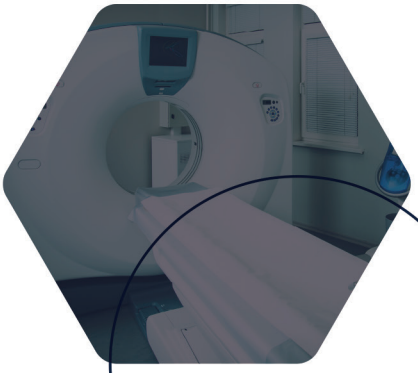
Turkish Medicines and Medical Devices Agency



Republic of Turkey
Ministry of Health
Turkish Medicines and Medical Devices Agency

Contents

* **Ü**rün **T**akip **S**istemi
** **İ**laç **T**akip **S**istemi
*** **E**lektronik **S**üreç **Y**önetimi

Our Mission

To serve human health by developing and implementing regulatory, supervisory, and guidance policies in regard to pharmaceuticals, medical devices and cosmetic products.

Our Vision

Being a pioneer and a reference institution in the international arena aiming for excellence, on the basis of health and science

Our Values

The core values of Turkish Medicines and Medical Devices Agency (TİTCK) are:

- scientificity
- transparency
- honesty
- equity
- service with quality
- acting with diligence
- liability
- self-criticism
- respectability
- value all people

President's Message

As Turkish Medicines and Medical Devices Agency, we serve as a supervisory, regulatory and leading authority relating to products such as medicines, medical devices, cosmetics, traditional herbal medicinal products, advanced therapy products, medicinal nutrition products that public can encounter at any time in their daily life.

These products mentioned above are strategic with regard to country politics, huge in terms of market size and substantial product groups that should be evaluated well as they are in contact with public health. We manage such a critical area with a well-trained, well-equipped, more than 1000 staff group consisting of pharmacists, doctors, engineers, chemists and biologists.

While we have an important role as a regulatory authority of which past based on many years, especially in the field of medicine, we come to the forefront with our leading role in recent years. In this context, we have put a new approach called "Value Based Licensing" into force. As a part of this approach we have established a prioritization mechanism in order to ensure that authorization processes of significant medicine groups such as innovative medicines, generic medicines which reduce health expenditures and guarantee the access to medicines and medicines that have export potential are carried out more quickly.

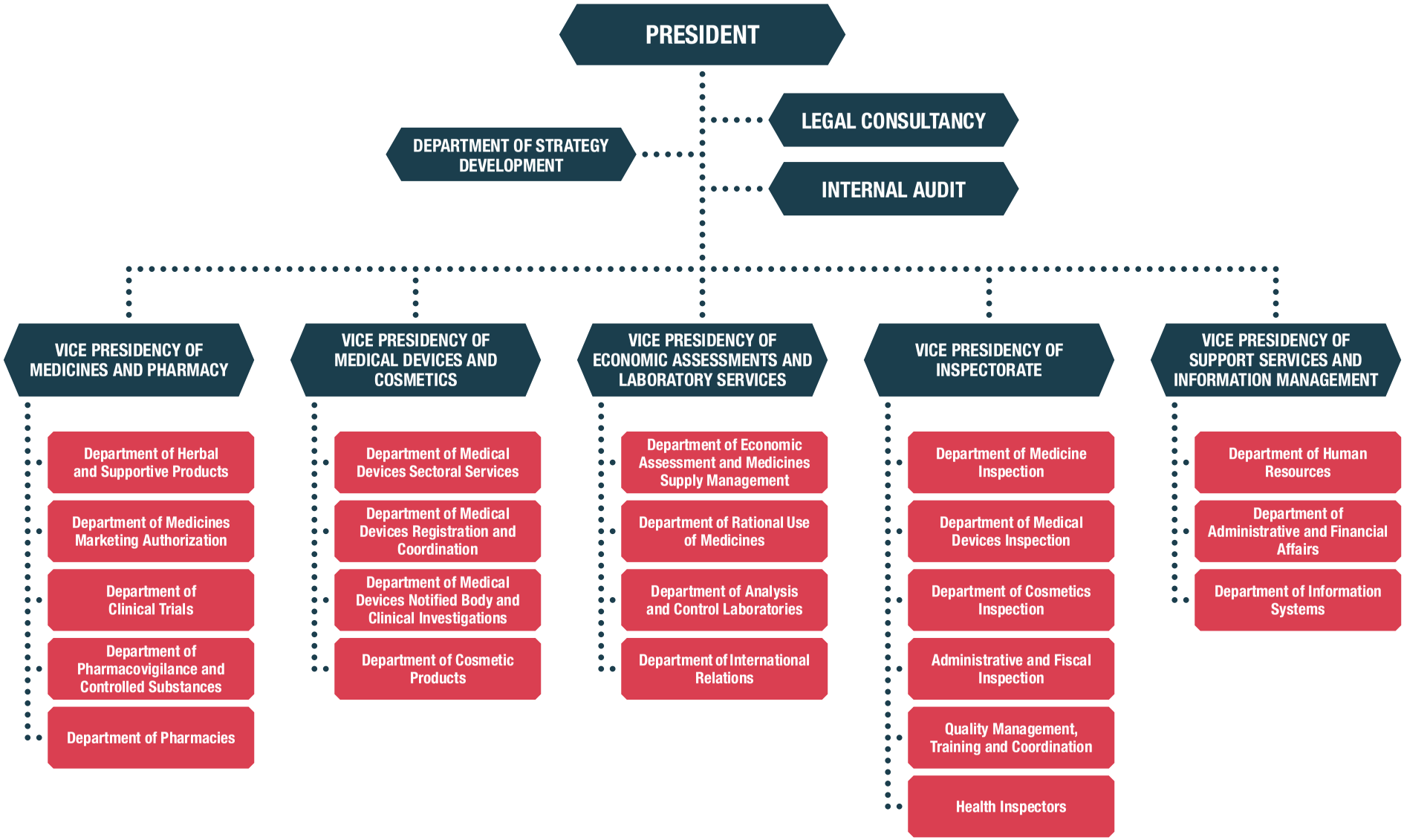
As a part of our leading activities, we have undertaken the secretariat duty of the Health Industries Steering Committee which can gather medicine and medical device sector and relevant ministries and public institutions around a table and overcome a huge gap in this area.

In the upcoming period, we will also continue to develop together with the sector towards the goal of becoming an institution recognized and referenced internationally.

Dr. Hakkı GÜRSÖZ
President of Turkish Medicines
and Medical Devices Agency

National Regulatory Authority

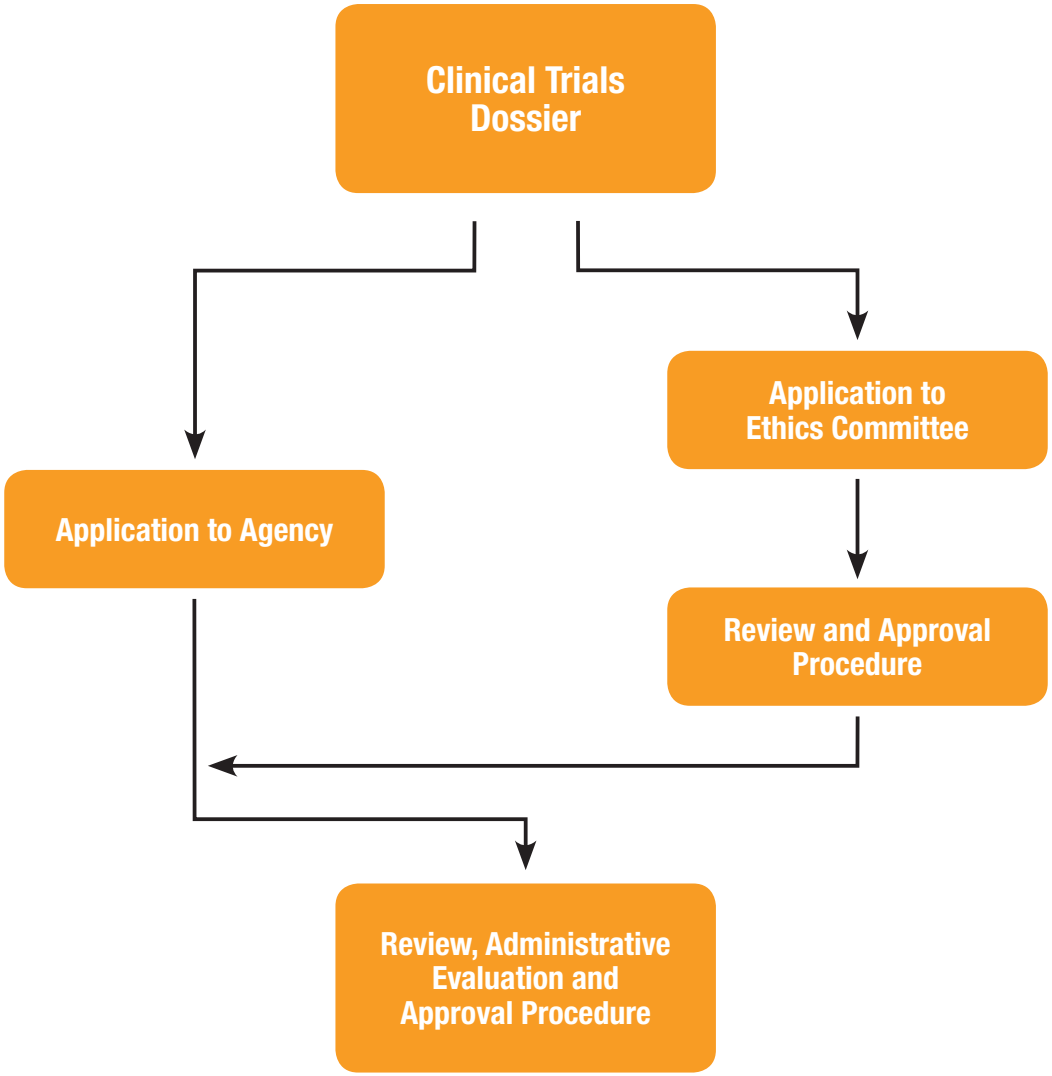
Organization Chart



We *evaluate* and closely *monitor* the clinical trials of all human medicinal products in compliance with international legislation

Clinical Trials

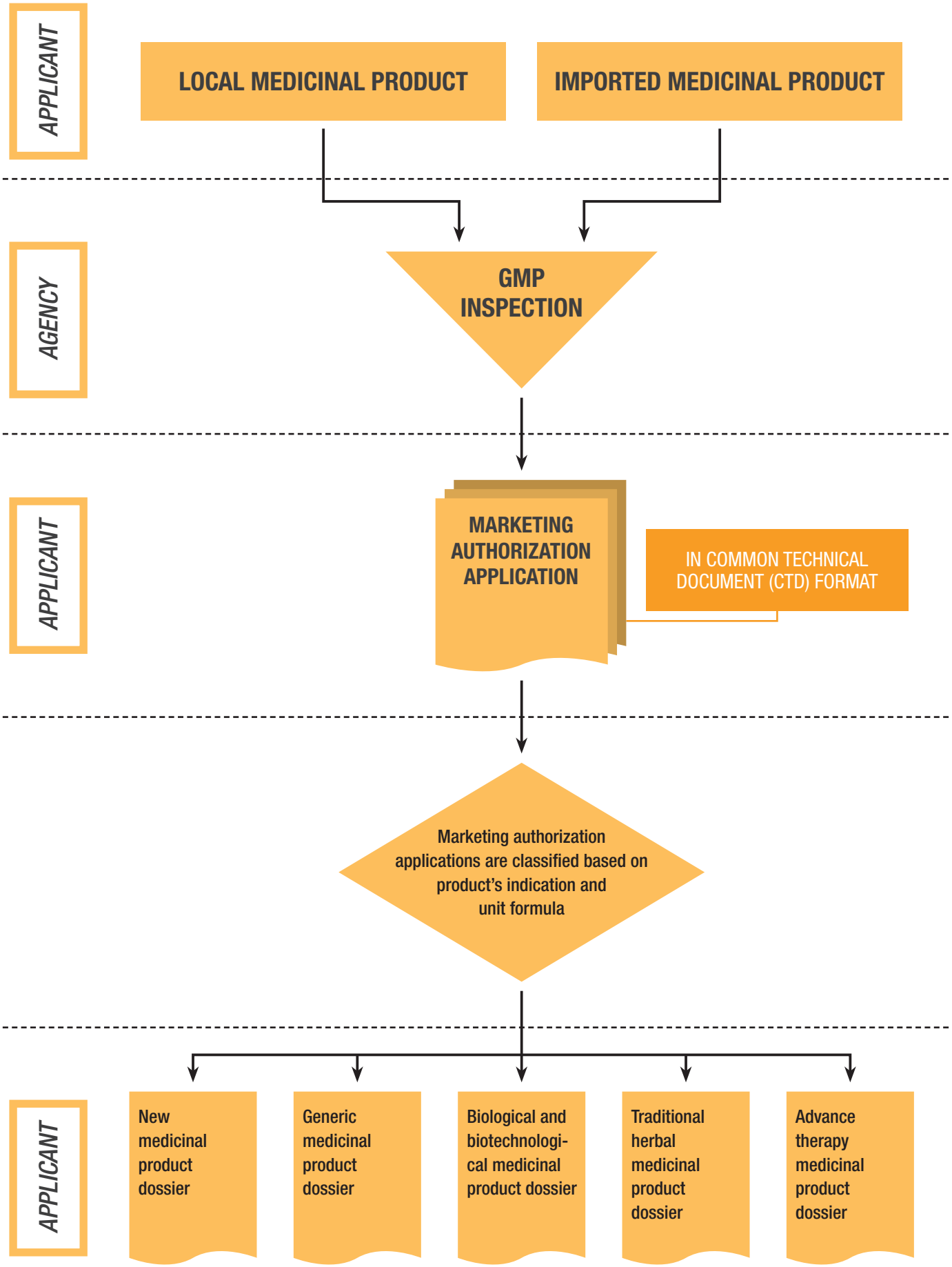
Application and Assessment Procedure

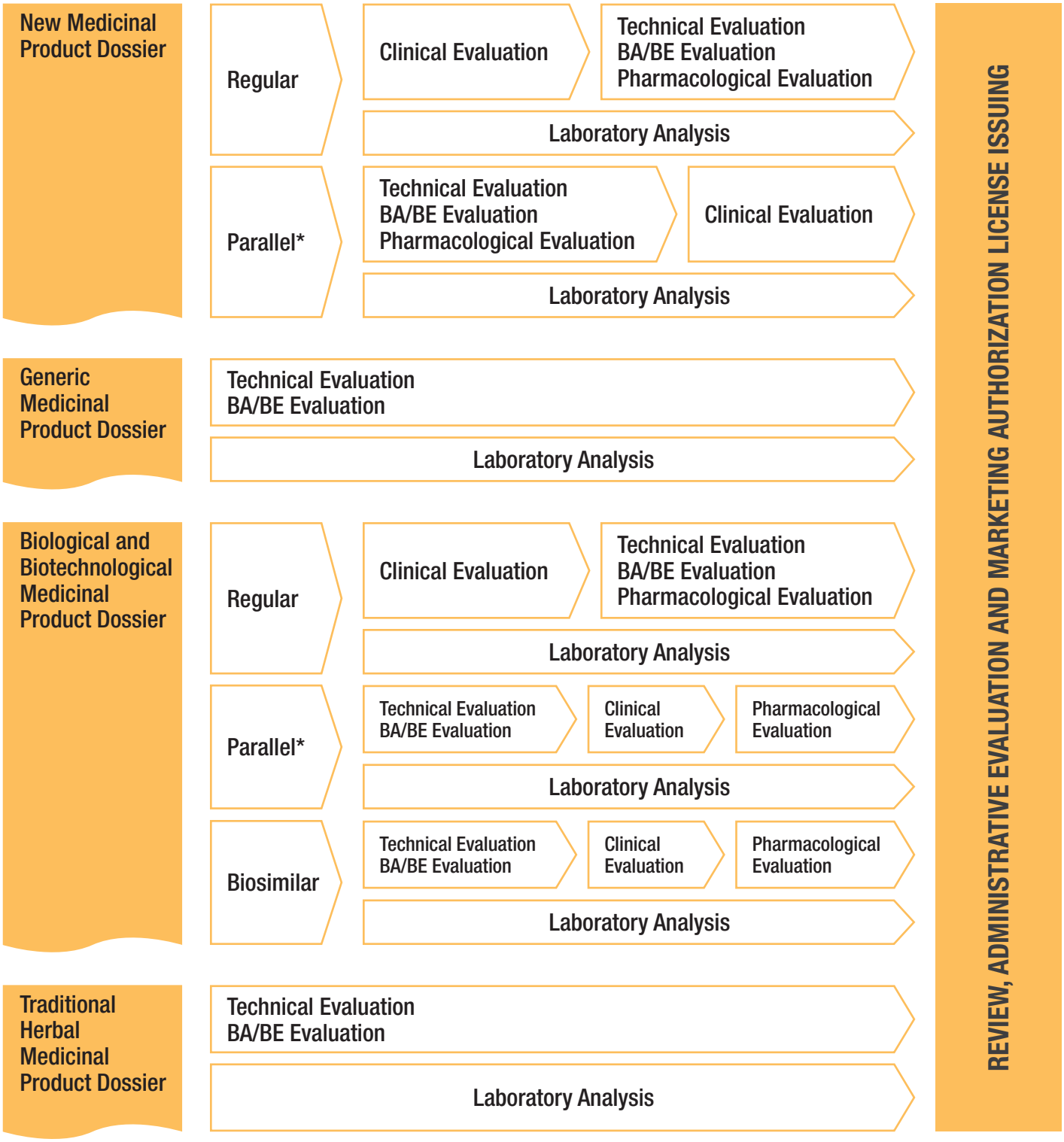


Parallel submission to both Ethics Committee and Agency

Official time for evaluation procedure is 7-15 days for Ethics Committee and 30 days for Agency

Marketing Authorization





* When marketing authorization application- for unauthorized medicinal products in worldwide- is obtained at the same/close date as in another country, this application is named as parallel application.

Marketing Authorization Process
GMP Inspections

1. GMP Prioritisation Application
2. GMP Inspection
3. GMP Certification

- GMP Prioritisation Applications can be made before the GMP Inspection Applications or simultaneously. (GMP 1, 2, 3)
- Marketing authorization process is **150 days** for high priority status.

Conventional Products

1. GMP for finished product must be issued by TİTCK
2. GMP for active substance is acceptable approval of other authorities
3. * GMP 1 is only for finished product: Application is acceptable without GMP certification

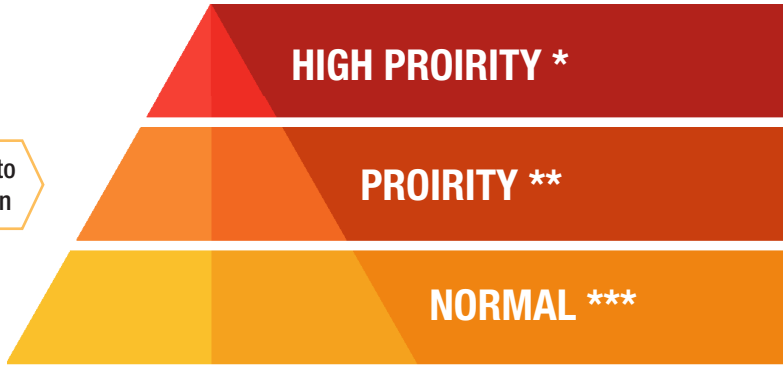
Biotechnological Products

1. GMP for finished product and active substance must be issued by TİTCK
2. * GMP 1 is for finished product and active substance: Application is acceptable without GMP certification.

* For the applications we accepted without the GMP documents to be issued by TİTCK, a document showing that GMP application has been made should be submitted to the Agency and GMP document should be submitted before marketing authorization.

Prioritization

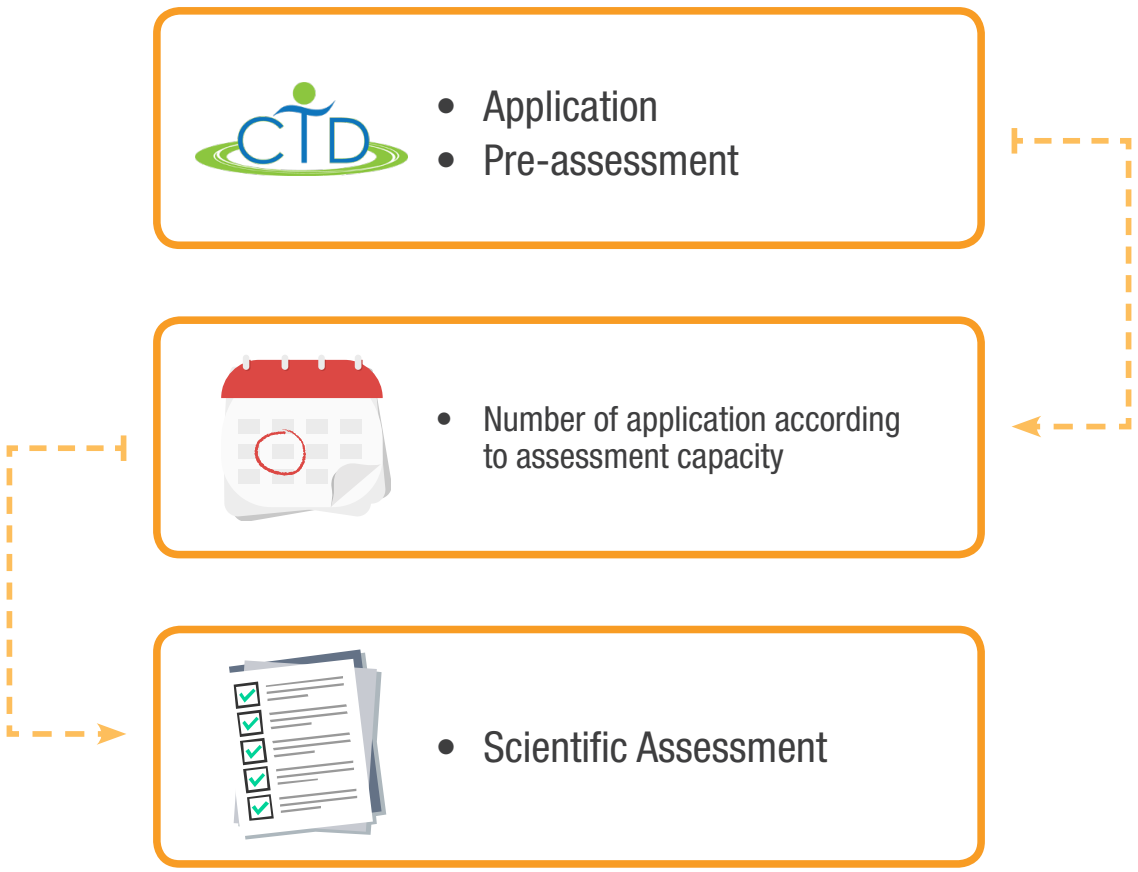
According to the importance with regards to public health and public finance, innovation



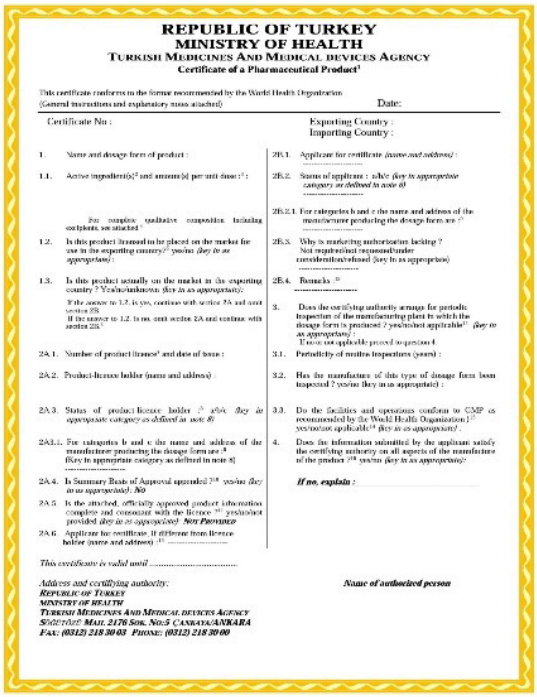
* Time of marketing authorization is **150** days
** Time of marketing authorization is **180** days
*** Time of marketing authorization is **210** days

Note
These periods do not include “clock stop” and “analysis” processes.

Slot Implementation



Certificates for Export



REPUBLIC OF TURKEY
MINISTRY OF HEALTH
TURKISH MEDICINES AND MEDICAL DEVICES AGENCY
Certificate of a Pharmaceutical Product[1]

This certificate conforms to the format recommended by the World Health Organization
(General instructions and explanatory notes attached)

Date:

Certificate No :

Exporting Country :
Importing Country :

1. Name and dosage form of product :

1.1. Active ingredient(s)[2] and amount(s) per unit dose[3] :

For complex qualitative composition. Including excipients, if so attached :

1.2. Is this product licensed to be placed on the market for use in the exporting country?[4] yes/no *(key in as appropriate)* :

1.3. Is this product actually on the market in the exporting country ? Yes/no/unknown *(key in as appropriate)*:

If the answer to 1.3. is yes, continue with section 2A and omit section 2B.
If the answer to 1.2. is no, omit section 2A and continue with section 2B.[5]

2A.1. Number of product licence[6] and date of issue :

2A.2. Product-licence holder (name and address) :

2A.3. Status of product licence holder [7] *who they is appropriate category as defined in note 8)*

2A3.1. For categories b and c the name and address of the manufacturer producing the dosage form are [8]
(Key in appropriate category as defined in note 8)

2A.4. Is Summary Basis of Approval amended [9] *yes/no (key in as appropriate). No*

2A.5 Is the attached, officially approved product information complete and consistent with the licence [10] yes/no/not provided *(key in as appropriate)*. *Not Provided*

2A.6 Applicant for certificate, if different from licence holder (name and address) [11] .....

2B.1. Applicant for certificate *(name and address)* :

2B.2. Status of applicant : *who (key in appropriate category as defined in note 8)*

2B.2.1. For categories b and c the name and address of the manufacturer producing the dosage form are [8]

2B.3. Why is marketing authorization lacking ?
Not required/not requested/under consideration/refused *(key in as appropriate)*

2B.4. Remarks : [12]

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant by which the dosage form is produced ? yes/no/not applicable[13] *(key in as appropriate)* :
If none not applicable proceed to question 4

3.1. Periodicity of routine inspections (years) :

3.2. Has the manufacture of this type of dosage form been inspected ? yes/no (key in as appropriate) :

3.3. Do the facilities and operations conform to GMP as recommended by the World Health Organization ? [14] yes/no/not applicable[14] *(key in as appropriate)* :

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product [15] yes/no *(key in as appropriate)*:

If no, explain :

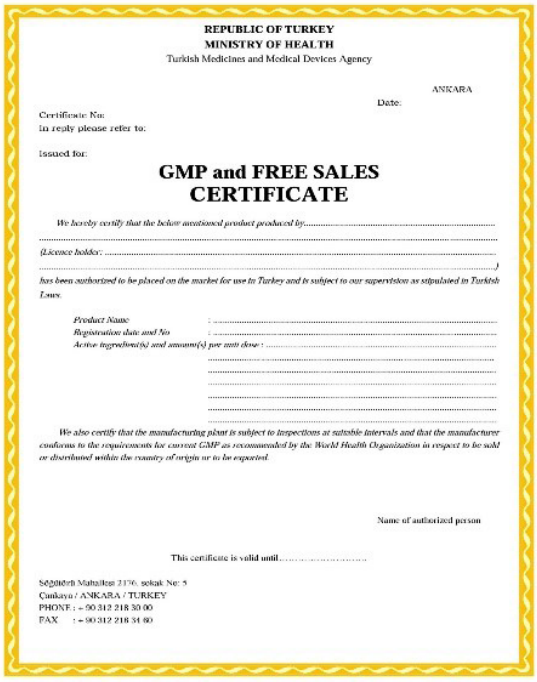
This certificate is valid until .....

Address and certifying authority:
REPUBLIC OF TURKEY
MINISTRY OF HEALTH
TURKISH MEDICINES AND MEDICAL DEVICES AGENCY
Street: MAH. 2176 SOK. NO:5 CANKAYA/ANKARA
FAX: (0312) 218 30 05 PHONE: (0312) 218 30 00

Name of authorized person

Medical devices vigilance system

The Certificate of a Pharmaceutical Product (CPP) is a certificate issued in the format recommended by the World Health Organization (WHO), which establishes the status of the pharmaceutical product and of the applicant for this certificate our country. (Ref. www.who.int)



REPUBLIC OF TURKEY
MINISTRY OF HEALTH
Turkish Medicines and Medical Devices Agency

ANKARA

Date:

Certificate No:
In reply please refer to:

Issued for:

GMP and FREE SALES CERTIFICATE

We hereby certify that the below mentioned product produced by.....

(Licence holder: .....)

has been authorized to be placed on the market for use in Turkey and is subject to our supervision as stipulated in Turkish Laws.

Product Name : .....
Registration date and No : .....
Active ingredient(s) and amount(s) per unit dose : .....

We also certify that the manufacturing plant is subject to inspections at suitable intervals and that the manufacturer conforms to the requirements for current GMP as recommended by the World Health Organization in respect to be sold or distributed within the country of origin or to be exported.

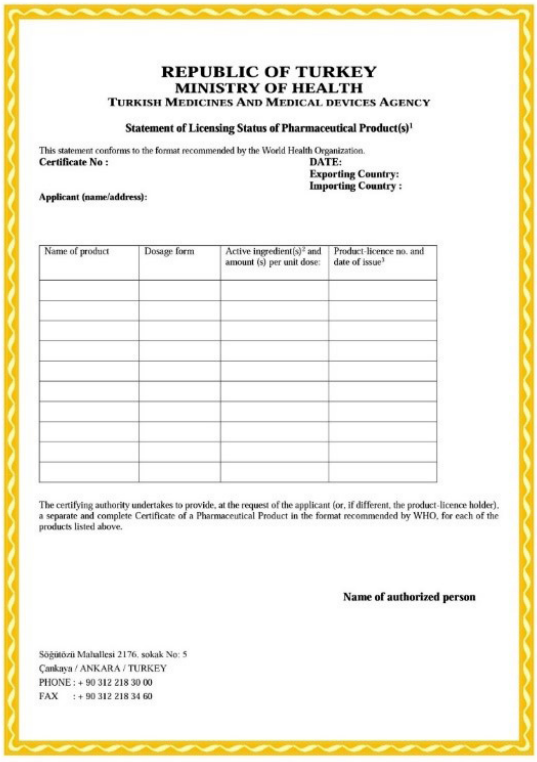
Name of authorized person

This certificate is valid until.....

Söğütözü Mahallesi 2176. sokak No: 5
Çankaya / ANKARA / TURKEY
PHONE : + 90 312 218 30 00
FAX : + 90 312 218 34 60

GMP and Free Sale Certificate

GMP and Free Sale Certificate indicate that the pharmaceutical product has been authorized to be placed on the market for use in our country and is subject to our supervision as stipulated in Turkey. It certifies that the manufacturer conforms to the requirements for current GMP as recommended by the World Health Organization in respect to be sold or distributed within the country of origin or to be exported. (Ref. www.who.int)



REPUBLIC OF TURKEY
MINISTRY OF HEALTH
TURKISH MEDICINES AND MEDICAL DEVICES AGENCY

Statement of Licensing Status of Pharmaceutical Product(s)[1]

This statement conforms to the format recommended by the World Health Organization.
Certificate No : **DATE:**
Exporting Country:
Importing Country :

Applicant (name/address):

Name of product	Dosage form	Active ingredient(s)[2] and amount (s) per unit dose:	Product-licence no. and date of issue[3]

The certifying authority undertakes to provide, at the request of the applicant (or, if different, the product-licence holder), a separate and complete Certificate of a Pharmaceutical Product in the format recommended by WHO, for each of the products listed above.

Name of authorized person

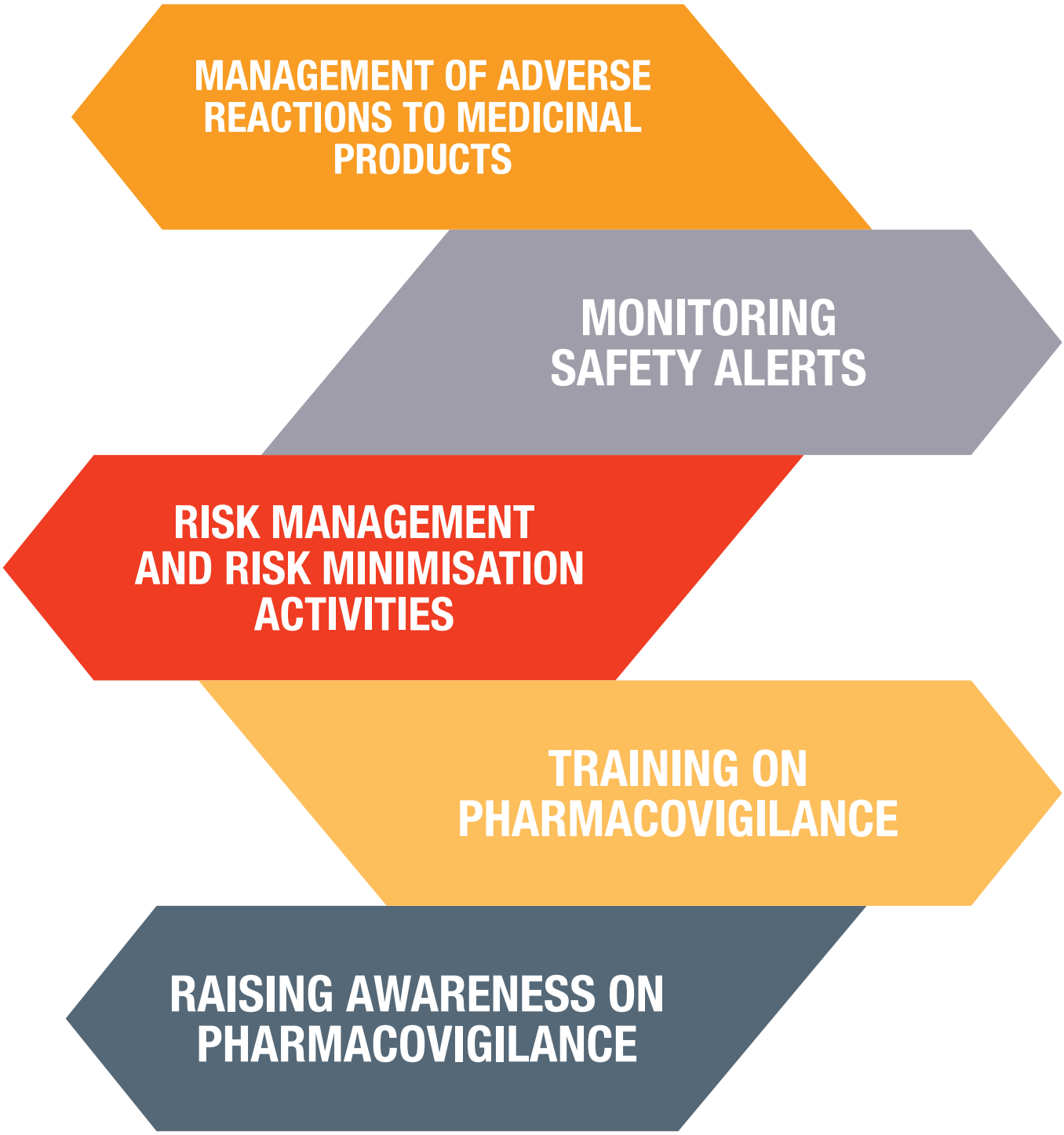
Söğütözü Mahallesi 2176. sokak No: 5
Çankaya / ANKARA / TURKEY
PHONE : + 90 312 218 30 00
FAX : + 90 312 218 34 60

Statement of Licening Status of Pharmaceutical Product (SLSPP)

The Statement of Licensing Status of Pharmaceutical Product indicates the licensing status of pharmaceutical products and undertakes to provide, at the request of the applicant (and, if different, the product-license holder), a separate and complete Certificate of a Pharmaceutical Product in the format recommended by WHO, for each of the products listed. (Ref. www.who.int)

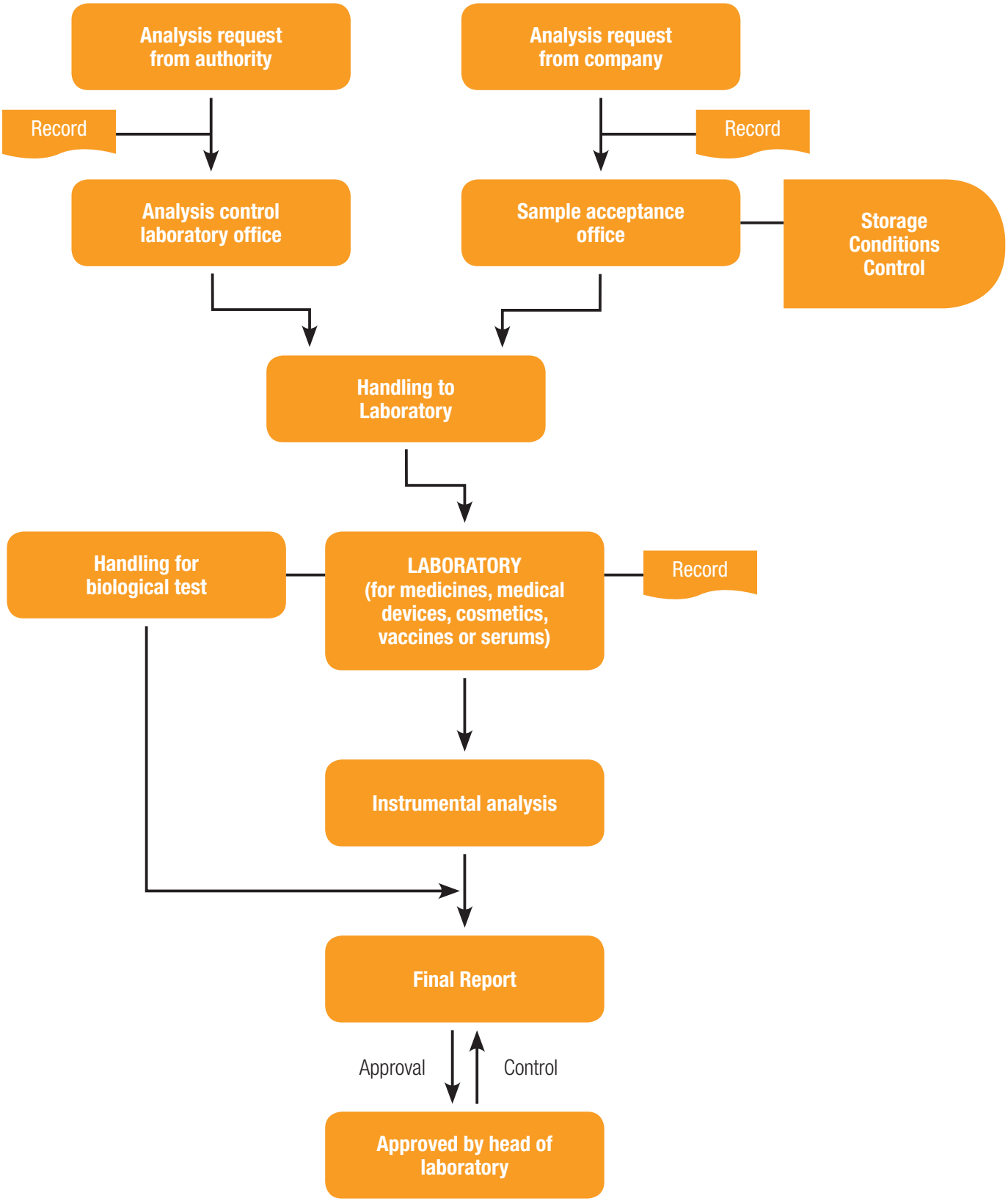
We closely
monitor the safety
of medicines and
take measures
to minimise risk

Our Pharmacovigilance Activities



We
conduct analysis
for all medical
products

Analysis and Control Process



We
inspect and *audit*
all human
medicinal products

GxP Inspections

Establishment of GMP in Turkey;

First Regulation on GMP for Human Medicinal Products was implemented in 1984 in Turkey by the Ministry of Health.

Legislation for GMP Inspections:

1. Pharmaceutical and Medical Preparations Law, No: 1262
2. Regulation on Manufacturing Plants of Medicinal Products for Human Use (Last Update April 27, 2013)
3. First GMP Guideline on Good Manufacturing Practise for Manufacturing Plants of Medicinal Products for Human Use was published in 1994.
4. Updated GMP Guideline (Compatible with the PIC/S GMP guideline) was approved on May 05, 2016. It has been effective since Sept 30, 2016. GMP Guideline Version 2017/01 approved on Sept 07, 2017. It's compatible with PIC/S GMP Guide V.PE009-13.

International regulations and guidelines have been implemented into our legislation. All manufacturers must comply with the cGMP requirements.

In scope of GMP Inspections:

Inspectors carry out domestic inspections in Finished Product Manufacturing Sites For Human Use, Active Pharmaceutical Ingredients (APIs) and Excipients Manufacturing Sites, Biological Medicinal Product Manufacturing Sites, Advance Therapy Medicinal Product Manufacturing Sites, Centers for Human Cells and Tissues, Radiopharmaceutical Manufacturing Sites, Herbal Medicinal Product Manufacturing Sites, Special Dietary Products Manufacturing Sites, Medical Gases Production and Filling Sites, Contracted Testing Laboratories, Secondary Packaging Sites.

Human Medicinal Product Manufacturing Sites as well as Drug Substance Manufacturing Sites of biological/biotechnological products are inspected abroad.

PIC/S

TİTCK made full membership application to PIC/S on May 03, 2013. The PIC/S Committee accepted the PIC/S membership application made by TİTCK. The PIC/S membership of TİTCK will become effective as of January 01, 2018.

GCP/GLP, GDP, GPvP inspections and marketing surveillance for medicinal products for human use

Based on the relevant regulations, GCP/GLP, GDP, GPvP inspections are conducted by auditors.

In scope of the GDP (Good Distribution Practices) inspections:

Pharmaceutical wholesalers, exporter/importer pharmaceutical warehouses and where necessary the pharmacies are inspected in order to ensure that the quality, efficacy and safety of medicines are maintained throughout the supply chain.

In scope of the GPvP (Good Pharmacovigilance Practices) inspections:

GPvP inspections are conducted in order to determine and ensure that marketing authorisation holders and contracted pharmacovigilance service organizations comply with the pharmacovigilance obligations in Turkey.

In scope of the GCP/GLP (Good Clinical /Laboratory Practices) inspections:

Domestic and foreign facilities where bioavailability /bioequivalence trials are conducted and domestic Phase I centers are inspectedand certifed within the scope of routine system inspection.

Phase II-III-IV clinical trials, sponsors, contracted research organisations and ethical committees are inspectedas part of triggered/risk based inspections.

In scope of marketing surveillance:

The human medicinal product samples taken from the market according to a risk based market surveillance program and those samples are sent to our laboratories for analysis in order to check the quality of products in the domestic market.

Pharmacies

In order to increase quality of pharmacy service, make people benefit more effectively from the pharmacy service and help public health protection, health-oriented, science-based regulations aiming excellence have been carried out.

It is allowed to open pharmacies through the Pharmacist Placement System (PPS) in accordance with the planning of pharmacy numbers in terms of population.

Medical devices; another big area of responsibility

Legislation

Three main EU Directives relating to medical devices are harmonized to Turkish Legislative Acts by Agency

1

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (**M**edical **D**evices **D**irective - **MDD**)

Relevant Turkish Legislation: Directive on Medical Devices published in Official Journal numbered 24694 and dated 13.03.2002

2

Directive 98/79/EC of The European Parliament and of the Council of 27 october 1998 on in vitro diagnostic medical devices (**I**n **V**itro **D**iagnostics **D**irective - **IVDD**)

Relevant Turkish Legislation: Directive on In Vitro Diagnostic Medical Devices published in Official Journal numbered 25259 and dated 14.10.2003

3

Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (**A**ctive **I**mplantable **M**edical **D**evices **D**irective - **AIMDD**)

Relevant Turkish Legislation : Directive on Active Implantable Medical Devices published in Official Journal numbered 24693 and dated 13.03.2002

Notified Bodies

Medical Devices are subject to conformity assessment procedures to ensure compliance to Medical Devices Directives provisions before placing them on the market.

As well as manufacturers, Notified Bodies also take part in conformity assessment procedures for all medical devices excluding Class I non-sterile and without a measuring function (low risk) ones.

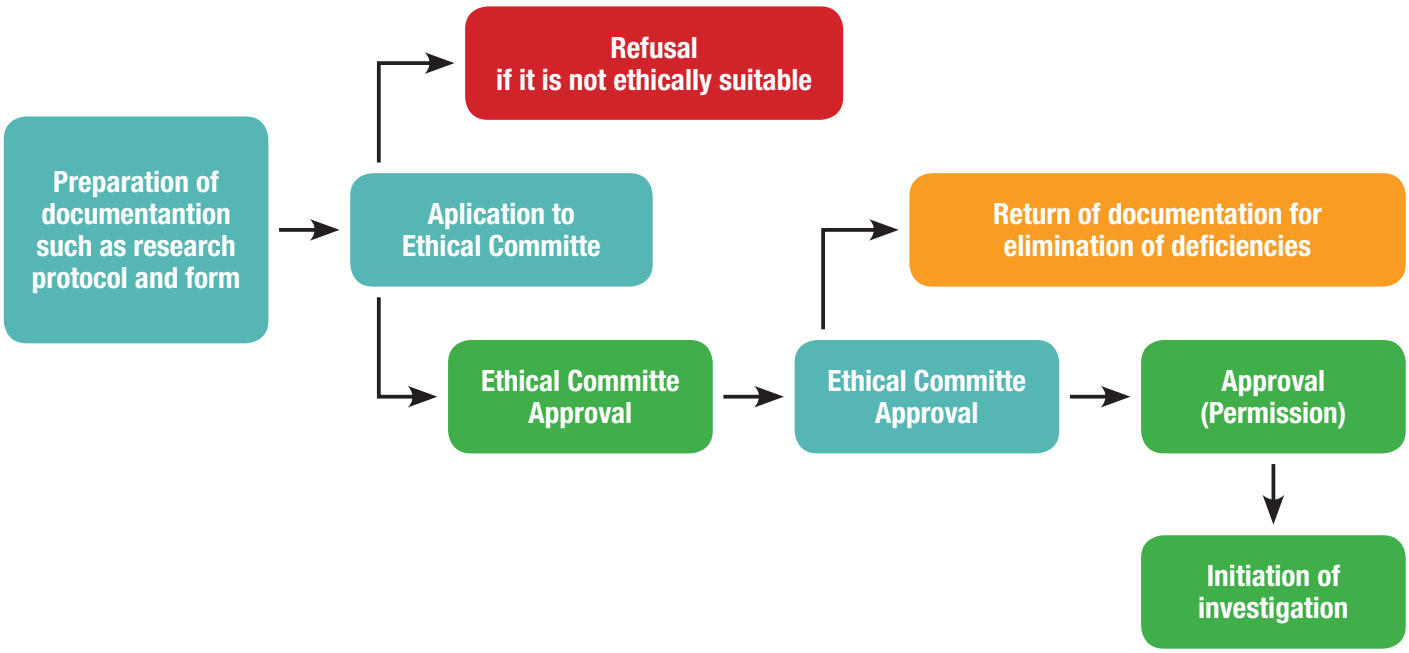
Designations and inspections of Notified Bodies taking place in the territory of Turkey are carried out by our Agency.

Such as over 50 EU Notified Bodies currently designated by their competent authorities, there are five Notified Bodies already designated by our Agency for all or some product categories according to Medical Devices Directives.

Clinical Investigations

Permission is reguired from our Agency for clinical investigations relating to medical devices.
The application process for medical device clinical investigations is as follow:

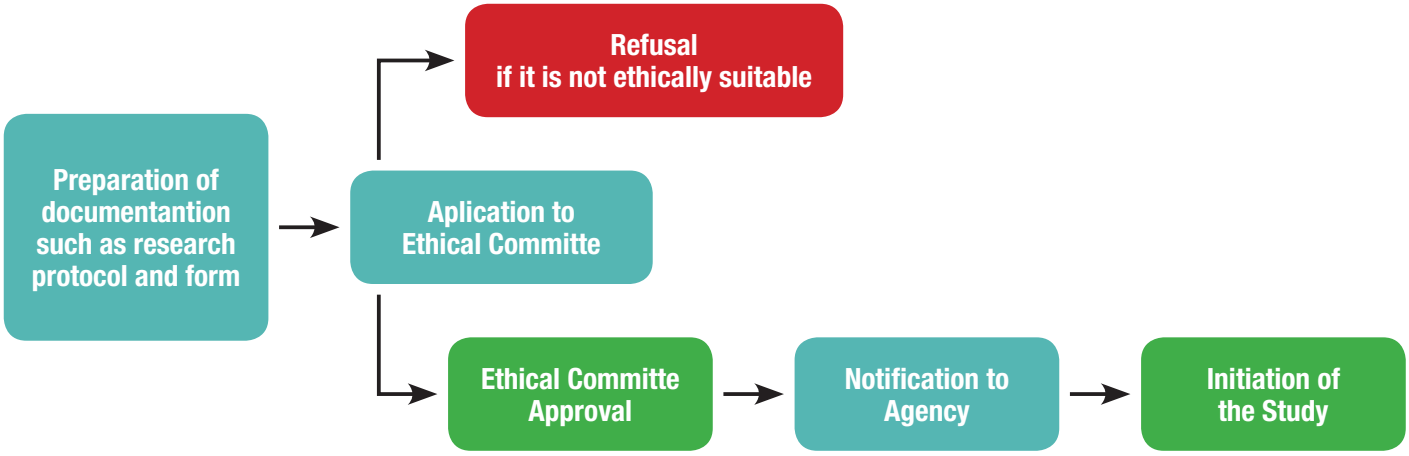
The Application Process for Medical Device Clinical Investigations



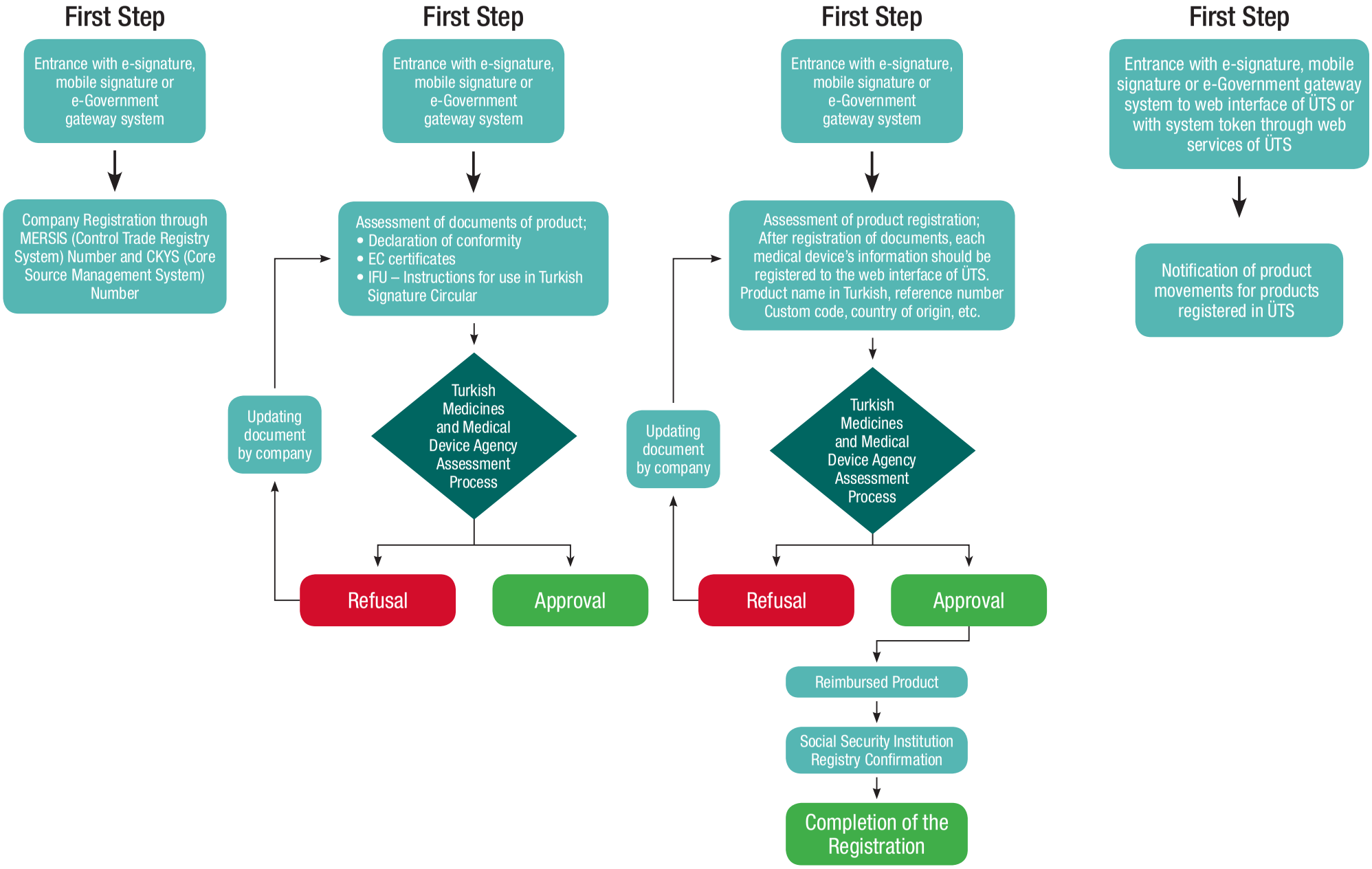
Performance Evaluations Studies for IVD

Recording of performance evaluation and verification studies performed with in vitro diagnostic medical devices is carried out by our Agency. The application process for performance evaluation studies is as follow:

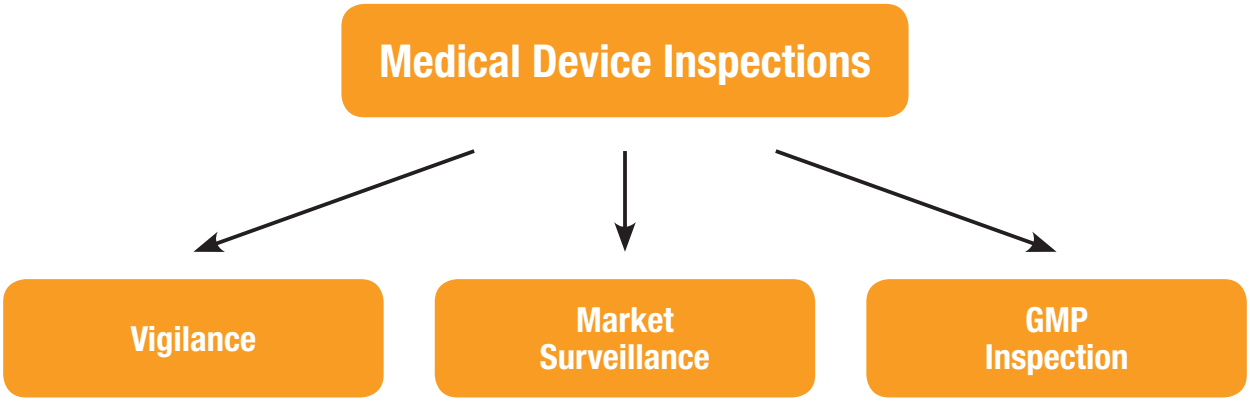
The Application Process for Performance Evaluation Studies on In Vitro Diagnostic Medical Devices



Registration to Product Tracking System (ÜTS)



Safe *medical devices* & improved patient safety and public health



Medical devices vigilance system to improve the protection of health and safety of patients, users and others by reducing the likelihood of reoccurrence of the incidents.

Market surveillance activities to ensure that medical devices are safe, perform as intended and do not pose unacceptable risks to patients, users and others.

Good Manufacturing Practices (GMP) Inspections at medical device manufacturing sites by voluntarily basis (ongoing project).

Inspections related to sales, advertisement and promotions of medical devices

On site audits to monitor compliance with relevant standards and legislation when necessary

Undertaking all necessary measures such as corrective and preventive actions, withdrawal, recall, and prohibition to supply to market when concerns relating to safety and performance of medical devices are identified

We are responsible of *cosmetic products* used daily by everyone

Vision & Aims of Cosmetic Products Department

Vision

It is attempted to reach corporate excellence keeping in the forefront of scientific truths at the operations and the decisions taken concerning cosmetics, manufacturers and consumers. In this process, Cosmetic Products Department aims to be a pioneer and reference unit at the international level.

LEGISTATION

Preparing legislations within the scope of cosmetics for needed areas and within the Customs Union consideration the conditions of our country, making adaptation studies of the EU legislations and legal arrangements for them

REGISTRATION & NOTIFICATION

In the points of the cosmetic products diversity, ensuring more effective registration and notification processes. Product Tracking System (ÜTS), is the World's leading portal in its field where cosmetic products and cosmetic firms are registered and it offers an infrastructure for providing "TRACEABILITY" which is a requirement for European Union. Furthermore, ÜTS includes registration with Barcode which is an argument for commercial tracking in European Union and other countries

CERTIFICATION

Engaging in activities for the improvements of the quality of manufacturing and exporting of cosmetics.

PROJECT

Executing processes of registration and tracking system project based on the unique identifiers for medical devices and cosmetics with Product Tracking System Project

CLINICAL RESEARCH AND STUDIES

Efficiency, safety studies or clinical research on cosmetic products or ingredients which are performed on human volunteers and organizing of Ethics Committees of Cosmetic Clinical Research Studies, are conducted with the permission of our department.

EDUCATIONAL, COMMUNICATIVE AND COORDINATION ACTS

Conducting training activities related to cosmetic products, following and participating to trainings and organizations in the field of cosmetic, planning sectorial trainings, following the news regarding cosmetic products and organizing cosmetics scientific advisory commission meetings.

Cosmetics; *market surveillance* and *inspection*

Types of Inspections on Cosmetics

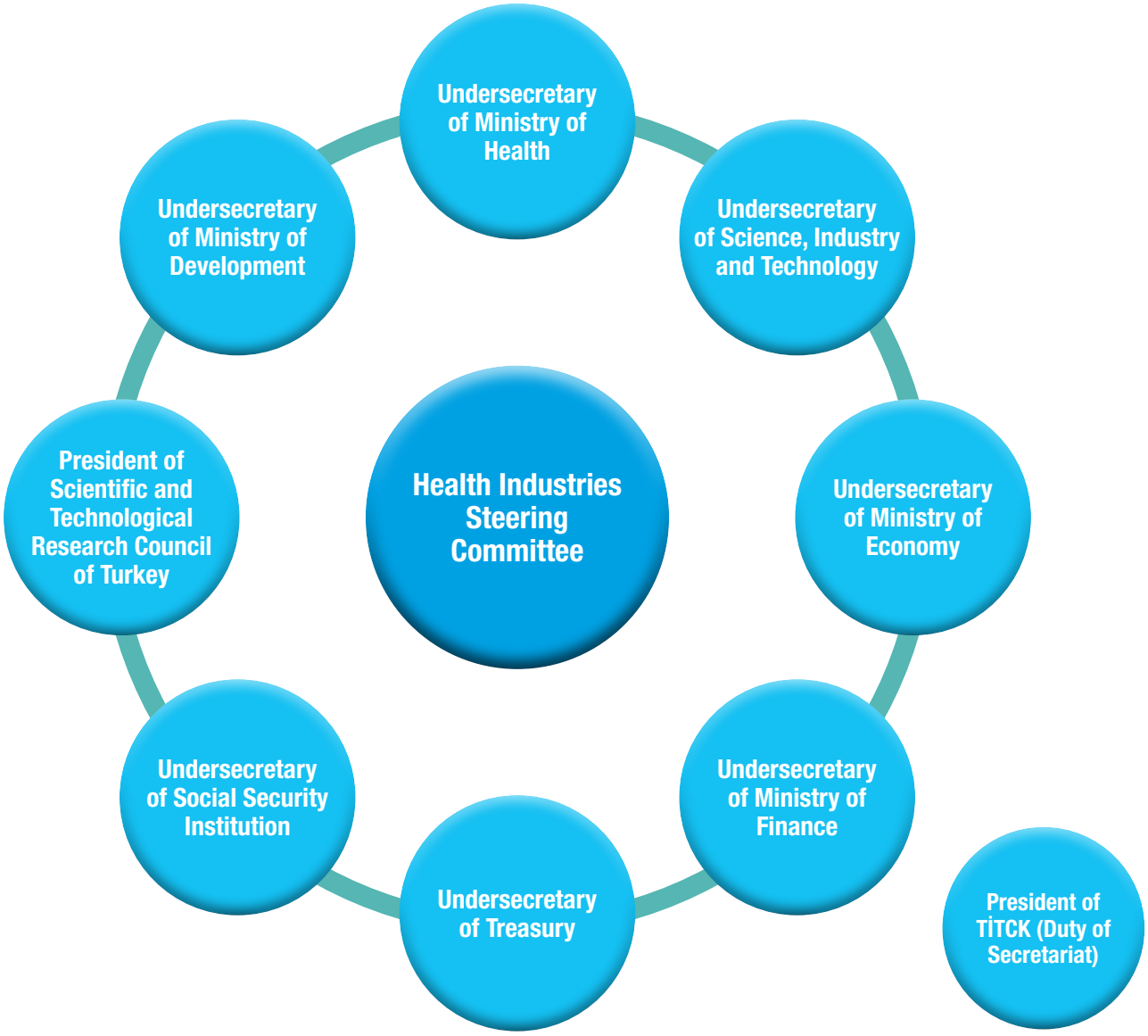
As a Competent Authority we carry out;

- **Good Manufacturing Practices** inspection of cosmetic production sites (according to ISO 22716 standard and national regulations).
- Cosmetic Good Manufacturing Practices **GMP) Certification Process** by application.
- **Market surveillance** of cosmetic products (Notification control and sensory investigation of cosmetic products and its packaging, control of cosmetic products information file-PIF, control of responsible person).
- Inspection of cosmetics related to **consumer complaints and cosmetovigilance notifications.**
- Inspection of **cosmetics and health-claimed products** related to **advertisements & promotions and sales.**
- **After the result of inspections some measures are taken such as** stopping the supply of products to the market, recall and withdrawal of the products supplied to the market, prohibition of supply to the market, implementation of permanent measures as disposal of non-compliant products, implementation of administrative fine process and announcement of non-compliant products to the public for the purpose of informing the public and warning of consumers who are at risk.
- **Within the scope of the procedures carried out within the framework of health claim regulations;** administrative fines, prevention of access and criminal prosecution procedures are implemented in radio and TV channels, internet sites and all kinds of promotional media.

Health Industries Coordination And Tracking

Health Industries Steering Committee has been established by the Notice of Prime Ministry No: 2015/19 published in the Official Gazette No:14653 dated December 22, 2015.

The Directive on Notice and Working Principles and Procedures of the Health Industries Steering Committee was approved in the second meeting and put into effect.



Turkish Pharmaceutical Sector Strategical Document and Action Plan (2015-2018)

Enhancing legal arrangements and administrative capacities in order to protect community health and improve export based investments

Creating qualified human power capable of meeting the needs of the sector

Developing cooperation and coordination between the public, university and private sector by establishing a confidential transparent environment

Providing rational drug use by establishing a mass of conscious physician, dentist, pharmacist, nurse and consumer

Planning R & D activities and ensuring coordination in order to develop products with high added value, supporting the products developed in this way

Establishing a rational financing structure to support sectorial investments in order to support sustainability and globalization of the sector

During the implementation, monitoring and evaluation processes of the Turkish Pharmaceutical Sector Strategical Document and Action Plan (2015-2018) tracking of these targets is carried out by the Turkish Medicines and Medical Devices Agency.

Human Medicinal Products Priority Assessment

Prioritization

Prioritization practice is carried out in order to provide earlier access to the patients of medicines that are important in terms of public health and country economy. With this prioritization practice, it is aimed to accelerate the evaluation processes of prioritized drugs carried out by our Agency.

Prioritization Criteria

- **Applications relating to first generic products or products of which equivalent is authorized but not on the market**
- **Applications relating to biosimilar products**
- **Applications relating to innovative products**
- **Applications relating to the production of imported medicines in our country**
- **Applications relating to locally manufactured products for exportation purposes**
- **Applications relating to products which cause serious public health problems in case they are not ready for use including vaccines or those which are included in the Agency's foreign medicine procurement list on the date of application**
- **Applications relating to products of companies which are benefited from the governmental incentives in the fields of R&D, manufacturing and marketing**
- **Special importation permit applications**
- **Applications relating to the Good Manufacturing Practices (GMP) audit**
- **Applications relating to products which have strategic importance in terms of country policies**

Structural Transformation Program Action Plan for Healthcare Industries

- The legislation related with Ethics Committee and Advisory Board will be updated in a manner so as to support basic and clinical researches.
- Tracking and comparison of the impacts on the patients of the medical devices implanted into the body will be monitored by the product tracking system.
- The products produced as a result of the planned R&D activities conducted according to requirements of Turkey will be supported in terms of pricing and reimbursement practices.
- A system will be established for monitoring and evaluating the outcomes of the public support programs related to the human medicinal product and medical devices sectors.
- The sector strategy for medical devices industry will be prepared.

Turkish Medicines and Medical Devices Agency has appointed for these actions which is published in Structural Transformation Program For Healthcare Industries with Tenth Development Plan (2014-2018)

Pharmaceutical
Track & Trace System

Pharmaceutical Track & Trace System's Advantages

- Prevents counterfeiting and smuggling
- Provides patient safety
- Supports rational drug use
- Enables drug market tracking
- Expedites reimbursement processes between phamacies and reimbursement agencies
- Providing information for inspections and legal issues.

İTS Mobile Application

- İTS mobile application that developed for public use, is available on AppStore, GooglePlay and Windows Store.
- Patients can see their drug's status by reading datamatrix on the drug box by using their smartphone's camera.
- İTS mobile also shows the expiration date, recall information, price of the drug.
- Patients can report adverse effects by using İTS mobile application.

Statistics

It is currently used by 40 thousand active stakeholders.

- 490 Warehouses
- 24826 Pharmacies
- 395 Manufacturers / Importers
- 45 Reimbursement Institutions
- 15771 Consumptions Centers
- 49 Exporters

Over 10 billions of drug units are being currently tracked with İTS
Response time is less than 0.2 second.

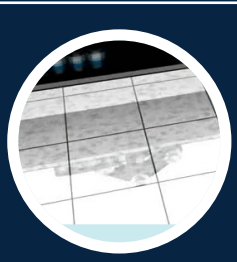
Track & Trace System

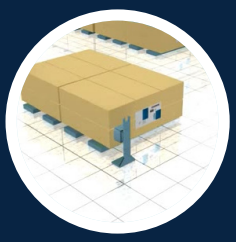
Datamatrix Printing
Manufacturing Company

Production Notification
Produced or imported product information are notified to İTS

Sale Notification
Sales made by producer to other stakeholders are notified to İTS

Package Delivery
Manufacturer > Warehouse





Package Delivery
Pharmacy Warehouse > Hospital

Production Purchase Notification
Hospital confirms products sold to hospital with product purchase notification. This notification is compulsory for the consumption of the product

Sale Notification
Sales made to other stakeholders by thewarehouse will be notified to İTS

Production Purchase Notification
The receiver confirms the purchase of products sold to the with this notification

Sale Notification
Sales made to other stakeholders by thewarehouse will be notified to İTS

Production Purchase Notification
Pharmacy confirms products sold to pharmacy with product purchase notification. This notification is compulsory for the sale of product to patients.

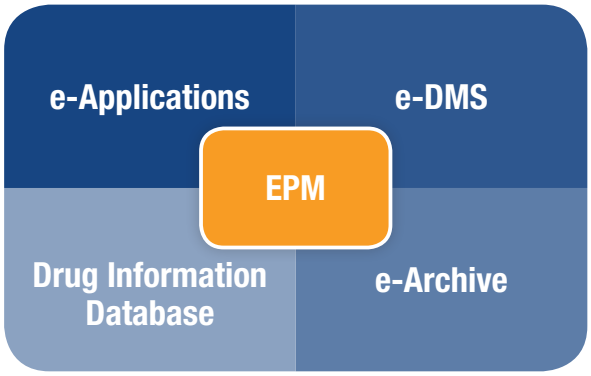
Sale Notification
Sales made to patients by the pharmacy will be notified to İTS

Package Delivery
Pharmacy Warehouse > Pharmacy

Making Payment
Reimbursement Institution

Electronic Process Management (ESY)

Transferring the work to the electronic environment is carried out by the EPM Project. All documents circulated in the Agency and sent to outside have been signed by e-signature.



EPM System's Advantages

- Accepting the applications and works electronically coming from the contacting firms, persons and institutions,
- Forming the related domains in the web interface in order to enable the applications to be made electronically,
- Forming an electronic database covering the pharmaceutical information,
- Accepting the marketing authorization applications in the electronic environment in the form of e-CTD,
- Accepting all applications in the electronic environment,
- Forming the electronic document management system,
- Ensuring the circulation of the documents electronically in the institution,
- Reduction of physical paper flow,
- Reduction in requirement for physical storage during review,
- Preparing, storing and accessing Marketing Authorization Licences and other licences through EPM,
- Forming an electronic archieve.

Electronic Application System

E-Submissions

- General applications made to the various departments of the TİTCK
- EMAA
- Import and Export Permit Applications
- Pricing Applications
- Meeting Applications

Advantages

- Applicants can only see their company information, applications and drugs.
- Applicants can access to real time information of their own products.
- The applicants can easily follow their previous applications.

The Flow Process of e-MAA on EPM (ESY)

Applicants

Submitting the electronic application on the Electronic Application System

Preparing the dossier

Sending e-CTD documents from a pc located in our building

Turkish Medicines and Medical Devices Agency

Application arrives

Technical validation (by validator)

Pre-examination period

Scientific validation

Assessment

Applications of the CTD format were accepted for the marketing authorization in 2005.

Applications of the e-CTD format were accepted for the marketing authorization in 2011.

Drug Information Database

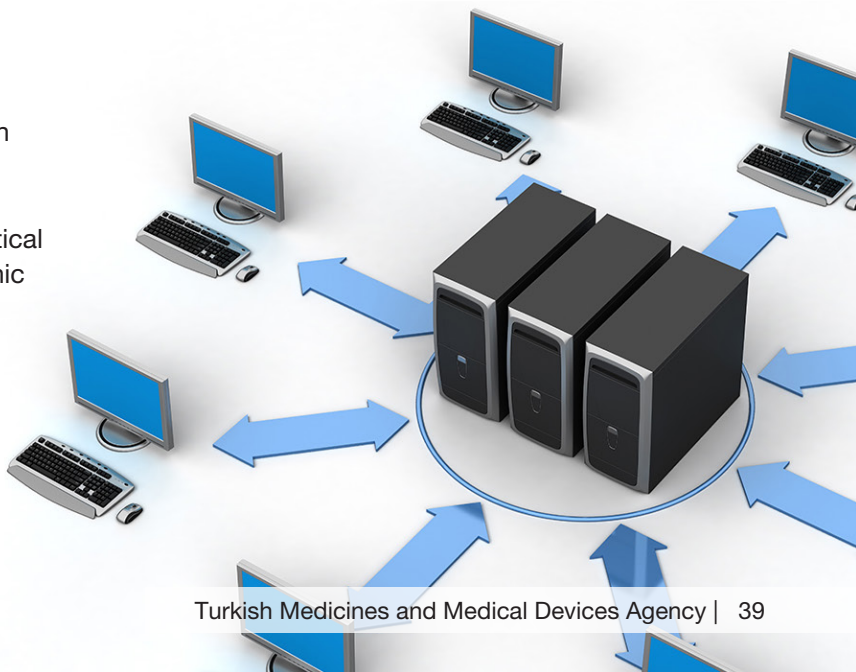
Data Entry

- by applicant

Verification of Database

- By registration department
- Synchronous with the assessment of the application

TİTCK has a huge drug database. Drug information database is used by both our agency and pharmaceutical companies. Applicants have to register to the Electronic Application System and enter the data of their all drugs in our database. Verification of database is made by the registration department and updating of the data is synchronous with the assessment of the application.



Republic of Turkey
Ministry of Health
Turkish Medicines and
Medical Devices Agency

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TÜRKİYE İLAÇ VE TIBBİ CİHAZ KURUMU

Söğütözü Mahallesi 2167. Sokak No: 5
06520 Çankaya / Ankara / TURKEY
Phone: +90 (312) 218 30 00
Fax: +90 (312) 218 34 60