makers have their manufacturing facilities inspected by regulatory authorities to ensure it is adequate to produce medicines in a safe and repeatable manner, for the protection of both employees and consumers. Therefore, acquiring the GMP certificate in most countries is a prerequisite for selling the pharmaceutical product on the market.

Although Turkey will accept submissions with GMP certificates issued in other countries, it will only do so if that country accepts the GMP certificates granted by the Turkish authorities. However, Turkey is not yet a member of the Pharmaceutical Inspection Convention and Cooperation Scheme, which provides guidance on international GMP standards. It therefore has to negotiate mutual agreements with each individual country to recognize each other's certification, which will further hinder the approvals process.

A GMP certificate, which must be submitted with each new drug application, can only be issued by the Ministry of Health following an on-site inspection of the manufacturing facility. The speed at which these inspections occur, while improved for some products, is delayed for others by opaque measures implemented in 2015. One such measure is the prioritisation of highly innovative and/or life-saving products with no alternatives in the country - but the process to identify an innovative product is unclear and often inconsistent.

The registration of medicines is required to take no more than 210 days according to current legislation; however, surveys have found that the average regulatory approval time in Turkey is 446 days. Changes to the Registration Regulation in 2010 have further exacerbated the delays in the approvals process. A GMP certificate, which must be submitted with each new drug application, can only be issued by the Ministry of Health following an on-site inspection of the manufacturing facility. The speed at which these inspections occur, while improved for some products, is delayed for others by opaque measures implemented in 2015. One such measure is the prioritization of highly innovative and/or life-saving products with no alternatives in the country - but the process to identify an innovative product is unclear and often inconsistent.

Local Industry

There are approximately 300 pharmaceutical entities operating in Turkey. Among the 81 manufacturing facilities in the country, 17of them are owned by multinational firms, according to the Pharmaceutical Manufacturers Association of Turkey (IEIS). Employment in the industry is around 35,000 people; a figure which increased during the last decade as the sector started attracting investment in both manufacturing and research activities. The top 25 companies hold a market share of 80% in value terms and employ around80% of the sales representatives operating in Turkey.

The Turkish drug sector has a strong industrial base, a large number of manufacturers and well-qualified human resources. The government is aiming to diversify its economy, with the pharmaceutical industry a key component of its development. The Vision2023 plan aims to boost domestic production of medicines to reverse the country's medicine deficit (which was USD3.1bn in 2018) and turn Turkey into a drug development and production hub and a net exporter of medicines. The government has sought to attract investment into the domestic industry, forming special pharmaceutical clusters, by providing incentives to multinationals such as corporate tax exemptions. Moreover, the state guarantees seven years of medicine procurement for multinational pharmaceutical firms when they partner with a local manufacturer to produce medicines within the country's borders.

Investment into the Turkish pharmaceutical industry has predominantly come in two forms: foreign direct investment into localised production through the construction of a medicine production facility, or cooperative agreements between multinational pharmaceutical forms and Turkish drug makers. We note that multinational pharmaceutical investment in Turkey remains relatively limited and the current environment is highly unattractive given the ongoing economic and political uncertainty. This will continue to restrict foreign direct investment into the domestic pharmaceutical production industry; instead, domestic firms are likely to increase their foothold. In addition, the pharmaceutical industry has been critical of the country's localisation policy, stating that it may disincentives' investment into the market.

Generic Drug Manufacturers

The Turkish pharmaceutical industry mainly produces non-innovative drugs including antibiotics, anti-rheumatics and analgesics, aswell as providing contract manufacturing services for multinationals. The industry is still in its development phase and does not haveenough funds to spend on product development, although the government has launched incentives to encourage R&D.

Turkey has a substantial pharmaceutical manufacturing sector, with a relatively large consumer base. Recent modernisation and new investments in production facilities have made the pharmaceutical sector one of the most progressive industries in Turkey. A significant proportion of generic sales in Turkey consist of unregistered copies, a considerable factor holding back the sector's high potential.

The Ministries of Economic Development and Health of Turkey are working to prepare a long-term strategic plan for the pharmaceutical sector in the country. Over the coming years, the two ministries hope to shape the development of a successful domestic industry within the spheres of pharmaceuticals, healthcare and medical devices.

The two ministries are aiming to influence the market such that domestic production of pharmaceuticals and medical devices will account for 60% and 20% of total domestic demand respectively (in volume terms).

Statistics

India Pharma exports to TURKEY by Category $ Million						
Category	2015-16	2016-17	2017-18	2018-19	2019-20	Change%
Bulk Drugs & Drug Intermediates	122.77	110.99	120.26	117.63	138.80	17.99
Drug Formulations & Biologicals	25.84	32.53	36.84	29.72	40.39	35.91
Ayush	0.70	0.67	0.81	0.89	0.92	4.23
Herbal Products	0.71	0.43	1.00	0.67	0.81	21.10
Surgical	4.15	5.07	6.70	7.45	8.13	9.16
Vaccines	5.50	16.11	7.84	8.19	27.52	235.85
Total	159.68	165.81	173.46	164.55	216.57	31.62

Imports of Turkey

Turkey's top Ten formulations Importing partners $ Mn					
Rank	**Country**	**2017**	**2018**	**GR%**	**Share%**
1	Germany	802.04	855.97	6.72	19.18
2	USA, Puerto Rico and US Virgin Islands	597.40	562.31	-5.87	12.60
3	Republic of Korea	175.24	377.83	115.61	8.46
4	Switzerland, Liechtenstein	394.09	355.05	-9.91	7.95
5	France, Monaco	332.83	306.49	-7.92	6.87
6	Italy	278.29	294.59	5.86	6.60
7	Ireland	381.67	288.92	-24.30	6.47
8	United Kingdom	366.89	280.60	-23.52	6.29
9	Belgium	152.45	149.90	-1.67	3.36
10	Spain	141.60	120.55	-14.87	2.70
18	India	62.31	58.24	-6.54	1.30
	Total of the above	3684.80	3650.44	-0.93	81.78
	World	4551.56	4463.55	-1.93	100.00
source:UNcomtrade					

REGISTRATION AND REGULATORY REQUIREMENTS

➢	**Regulatory Authority**	**:**	Turkish Medicines and Medical Devices Authority (TMMDA)
➢	**Website of regulatory Authority**	:	www.saglik.gov.tr
➢	**Fees for Drug Registration**	:	TRY 45,788 (produced abroad) TRY 22,894 (produced in Turkey)
➢	**Normal time taken for registration**	:	6-7 Months
➢	**Registration Requirement [Dossier Format]**	:	CTD
➢	**Whether plant inspection is mandatory**	:	No
➢	**Requirement of Local agent/ Subsidiary**	:	Local agent is not required for registration.

Regulatory

The main regulatory authority in Turkey is Medicines and Medical Devices Agency (TITCK). A number of laws, some dating back to 1928, comprise the basis for market regulation. The key piece of legislation is Registration Regulation of Medicinal Products for Human Use.

The key issues facing innovative pharmaceutical firms in key international markets are reported in the Pharmaceutical Research and Manufacturers of America (PhRMA)'s annual submission to the United States Trade Representative (USTR)'s Special 301 Report. The annual submission highlights countries with significant market access barriers to these pharmaceutical firms, including issues in intellectual property protection and regulatory approvals. As with the 2016-2018 submissions, Turkey has been recommended to be placed on the Priority Watch List of countries in the 2019 Special 301 Report. This designation identifies Turkey as having serious intellectual property rights deficiencies' that require increased USTR attention.

Notable market access barriers in Turkey for PhRMA and its members include a challenging and non-transparent pricing environment, weak intellectual property enforcement, a restrictive localisation policy and regulatory approval delays.

In the past few years, the PhRMA submissions have noted improvements in Turkey's regulatory environment, through increased dialogue between industry stakeholders and the government.

Furthermore, the Industrial Property Law (December 2015), the admission to the Pharmaceutical Inspection Co-Operation Scheme (PIC/S) in January 2018, and the TITCK's aim to become a full member of the International Council for Harmonisation (ICH) by 2021 have been highlighted as positive developments which will move Turkey toward closer alignment with international standards

About Turkish Medicines and Medical Devices Agency TMMDA:

The Turkish Medicines and Medical Devices Agency (TMMDA) is the governmental regulatory authority on human medicinal products, medical devices and cosmetics in Turkey.

•TMMDA is responsible for;

- Regulation
- Evaluation and
- Monitoring all these product groups

Main activities of TMMDA:

Marketing authorization of local/imported medicinal products

- Marketing authorization application dossier;

A. new medicinal product

B. generic medicinal product

C. biological and biotechnological medicinal product

D. traditional herbal medicinal product

E. advance therapy medicinal product

- Medical devices

Registration to Republic of Turkey Medical Devices and Drugs Databank (TITUBB)

- Cosmetic products

Notification

- Analysis and control process of medicines, medical devices, cosmetics, biotechnological products, enteral nutrition products, biological products
- GxP inspections & Certification of manufacturing sites of human medicinal products
- Market surveillance of medical devices & cosmetics
- Pharmaceutical Track & Trace System (ITS)

DOCUMENTS TO BE PRESENTED AT THE REGISTRATION APPLICATION FOR MEDICINAL PRODUCTS

Introduction and general principles

(1) The particulars and documents accompanying an application for registration pursuant to the provisions of this

Regulation, shall be presented to the Ministry in accordance with the requirements set out in this Annex and shall follow the guidelines published by the Ministry regarding the Common Technical Document (CTD). Pursuant to the enforcement of the Common Technical Document to be published by the Ministry as guidelines, applications shall be submitted in accordance with the referred guidelines.

(2) The particulars and documents shall be presented as five modules:

Module 1 Administrative Data

Module 2 Quality Information, Non-clinical and Clinical Summaries

Module 3 Chemical, Pharmaceutical and Biological Information

Module 4 Non-clinical Reports

Module 5 Clinical Study Reports

(3) The presentation of CTD to the Ministry is applicable for all types of registration applications irrespective of whether they are based on a full or abridged application. It is also applicable for all types of products including new chemical entities (NCE), radio-pharmaceuticals, plasma derivatives, vaccines, herbal medicinal products, etc.

(4) In assembling the dossier for application for registration, applicants shall also take into account the other legislation published by the Ministry, pertaining to medicinal products for human use.

(5) With respect to the quality part (chemical, pharmaceutical and biological) of the dossier, all monographs including general monographs and general sections of the European Pharmacopoeia are applicable. The manufacturing process shall comply with the requirements of the "Regulation Regarding the Manufacturing Sites of Medicinal Products for Human Use", published on the Official Gazette dated 23/10/2003, with no. 25268 and with the principles set forth in the guidelines prepared on the basis of this Regulation.

(6) All information, which is relevant to the evaluation of the medicinal product concerned, shall be included in the application, whether favorable or unfavorable to the product. In particular, all relevant details shall be given of any incomplete or abandoned pharmaco-toxicological or clinical test or trial relating to the medicinal product and/or completed trials concerning therapeutic indications not covered by the application.

(7) All clinical trials conducted in Turkey, must fully comply with the requirements of the "Regulation Regarding Drug Trials", published on the Official Gazette dated 29/01/1993, with no. 21480. During the assessment of an application, clinical trials, conducted outside Turkey, which relate to medicinal products intended to be used in Turkey, shall be designed, implemented and reported on the basis of good clinical practice and ethical principles which have been set forth in accordance with the principles specified in the relevant Regulation..

(8) Non-clinical (pharmaco-toxicological) studies shall be carried out in conformity with the provisions specified in the "Regulation Regarding Good Laboratory Practice Principles and the Documentation of Test Laboratories" published on the Official Gazette dated 25/06/2002, with no. 24796 and in the "Regulation Regarding the Inspection of Good Laboratory Practice and the Control of the Studies", published on the Official Gazette bearing the same date and number.

(9) All tests conducted on animals for experimental and other scientific purposes, shall be carried out in accordance with the relevant legal arrangements, for ensuring the protection of animals.

(10) In order to monitor the benefit/risk assessment, any new information not in the original application and all Pharmacovigilance information shall be submitted to the Ministry. After registration has been granted, any change to the data in the dossier shall be submitted to the Ministry, in accordance with the provisions of the relevant guidelines and, if relevant, Pharmacovigilance implementations.

This Annex has been divided into four different parts:

Section I: describes the application format, the summary of product characteristics, the labeling, the leaflet and presentation requirements for all registration applications (Modules 1 to 5).

Section II: comprises 'Specific applications', i.e. well-established medicinal use, essentially similar products, fixed combinations, similar biological products, exceptional circumstances and mixed applications (bibliographic part and the part comprising own studies).

Section III: deals with 'Particular application requirements' for biological medicinal products (Plasma Master File; Vaccine Antigen Master File), radio-pharmaceuticals, herbal medicinal products and orphan medicinal products.

Section IV: deals with 'Advanced therapy medicinal products' and concerns specific requirements for gene therapy medicinal products (using human autologous or allogeneic system, or xenogeneic system) and cell therapy medicinal products both of human or animal origin and xenogeneic transplantation medicinal products.

Among the products of which marketing authorization applications are made, it is aimed to complete the registration process of high priority products in 150 days and of priority products in 180 days.

Issuance of Registration

As a result of the inspection and evaluation of the information and documents submitted by the applicant to the Ministry, the product determined to be in compliance with the aspects envisaged by this Regulation shall be drafted and the applicant shall be duly informed.

A second local or import registration shall not be issued for any product with the same formulation and pharmaceutical form, registered by the Ministry, to the same real or legal person, even if the product has a different commercial name.

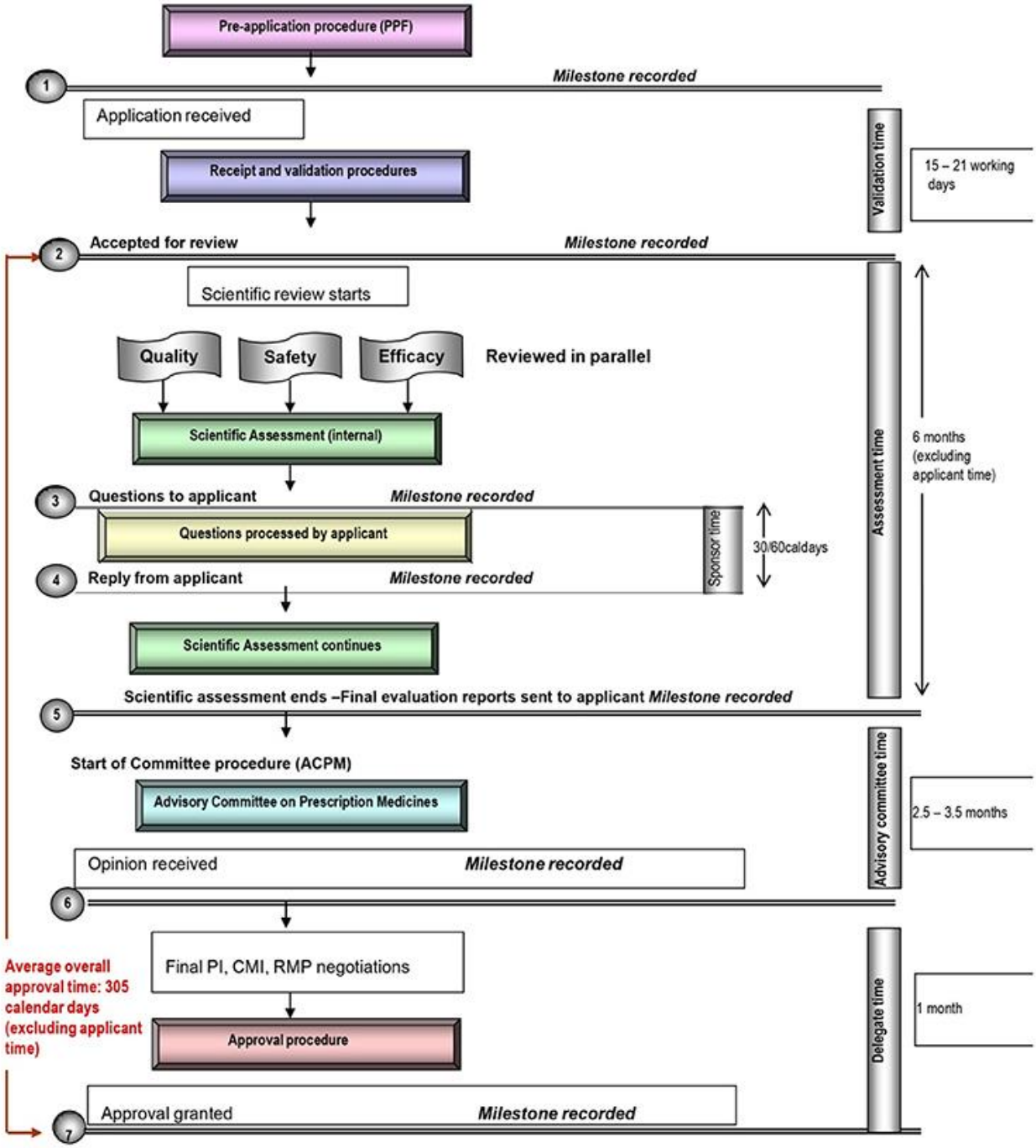
The names of products for which a registration is issued by the Ministry, shall be declared on the Official Gazette with the name and surname as well as the registration number of the application holder.

Validity of Registration

By no later than 3 (three) months before the end of 5th (fifth) year after the grant of authorization, the authorizations shall be presented to the Ministry with necessary Pharmacovigilance data as well as the data on quality, safety and efficacy, reflecting all changes that occurred since the grant of authorization.

The marketing authorizations granted are valid for 5 years.

Process of Registration:



REFERENCES:

- CIA world fact book last updated in June 2020. https://www.cia.gov/library/publications/the-world-factbook/geos/tu.html

- Research article on Pharmaceutical industry of Turkey prepared by Directorate general of Exports, Ministry of Economy Turkey 2018. https://www.trade.gov.tr/data/5b9229ab13b876136466584b/Turkey.pdf

- Presentation on TMMDA by Gulsen ONER, Pharm. M.Sc. & Melda KECIK, Pharm. M.Sc. https://www.who.int/medicines/technical_briefing/tbs/TURKEY_TBS_KECIK_ONER_2014.pdf?ua=1

- Article on Regulation on the Registration of Medicinal Products for Human Use by Ministry of health Turkey .https://titck.gov.tr/storage/legislation/QEv7VEBH.pdf

- Turkish Medicines And Medical Devices Agency Guideline For Working Principles And Procedures Of Human Medicinal Products Priority Assessment Commission https://titck.gov.tr/storage/legislation/QgR2Se2X.pdf

- Article on Turkey Pharmaceuticals and Biopharmaceuticals 2020 by Global Business reports. https://www.gbreports.com/publication/turkey-pharmaceuticals-biopharmaceuticals-2020

- Article on Regulatory, Pricing and Reimbursement of pharmaceuticals in Turkey by Moroğlu Arseven / Turkey 2018. https://pharmaboardroom.com/legal-articles/regulatory-pricing-and-reimbursement-turkey/

Details of Indian Embassy abroad: https: https://www.indembassyankara.gov.in/

Details of importing country Embassy in India: http://newdelhi.emb.mfa.gov.tr/Mission