REPUBLIC OF TURKEY
MINISTRY OF HEALTH
EUROPEAN UNION COORDINATION DEPARTMENT

ALLIGMENT STUDIES BY THE MINISTRY OF HEALTH DURING THE NEGOTIATION PROCESS WITH THE EUROPEAN UNION

CURRENT SITUATION AND RECENT IMPROVEMENTS

July, 2011
Ankara
1- EUROPEAN UNION COORDINATION DEPARTMENT

1.1. MISSION AND VISION

**Our mission**

Our mission, on the basis of our responsibilities and authorities described in the relevant legal regulations and the internal legislation on which the relations between Turkey and the European Union (EU) is founded, is to ensure coordination, information and guidance as well as to provide training services by increasing awareness with regard to health matters related with the scope of the European Union among all our partners, especially the departments of the Ministry of Health.

**Our vision**

Our vision is to become a recognized and dynamic institution playing an effective role and acting in compliance with the EU along with its personnel, institutions and system in the health sector within the scope of the EU policies of Turkey.

1.2. RESPONSIBILITIES

The European Union Coordination Department was founded with in order to conduct the harmonization studies with the European Union legislation for the issues included under the scope of the responsibilities of the Ministry of Health and to maintain the essential cooperation and coordination during the full membership process Turkey is currently undergoing.

The legal basis of the department, included as an individual department as one of the major service units in the organizational chart of the Ministry, is the Decree Law providing the foundation of units on the European Community in ministries and their dependant institutions No:367, published in the Official Gazette of May 4, 1989 No:20158. The name of the department, founded after the decree law as the “Department of European Community Coordination”, was changed to be the “European Union Coordination Department” in accordance with the Provisional Article 2 of the Law on the Organization of the Ministry of

The department primarily carries out its coordination responsibilities for issues such as alignment with the European Union legislation and thus benefitting from the financial resources of the European Union via submission of a project in order to achieve such alignment and executing accession negotiations. Within this scope, the department provides services in terms of maintaining coordination between the relevant institutions and within the Ministry and providing information with the aim of supporting the executive units which work for harmonization of legislation, conduct projects and play an effective role during accession negotiations.

The responsibilities of the department can be categorized under 3 headings:

1. Studies on legislation harmonization
2. Studies on Project Improvement and Coordination
3. Studies on Training

1.3. PERSONNEL STRUCTURE

The European Union Coordination Department provides services with a personnel capacity of 30 people, 14 of which are EU experts.

The positions of EU Experts are only available in the Department of EU Coordination in the Ministry and the department employs its personnel by a competitive examination executed under the scope of the “Implementing Regulation on the Entrance Examination of European Union Assistant Experts by the Ministries and Institutions of Prime Ministry and the Procedures and Principles of Competency Examinations of European Union Experts”
2. ABOUT THE EUROPEAN UNION

2.1. WHAT IS THE EUROPEAN UNION?

The European Union is a regional unification Project with social and political objectives. It started as an economical unification and in time with an increase of its members it has become the most comprehensive unification model for the rest of the world.

The concept of unification in Europe and the emergence of ideas towards constituting a unified Europe date back to the Medieval Time. As a project, the first steps of the European Union were taken during the years after the World War II.

The reasons for constituting unification in Europe might be as follows:

- To ensure permanent peace in Europe after the World War II,
- To remove destruction after the World War II in Europe,
- To bring permanent solutions for the problems between Germany and France,
- To keep war raw materials -coal and steel products- under control,
- To ensure that Marshall aids are distributed in an effective and fair way,
- To unite against Soviet threat.

The organization, functioning and decision taking mechanisms of the EU are quite different from other traditional and international systems. Principally, the EU is different from the United Nations, NATO or World Health Organization due to it supranational qualities.

Member States delegated their mandates to the Union in certain fields; therefore, the EU is directly authorized to create legal provisions in Member States.

2.2. FOUNDATION AND EXPANSION OF THE EUROPEAN UNION

The EU traces its origins from the European Coal and Steel Community (ECSC), founded to co-manage war raw materials coal and steel resources in 1951. Germany, France, Italy, Belgium, Holland and Luxemburg delegated their mandates to an independent and supra-state authority for issues with regard to coal and steel industry.
In 1957, the unification process in Europe still continued and two more communities were constituted: European Economic Community (EEC) and European Atomic Energy Community (EURATOM). EEC is a means produced in order to ensure stability and welfare in Europe via a common market and economic integration among the six founder countries. EURATOM was created in order to make sure that atomic energy is used for peace purposes. In 1956, these three communities (ECSC, EURATOM, EEC) were named under the heading “European Communities” by means of uniting only their organs without prejudice to their legal entities.

In 1973, the Communities enlarged with the participation of England, Ireland and Denmark. Norway had negotiated to join at the same time but Norwegian voters rejected membership in a referendum and so Norway remained outside.

The second and the third expansions were towards south; in 198, Greece joined and in 1986 Spain and Portugal were included.

In 1995, the EU reached to 15 members with the participation of Austria, Sweden and Finland.

On May 1, 2004 the European Union experienced its largest expansion and turned into a union with 25 member states including Czech Republic, Estonia, Greek Cypriot Administration of Southern Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovakia and Slovenia. Bulgaria and Romania joined on January 1, 2007 and the number of its members reached to 27.
2.3. CANDIDATES

<table>
<thead>
<tr>
<th>Country</th>
<th>Application date</th>
<th>Admission date as a candidate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Turkey</td>
<td>1959</td>
<td>1999</td>
</tr>
<tr>
<td>Croatia*</td>
<td>2003</td>
<td>2004</td>
</tr>
<tr>
<td>Macedonia</td>
<td>2004</td>
<td>2005</td>
</tr>
<tr>
<td>Iceland</td>
<td>2009</td>
<td>2010</td>
</tr>
<tr>
<td>Montenegro</td>
<td>2008</td>
<td>2010</td>
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* Croatia is expected to join on July 1 2013.
2.4. ORGANIZATIONAL STRUCTURE OF THE EUROPEAN UNION

EUROPEAN UNION AUTHORITIES

**Principal Institutions**

<table>
<thead>
<tr>
<th>Summit</th>
<th>European Parliament</th>
<th>Council of Ministers</th>
<th>European Commission</th>
<th>European Court of Justice</th>
<th>European Court of Auditors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consists of presidents and head governments of Member States, the highest policy determiner</td>
<td>Consists of the representatives of citizens of Member States, shares legislative powers with the Council; however, the final decision is taken by the Council of Ministers</td>
<td>Consists of the relevant Ministers of Member States and shares legislative powers with the Parliament</td>
<td>Consists of 27 members coming from each Member State. It is the executive branch of the Community.</td>
<td>It is the judicial branch of the Community. A judge per member state takes office for a period of 6 years.</td>
<td>It is the financial audit organ of the Community.</td>
</tr>
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**Consultation Institutions**

- Economic and Social Committee
- Committee of the Regions

**Ancillary Institutions**

- European Ombudsman
- European Central Bank
- European Investment Bank

3. NEGOTIATION PROCESS AND TURKEY

3.1. NEGOTIATION PROCESS

The negotiation process is a detailed course of review in which the way and the schedule for adoption of the Acquis Communitaire by the candidate country and how to structure the administrative organization is determined.

The EU accession negotiations are not typical negotiations. The candidate country is supposed to adopt and implement the entire acquis communitaire. The issue negotiated is the implementation schedule. The negotiations between Turkey and the EU started on October 3, 2005.

During the phase of the de facto negotiations, negotiation chapters are opened by the EU through consensus and closed temporarily on condition that there is an improvement with regard to that chapter or a solid plan in terms harmonization through consensus.
3.2. NEGOTIATIONS CHAPTERS

The 35 chapters consisting of the acquis communitaire and negotiated by candidate countries are as follows:

<table>
<thead>
<tr>
<th>CHAPTERS OF THE ACQUIS</th>
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<tbody>
<tr>
<td>2. Freedom of Movement for Workers</td>
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<tr>
<td>3. Right of Establishment and Freedom to Provide Services</td>
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<tr>
<td>4. Free Movement of Capital</td>
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<tr>
<td>5. Public Procurement</td>
</tr>
<tr>
<td>8. Competition Policy</td>
</tr>
<tr>
<td>9. Financial Services</td>
</tr>
<tr>
<td>10. Information Society and Media</td>
</tr>
<tr>
<td>11. Agriculture and Rural Development</td>
</tr>
<tr>
<td>12. Food Safety, Veterinary and Phytosanitary Policy</td>
</tr>
<tr>
<td>13. Fisheries</td>
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<tr>
<td>14. Transport Policy</td>
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<tr>
<td>16. Taxation</td>
</tr>
<tr>
<td>17. Economic and Monetary Policy</td>
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<tr>
<td>18. Statistics</td>
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3.3. SCREENING PROCESS

The first phase of the negotiations starts with the screening process. This process is simply the analytical review of the acquis communitaire. During this phase, candidate countries are closely informed of the acquis and the national legislation of the country concerned is screened in terms of its compatibility with the acquis communitaire.

During the screening phase, started on October 20, 2005, the Turkish legislation and the acquis communitaire were reviewed and this phase was completed on October 13, 2006. At the first stage of the screening process, the authorities from the EU provided information about the relevant chapters of the acquis and then Turkish bureaucrats informed them about the current situation in Turkey.

After screening each negotiation chapter, the Commission communicates a report named “screening report” to candidate countries. The evaluations and the suggestions included in this
report constitute the basis to open negotiations with regard to the chapter concerned. The commission evaluates Turkey in terms of eligibility for negotiations and either proposes to open the chapter for negotiations or defines the opening benchmarks in order to complete this.

3.4. CURRENT SITUATION DURING THE NEGOTIATION PROCESS

During the negotiation between Turkey and the EU, 13 chapters were opened for negotiations. These negotiations are:

- The chapter opened and closed up temporarily
  - 25. Science Research (Austria June, 12 2006)
- The chapters opened:
  - 20. Enterprise and Social Industry (Germany March 29, 2007)
  - 18. Statistics (Germany June 26, 2007)
  - 32. Financial Control (Germany June 26, 2007)
  - 21. Trans – European Networks (Portugal December 19, 2007)
  - 28. Consumer and Health Protection (Portugal December 19, 2007)
  - 6. Company Law (Slovenia June 17, 2008)
  - 4. Free Movement of Capital (France December 19, 2008)
  - 10. Information Society and Media (France December 19, 2008)
  - 16. Taxation (Czech Republic June 30, 2009)
  - 27. Environment (Sweden December 21, 2009)
  - 12. Food Safety, Veterinary and Phytosanitary (Spain June 30, 2010)

As the Additional Protocol was not implemented during the EU Summit in December 2006, (because the Additional Protocol was not implemented to include Greek Cypriot Administration of Southern Cyprus) negotiations have been suspended for the following 8 chapters:

- Free Movement of Goods
- Right of Establishment and Freedom to Provide Services
- Financial Control
- Agriculture and Rural Development
Some of the chapters apart from the ones mentioned here have not yet been opened for negotiation due to the reasons such as prevention of France and Greek Cypriot Administration of Southern Cyprus, the failure to fulfil opening benchmarks and the results of the screening reports having not been notified by the EU to Turkey. The studies are still continuing about the three chapters likely to be opened on Competition Policy, Public Procurements and Social Policy and Employment.

4. HARMONIZATION STUDIES BY THE MINISTRY OF HEALTH DURING THE NEGOTIATION PROCESS

The issues with regard to health are collected in various chapters in the acquis rather than opening a dedicated chapter on health.

The regulations on health are mainly included in the chapters on “Consumer and Health Protection”, “Free Movement of Goods”, “Right of Establishment and Freedom to Provide Services”, “Environment” and “Intellectual Property Law”. Additionally, the issue of health is also hinted in chapters on “Justice, Freedom and Security”, “Social Policy and Employment”, “Statistics” and “Food Safety” as well.

4.1. CONSUMER AND HEALTH PROTECTION (Chapter 28)

4.1.1. Scope

The Chapter Consumer and Health Protection No: 28 can be categorized into two main groups as “consumer protection” and “public health”.

The regulations with regard to consumer protection are under the responsibility of the Ministry of Industry and Commerce. These regulations include a variety of subjects which
interest consumers such as faulty products, prevention of deceiving commercials, consumer loans, door step sales, distance sales without meeting consumers.

The part of this chapter on “public health” directly interests the Ministry. The issues covered under this scope are as follows: communicable diseases; transplantation of organs, tissues and cells, harms resulting from tobacco consumption, the effects of electromagnetic areas on human health, cancer, nutrition, physical activities and mental health.

This chapter was opened for negotiations on December 19, 2007 during the Portuguese Presidency.

4.1.2. Studies carried out by the Ministry of Health for the Chapter on Consumer and Health Protection

The Ministry of Health primarily executes studies for the following issues:

- Communicable Diseases
- Blood and Blood Components
- Tissues-Cells
- Tobacco-Alcohol-Substance Addiction
- Electromagnetic Areas\(^1\)
- Cancer
- Nutrition and Physical Activities
- Mental Health

Along with the primary issues mentioned above, with regard to Consumer and Health Protection, 5 technical closing benchmarks were defined as well in the EU Common Position Paper during the negotiations. These are:

- Closing benchmarks with regard to blood and blood products
- Closing benchmarks with regard to tissues and cells
- Closing benchmarks with regard to communicable diseases

\(^1\) The authority with regard to electromagnetic area was transferred to the Ministry of Industry and Forestry on the basis of the relevant correspondence of the Prime Ministry.
Closing benchmarks communicated to Turkey by the EU with regard to blood and blood products:

“Turkey should adopt the legislation aiming at transposing the Commission implementing directives in the area of technical requirements for blood and blood components, traceability requirements and notification of serious adverse reactions and events and of a quality system for blood establishments. Turkey needs to demonstrate that adequate institutional and administrative capacity will be put in place in order to implement this acquis by the membership date.”

The legislation harmonization studies on “The Law on Blood and Blood Products” published on May 2, 2007 and “the Implementing Regulation on Blood and Blood Products” No:2008/14319 published in the Official Gazette of 04.12.2008 No:27074 have been completed. The studies on the Blood and Blood Products Guideline was also completed and published in July 2009. The Blood and Blood Products Guideline, a manual for health professionals and clinic users on preparation and use of blood and blood products and quality guarantee, was updated by June 2011 and published. The working principles of Regional Blood Centres are also described in the guideline.

With this respect, the Ministry of Health envisages a significant transformation with the introduction of the new blood legislation, which enables transition to a region-based blood centre system. The principal basis in this transformation, rather than the use of replacement (exchange) method, is the transition to voluntary, regular and unpaid blood donation system as one of the indispensible conditions of access to safe blood. Under this scope, access to safe blood will be simply achieved on the basis of the EU standards including all the stages of transplantation. With the new system, all the stages, from the receiver to the donor or vice versa, of blood will be monitored (hemovigilance) and serious adverse reactions and events will be notified to the Ministry of Health. Comprehensive training programs are held in order to ensure access to safe blood and the technical specifications with regard to the quality of blood facilities have been drawn up. Thus, issue of access to safe blood, obtained on the basis of voluntarism in modern facilities will be achieved.

Closing benchmarks communicated to Turkey by the EU with regard to tissues and cells:

“Turkey adopts the legislation aiming at transposing the acquis on tissue and cells, especially with regard to record keeping for 30 years, reproductive cells, reporting of serious adverse events and reactions, data protection and standard operating procedures for processing and testing of cells and tissues. Turkey demonstrates that it will have the adequate administrative capacity to properly implement and enforce this legislation by the time of accession.
“The Implementing Regulation on Human Tissues and Cells and Quality and Safety of Related Facilities” was published in the Official Gazette of October 27, 2010 No:27742. The closing benchmarks stated in this field are envisaged to be fulfilled via this implementing regulation. The EU Directives No: 2004/23/EC, 2006/17/EC and 2006/86/EC were aligned in this implementing regulation. Studies are still going on for the secondary legislation to be published under the scope of the implementing regulation. This legislation will be published by October 21, 2011.

This implementing regulation enables that activities are carried out on the basis of the EU standards for all the stages including donation, provision, labelling, registration, monitoring, test, processing of human tissues and cells and the products derived from these as well as their packaging, preparation for storage in a way to conceive their functions, storage and distribution. Thus, the quality and safety standards for maximum prevention of human health have been determined and the facility, personnel and infrastructure to open tissue and/or cell centres, provision institutions and test laboratories and for the activities of such places have been regulated to be audited in accordance with the EU standards.

On the other hand, the legal process for the National Cell Coordination centre (TURKOK) was completed via the Ordinance of 14.10.2009.

_Closing benchmarks communicated to Turkey by the EU with regard to communicable diseases:_

“Turkey demonstrates that adequate institutional and administrative capacity will be in place to fulfil by the time of accession EU reporting and coordination obligations, including participation in the Early Response System (EWRS), in the field of communicable diseases.”

“The Implementing Regulation on the Principles of Surveillance and Control of Communicable Diseases” was published in the Official Gazette of 30.05.2007 No: 26537 and put into implementation. After the publication of this implementing regulation, amendment studies with regard to implementing regulations in parallel with the acquis issued in this field were completed. The implementing regulation was harmonized with the relevant acquis and published in the Official Gazette of April 2, 2011 No: 27893.
The ordinance with regard to the “Committees and Commissions” to take office in the field of communicable diseases described in the implementing regulation concerned was completed as well and these committees and commissions are still continuing their studies.

On the basis concerned, disease notification system has been updated, case descriptions has been determined for standard notification, contributions with regard to international disease webs included in the EU and WHO organization have been provided and the system has been aligned to enable data exchange. Due to these studies, case and laboratory based notifications have been executed for the diagnosis of communicable diseases and the data and technical information acquired for the solution of the problems resulting from boundless nature of communicable diseases has been maintained with the EU.

The law on the establishment of the National Public Health Care Institution is being worked on along with the Law on the Organization of the Ministry of Health.

Additionally,

- The draft for the “Implementing Regulation on the Establishment, Working Procedures and Principles of Public Health Laboratories” has been prepared as undertaken in the National Program Commitments and made available for internal and external opinions. The implementing regulation concerned will be published in August 2011.

- The draft for the “Implementing Regulation on Working Procedures and Principles of Microbiological Diagnosis Laboratories” has been prepared as included in the National Program Commitments. The followings are aimed at with this implementing regulation: strengthening the laboratory based component of the surveillance, establishment of a web structure for laboratories and provision of reliable and accurate data flow into the surveillance system via this web.
4.1.3. Projects with Regard to the Closing Benchmarks of the Chapter on Consumer and Health Protection

Projects in the Field of Blood and Blood Products

With “the Project on Strengthening Blood Provision System” admitted under the scope of the Program of Instrument for Pre-Accession Assistance (IPA) 2008, the followings were aimed at: improvement of a national blood program on basis of a regional blood centre, legislation alignment, improvement of human resources via training programs and establishment of a data management system.

The technical documents were prepared for the procurements under the scope of the project and forwarded to the Central Finance and Contract Unit. The documents reviewed by CFCU in terms of their quality were sent to the Delegation of the European Union to Turkey in order to initiate the tendering process. The project was forwarded to Brussels by the Delegation of the European Union to Turkey in order to be circulated throughout the Member States and the activities of the project are supposed to be started by November 2011.

The project on Strengthening the Blood Provision System;

- Implementation of the blood legislation harmonized with the acquis in the field,
- Establishment of the database required to found the National blood program,
- With the aim of alignment in accordance with the requirements envisaged in the relevant acquis, improvement and publication of a re-organization model for the blood banking and transfusion system in Turkey,
- Foundation of a legal and technical infrastructure in order to ensure an effective implementation of the standards of blood transfusion chain,
- Improvement of human resources in order to ensure effective functioning of national higher authorities required for the management and inspection of regional blood centres,
- Establishment of human resources for sufficient, productive, safe and high-quality blood provision system in accordance with the EU standards,
- Ensuring regular information flaw between blood institutions and the national authority.

“The Project on Gaining Safe Blood Donors of Future” submitted under the scope of the Program of IPA 2010 was admitted by the European Union Commission. The project to be executed under the cooperation of the Ministry of Health, the Ministry of Education and Turkish Red Crescent aims at creating awareness and consciousness among students, teachers and parents for safe, voluntary and unpaid blood donation and in parallel to this, review of the curriculum and developing various educational materials and holding blood campaigns.

The 2010 Financing Agreement, in which the project is included, was signed on April 11, 2011. The tenders under the scope of the Project, which started legally with the Financial Agreement, should be executed with the relevant firms and contracts should be signed. In order to achieve this, first of all, a protocol defining the general framework with regard to the execution of the project should be signed among the relevant parties, i.e. the Turkish Crescent, the Ministry of Education and the Ministry of Health. The studies on the draft protocol are at the final stage. The protocol is planned to be signed among the parties in July 2011.

**The project on Tissues and Cells**

“The Project on Tissues and Cells” aims at legislation harmonization, tissue data banking, voluntary donor centres, increasing the administrative capacity of the personnel employed in the cord blood bank, establishment of a data gathering system and bringing international standards for bone marrow centres, tissue-typing laboratories and cord blood banks.

The 2009 Financing Agreement, in which the project is included, was signed on December 13, 2010. The forecast notice was published in the Official Gazette of February 22, 2011 for the technical service procurement for the project. The Terms of Reference was also forwarded to CFCU in order to publish the procurement notice for the project. As a result of the negotiations with the CFCU, the need for a series of updates was put into the agenda with regard to the activities of the project. These changes do not have the potential to alter the result of the project; however, the justification of such change will be communicated to the Ministry for EU Affairs between the dates of July 11-15.
The Projects on Communicable Diseases

Significant steps were taken in terms of harmonization with the acquis in the field of communicable diseases via the projects submitted in 2004, 2005 and 2008 Financial Cooperation Programming. With these 3 projects a fund of more than 13,000,000 Euro was granted by the EU.

With the first project executed in the field of communicable diseases, the organizational structure, capacity and legislative infrastructure of the surveillance system for communicable diseases in Turkey were strengthened in accordance with the EU decisions. Additionally, health professionals were provided with training programs with regard to communicable diseases under the scope of the project. With the second project, the technical and diagnostic capacities of test laboratories and their infrastructure were improved.

In the third and the final project, a sequence of the first two projects, institutionalizing of servicing executed and the establishment of the Early Warning and Response System were aimed. The Description of Action of the Project was prepared with the authorities of the WHO and was forwarded to CFCU for the approval of the European Union Delegation to Turkey. After the approval of the Description of Action, the “Grant Agreement” was signed between the WHO and the European Commission on 29.10.2010 and the project activities were initiated. These activities are still continuing.

The project technically supported by the WHO aims at institutionalizing the courses under the scope of the National Field Epidemiology Training Program, determining, evaluating, reporting and responding public health events and risks (infectious, chemical, radio-nuclear or health threats from an unknown source) on the basis of the International Health Regulation and the relevant legislation of the EU along with the establishment of an Early Warning and Respond System.
4.1.4. Cooperation with the European Centre for Disease Prevention and Control (ECDC)

The Ministry pays significant attention to being in cooperation the Member States and the international organizations within the EU about issues on the surveillance and control of communicable diseases. Based on this fact, a delegate from the European Centre for Disease Prevention and Control, the principle organization dealing with the surveillance and control of communicable diseases in the EU, visited Turkey and contacted several units in the Ministry.

As a result of these contacts, the Ministry took a step in improving relations between the ECDC and the Ministry and Turkey was admitted to participate in ECDC activities as an observer. So far, the ECDC paid some mission visits to Turkey for the issues of Pandemic Influenza and Tuberculosis strengthening communications means.

Additionally,

- Participation in a number of meetings such as the National Microbiology Focal Points Meeting, Eurosurveillance Editorial Board Meeting, Competent Authorities Meeting for Scientific Advices, the Annual Meeting of Food and Water Born Diseases, the Annual Meeting of Preparedness and Response for Competent Authorities, the Meeting on Displaying Research Problems Encountered during Modelling of Communicable Diseases in order to Ensure Planning in Public Health Policies, the “ECDC CDAD” on European C. Difficile Surveillance Study, the Meeting on HIV Surveillance Focal Points and National Anti-Microbiology Focal Points hosted by the ECDC,
- A delegate from the Ministry participates in the studies carried out by the editorial board of “Eurosurveillance”, an electronic magazine published by the ECDC.
- Two persons from the personnel of the Ministry had an internship at the ECDC.

The studies of the Ministry with regard to the Dedicated Surveillance Networks, functioning within the scope of the ECDC, are still going on via contact points. The networks for which the Ministry have a membership are as follows:

- Surveillance of Tuberculosis in Europe (EUROTB)
- European Working Group for Legionella Infections (EWGLI)
• International Surveillance Network for Enteric Infections (ENTER-NET)
• European Influenza Surveillance Scheme (EUROFLUE)

The ones which can not be categorized as the Dedicated Surveillance Networks but included under the scope of “the European Surveillance System for the Communicable Diseases and Health Threats” are as follows:

• European Laboratory Working Group on Diphtheria (ELWGD),
• European Diphtheria Surveillance Network (DIPNET),
• European Project on the Surveillance of Sexually Transmitted Diseases,
• EuroHep.net, EUVAC.NET

4.1.5. Studies carried out with Regard to Cancer Control

The Law on the Establishment of the National Cancer Institute”, which is among the commitments of the Ministry in the 2008 National Program and the 2007-2013 Legislation Alignment Program (LAP) is being worked on with the Law on the Organization of the Ministry of Health, even though this issue is excluded from the scope of the legislation studies on closing benchmarks of the Chapter on Consumer and Health Protection; nevertheless is evaluated under this chapter.

There are two more relevant commitments under the scope of LAP as “National Standards for Cervix Cancer Scanning” and “National Standards for Colorectal Cancer”.

With regard to these commitments, the Circular on National Standards for Cervix Cancer Scanning and the Circular on National Standards for Colorectal Cancer were published and harmonized with the Council Recommendation No: 2003/878/EC.
**Cancer Projects**

The KETEM (Early Cancer Diagnosis and Scanning Centre) was first established via a project executed between the years of 2002-2004 under the MEDA fund of the EU and the number of the KETEMs was increased to 122. There is at least one KETEM in every province. KETEMS does public-based scans for breast, cervix and colorectal cancer along with creating regional awareness and public training.

Under the scope of the project on “Cancer Scan and Palliative Care” included in the 2011 programs and planned to be initiated by 2013, a central web base is planned to be established in order to monitor scanning activities carried out in KETEMs in 8 provinces\(^2\) and a quality assessment system will be improved in order to develop the quality of the scanning services. Additionally, under the scope of cancer scanning, curriculum provided for the KETEM personnel and family practitioners will be updated and the relevant personnel will be provided with the updated training program. With regard to palliative care, domestic care personnel will be trained accordingly as well. Finally, under the scope of this project, campaigns will be held with regard to cancer scanning and palliative care services in order to increase awareness in this field.

As preparation studies for the project, under the scope of the financial resource of the Support Activities to Strengthen the European Integration Process (SEI) executed under the coordination the Ministry of the European Union, a short-terms (3-4 months) project is planned. The studies for the ToR for the project concerned are still continuing.

**4.1.6. Studies carried out with Regard to Tobacco, Alcohol and Substance Addiction**

Regulations with regard to tobacco and tobacco products are included among the closing benchmarks of the Chapter on Consumer and Health Protection. However the studies for the closing benchmarks\(^3\) of this chapter are included in the scope of the Tobacco and Alcohol Market Regulatory Authority. In order to keep smoking under control, the Ministry prepared

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\(^2\) Ankara, Izmir, Antalya, Samsun, Trabzon, Eskisehir, Bursa and Erzurum

\(^3\) The relevant closing benchmarks are as follows: “Turkey achieves substantive progress in transposing the tobacco product regulation acquis, especially by focussing on high tar yields and oral tobacco, as well as in transposing the tobacco advertising acquis.”
the “National Tobacco Control Program” and the “Action Plan” covering the years of 2006-2010.

By July 19, 2009 all closed and public areas have been Smoke-Free Zones.

The “Study Group on Prevention of Passive Influence” working under the scope of the National Tobacco Control Program are still continuing its studies with the participation of the representatives from the relevant institutions and non-governmental organizations and carrying out activities in order to create awareness in different parts of the society in order to prevent passive influence.

With regard to alcohol, the draft for the “National Alcohol Control Program” has been prepared.

**4.1.7. Studies carried out with Regard to Electromagnetic Areas**

In Parallel with the Council Recommendation No: 1999/519/EC, the publication of the Implementing Regulation on the Effects of Electromagnetic Areas on Public Health is included among the commitments mentioned in the 2008 National Program and Legislation Alignment Program. However, in parallel with the opinion of the Prime Ministry, the authorities with regard to the issue of the implementing regulation finalized by the Ministry have been turned over to the Ministry of Environment and Urban Development.

“The Implementing Regulation on the Measurement required to be taken in Order to Protect Environment and Public Health against the Negative Effects of Un-ionizing Radiation” was published in the Official Gazette of 24/07/2010 and No: 2765.

**4.1.8. Studies carried out with Regard to Mental Health**

“The Ordinance on Public Mental Health Centres” was published in December 2011 and put in effect. With this ordinance, the followings are aimed at under the scope of the public-based mental health model for patients with severe mental health problems: providing psycho-social support, establishment of mental health care centres functioning in accordance with in-patient health facilities of the Ministry of Health in order to ensure that domestic health care services
are provided in integrated way, determination of procedures and principles of such facilities in order to audit the duties, authorities, responsibilities of the personnel assigned and the implementations in such places, ensuring services provided are effective and accessible.

After the publication of the ordinance, the number of Public Mental Health Centres reached to 12. Additionally, the first Autism Perfection Centre was opened in Ankara in March 2011. The first Child Monitoring Centre was established in 2011 and the number of these places was planned to be increased to 12.

In response to our commitments defined in the Negotiation Position Paper, the draft on the Mental Health Action Plan was prepared. This plan will be published in August 2011.

Projects on Mental Health

The project on “Improvement of Services provided for the Disabled” proposed by Social Services and Children Protection Directorate General for the program of the European Union IPA 2008 was admitted by the Commission. The main beneficiary of the project covering the years between the years 2009-2010 is the Ministry of Health. The Curative Service Directorate General and Primary Health Care Services Directorate General of the Ministry of Health are working in coordination for the project concerned. In the first phase of the project, analyzing the service provision system of the Ministry of Health for the mentally and physically disabled is include; in the second phase: ensuring an effective cooperation among key shareholders (relevant public institutions and Non-governmental organizations); in the third phase: review of the implementations in Europe in terms of care service models for the mentally disabled. Finally, the curriculum program for the Ministry of Health and Social Services and Children Protection Directorate General will be improved.

Due to the subject of the project, the technical assistance of the WHO has been demanded on the basis of the opinion of the EU Delegation to Turkey and with the positive reply obtained preparation studies of the project have been initiated. The details of the project were defined as a result of the discussions and these detailed have been confirmed via the studies carried out by inter-agencies. The team appointed by the WHO in order to execute the activities of the project started studies in the second quarter of 2011.
4.1.9. Studies carried out with regard to Organ Donation and Transplantation

The Directive on quality and safety of human organs to be transplanted No: 2010/45/AB was adopted by the Parliament and the Council of the European Union on 07.07.2010 and published in the Official Gazette and put into effect. The commission allowed for a period of two years for the Member States in order to align the legislation concerned.

The Ministry carried out a workshop in May 2011 in order to update the current legislation in the field of organ transplantation and ensure alignment to the acquis under the light of the scientific improvements. These alignment studies are still continuing.

Organ Projects

“Alignment Project on Organ Donation”, included in 2008 IPA program, aims at quality and safety standards in organ donation and transplantation. Actualizing the project activities has gained importance along with the publication of the new Acquis Communitaire. This issue is included among the headlines to be monitored in the Chapter on Consumer and Health Protection by the European Commission due to the publication of the new Acquis Communitaire. The followings are envisaged in the project: legislation alignment, increasing awareness in the relevant personnel with regard to organ donation and transplantation, creating public awareness and signing mutual contracts and protocols.

4.2. FREE MOVEMENT OF GOODS (Chapter 1)

4.2.1. Scope

The chapter on Free Movement of Goods (FMG) is a comprehensive field including regulation of several areas inter related with each other. This chapter also includes customs duty, equivalent effect taxes and elimination of quantitative restrictions and certain horizontal issues such as standardization, accreditation, market surveillance and inspection as well as joint regulations with regard to commercial products.

FMG is of great importance in terms of Customs Union (CU) established by the Association Council Decision (ACD) No:1/97 and the ACD No:2/97 determining the list of the Acquis
Communitaire required to be aligned by Turkey within this scope. The acquis list on industrial products is the EU legislation included under the scope of the FMG. Thus, a majority of the legislation required to be aligned by Turkey under FMG is the same with the legislation required to be aligned under the scope of CU.

4.2.2. Issues Included in the Chapter and the Relevant Units of Ministry of Health

**Horizontal Issues**
- Market Surveillance and Inspection\(^4\): PHCSDG, PPDG (Pharmacy and Pharmaceutical Directorate General) RSHC (Refik Saydam Hygiene Centre) (laboratory analysis), DEUC (the European Union Coordination Department) (general coordination)
- Unregulated area – Notification Procedure: all the direct or indirect addressee units with regard to produce trade especially PHCSDG, PPDG

**Directly related issues**
- Toys- PHCSDG
- Detergents- PHCSDG
- Medical Devices- PPDG
- Medicinal Products for Human Use- PPDG
- Cosmetics- PPDG
- Dietary Foods for Special Medical Purposes - PPDG

**Issues Executed Jointly with other Institutions**

4.2.3. Legislation Alignment Studies

The European Union alignment studies have been primarily continuing under the scope of Customs Union (CU) established by the Association Council Decision (ACD) No:1/95 and

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\(^4\) Piyasa Gözetim ve Denetimi ile ilgili ayrıntılı bilgileri içeren bilgi notu ek olarak ayrıca verilmektedir.
ACD 2/97 determining the list of the Acquis Communitaire required to be aligned by Turkey and secondarily under the scope of full accession.

Within this respect, regulations constituting the legal basis for certain implementations in terms of especially the products requiring CE (Conformité Européenne) sign were issued by the Undersecretariat of Foreign Trade (UFT). Subsequently, the Ministry of Health issued regulations with regard to the products under its responsibility. These regulations are as follows:

- The Law on Preparation and Implementation of the Technical Legislation on Products No:4703 (the Official Gazette of July 11, 2001 No: 24459)
- The Implementing Regulation on Market Surveillance and Inspection (the Official Gazette of January 17, 2002 No:24643)
- The Implementing Regulation on Attachment and Use of the CE Sign (the Official Gazette of January 17, 2002 No:24643)
- The Implementing Regulation on Conformity Assessment Institution and Notified Bodies (the Official Gazette of January 17, 2002 No:24643)

4.2.3.1. Toys

The Directive on Safety of Toys No: 88/378/EEC was aligned by the Ministry and transferred to the internal legislation via “the Implementing Regulation on Toys”. This implementing regulation is full conformity with the acquis.

However, the Directive on Safety of Toys No: 2009/48/EC is going to abolish the Directive No: 88/378/EEC. Thus studies in order to align the new acquis have been initiated and are planned to be completed by the end of 2011.

There two notified bodies working in Turkey with regard to toys. These are Turkish Standards Institute and SGS Supervised Surveillance Etude Control Services Inc.
Other regulations on toys are as follows:

- The Communiqué on Notified Bodies Working on Toys (the Official Gazette of February 28, 2004 No: 25387)

- The Communiqué on Harmonized Standards with regard to the Implementing Regulation on Toys (the Official Gazette of November 15, 2003 No: 25290)

- The Communiqué on Phthalates on Toys and Children Care Materials (the Official Gazette of October 20, 2005 No: 25972)

- The Communiqué on Assigning the Turkish Standards Institute as a Notified Body (the Official Gazette of November 03, 2009 No: 27395)

- The Communiqué on Assigning SGS Supervised Surveillance Etude Control Services Inc. as a Notified Body (the Official Gazette of April 24, 2010 No: 27561)

4.2.3.2. Detergents

The European Union regulations with regard to detergents were transferred into the Turkish legislation in 2005. The regulation of the European Parliament and of the Council on Detergents No: 648/2004/EC, the new regulation on this issue, was published in the Official Gazette of December 23, 2010 as the “Communiqué on Detergents and Surface Active Agents” and transferred into the Turkish legislation. This communiqué is in total compliance with the Regulation No: 648/2004/EC.

4.2.3.3. Medical Devices

4.2.3.3.1. Medical Devices

The “Implementing Regulation on Medical Devices” prepared having regard to the Directive on Medical Devices No: 93/42/EEC and published in the Official Gazette of March 13, 2002 was updated and published in the Official Gazette of June 07, 2011 No: 27957. This
implementing regulation was prepared in parallel with the Directive No: 2007/47/At as well as the Directive No: 93/42/EEC.

4.2.3.3.2. Active Implantable Medical Devices

The “Implementing Regulation on Active Implantable Medical Devices” prepared having regard to the Directive on Active Implantable Medical Devices No: 90/385/EEC and published in the Official Gazette of March 12, 2002 was updated and published in the Official Gazette of June 07, 2001 No:27957. This implementing regulation was prepared in parallel with the Directive No: 2007/47/EC as well as the Directive No: 90/385/EEC.

4.2.3.3.3. In Vitro Diagnostic Medical Devices


4.2.3.3.4. Medical Devices Manufactured Utilising Tissues of Animal Origin

In parallel with the Directive on specifications on medical devices manufactured utilizing tissues of animal origin No: 2003/32/EC, the draft for the “Communiqué on Medical Devices Manufactured Utilizing Tissues of Animal Origin” was prepared and submitted to internal and external opinions.

There are three notified bodies working on medical devices. These are: Meyer Documentation Services Ltd. Company, Szutest Technical Control and Certification Services Co. Ltd. and Kalitest Documentation and Training Services Ltd. Company.

Other regulations with regard to medical devices are as follows:

- The Communiqué on Notified Bodies to Work on Medical Devices (The Official Gazette on March 03, 2001 No: 27863. The first one was published in the Official Gazette on November 14, No: 25286.)
• The Communiqué on Common Technical Specifications on In-vitro Diagnostic Medical Devices (2005/1) (The Official Gazette on April 07, 2005 No: 25779)

• The Communiqué on the Procedures and Principles on Medical Devices Warning System (The Official Gazette on July 14, 2010 No: 27641)

• The Communiqué on Assigning Meyer International Conformity Assessment Services Limited Company as a Notified Body under the Scope of the Implementing Regulation on Medical Devices (The Official Gazette on December 08, 2001 No: 27426)

• The Communiqué on Assigning Szutest Technical Control and Certification Services Co. Ltd. as a Notified Body under the Scope of the Implementing Regulation on Medical Devices (The Official Gazette on March 09, 2010 No: 27516)

• The Communiqué on Assigning Kalitest Documentation and Training Services Ltd. Company as a Notified Body under the Scope of the Implementing Regulation on Medical Devices (The Official Gazette on August 13, 2010 No: 27671)

4.2.3.4. Medicinal Products for Human Use

4.2.3.4.1. Good Manufacturing Practices (GMP) for Medicinal Products for Human Use

GMP, in accordance with the quality standards and the intended way of use, means a part of the quality assurance guaranteeing production and control of pharmaceuticals as defined by the information in the licensing and the product specification.

The GMP document, initiated by the Pharmacy and Pharmaceuticals Directorate General, demonstrates that “the producer can produce under the scope of the Good Manufacturing Practices granted by the Ministry or the internationally recognized institutions and approved by the competent authority of that country and adopted by the Ministry.” The fact that the GMP document is to be demanded is decided in “the paragraph (r) of the Article 3 of the
Implementing Regulation on Amending the Implementing Regulation on Licensing Medical Devices for Human Use” published in the Official Gazette of April 22, 2009 and No: 27208

On the basis of the amendment of the implementing regulation mentioned above, the Pharmacy and Pharmaceutical Directorate General of the Ministry published an announcement stating that “by 01.03.2010, the applications for Common Technical Document (CTD) licenses requires the GMP document granted by the Ministry after an inspection process or the GMP document granted by competent authorities of countries which Turkey has a mutual recognition agreement for the pre-review. The applicants which do not meet this requirement will be declined.”

The justification of the Ministry with regard to this implementation is to protect public health given to the withdrawals of Level 1, which has a vital importance in terms of exported medicines in the global market recently.

**4.2.3.4.2. Data Exclusivity for Medicinal Products for Human Use**

Data exclusivity period for medicinal products in the EU is regulated on the basis of the Directive No: 2001/83/EC; thus this period is minimum 6 years and maximum 10 years. However the directive mentioned was amended and this period was extended to 11 years as in the form of 8+2+1 years.

Within this scope, the first 8 years none of the generic applications can be accepted. Generic application can be received for a period of 8-10 years; however, the product is not supplied to the market. An extra exclusivity period of 1 year can only be granted on condition that the medicine concerned is claimed to have an additional indication by the producer within the first 8 years.

The article 10(1)(b) of the European Directive No:2001/83/EC on Medicinal Products for Human Use requires the pre-clinic and clinic tests on the combination by the applicant with required to the combined products, if the active substances, known to be safe and effective when used independently, are used for the first time in the combination. The EU demands a different licence for such combined products considering these products as new medicinal products for human use. Therefore, these products can benefit from data exclusivity practice.
The issue of data exclusivity for medicinal products for human use was regulated the “Implementing Regulation on Licensing Medicinal Products for Human Use” and the practice of data exclusivity is for a period of 6 years. The Article 9 of the implementing regulation rules the data exclusivity periods as follows under the heading of “abridged application”:

- In one of the countries under the scope of CU, original products which are licensed for the first time by 1/1/2001 and without a generic application until 1/1/2005 in Turkey

- In one of the countries under the scope of CU, original products which are licensed for the first time after 1/1/2001 and without a generic application until 1/1/2005 in Turkey

- In one of the countries under the scope of CU, it is valid for the original products which are licensed for the first time after 1/1/2001 and its validation period is years beginning from the date of licence in CU.

- For the products benefitting from patent protection in Turkey, the practice of data exclusivity of 6 years is limited by this patent period.

If the product is not patented in Turkey, the data exclusivity is applied as 6 years.

In 2008 National Program, it is stated that the alignment with regard to the practice of data exclusivity (8+2+1), regulated in the Directive No: 2004/27/EC, will be evaluated with the perspective of full accession.

In the article on combined products of “The Implementing Regulation on Amending the Implementing Regulation on Licensing Medicinal Products for Human Use”, published in the Official Gazette of April 22, 2009 and No: 27208, it is stated that licence applications for the combinations excluding a new indication will be evaluated as a part of the first licence and there is no need for further pharmacologic and toxicological tests for such combined products on condition that the products includes known components and each component/combination is accepted in terms their common and effective medicinal use.
4.2.3.5. Cosmetics

The cosmetics acquis was transferred into the Turkish legislation as:

- The Law on Cosmetics No: 5324 (the Official Gazette of March 30, 2005 and No: 25771)
- The Implementing Law on Cosmetics (the Official Gazette of May 23, 2005 No: 25823)
- 7 the Communiqués on Cosmetic Analysis (the Official Gazette of July 1, 2005 No: 25862)

There are some amendments in the implementing regulation on cosmetics in parallel with the improvements in the Acquis Communitaire.

The Regulation on Cosmetics setting out certain arrangements with regard to the cosmetovigilance system, auditing mechanism and market surveillance was published in November 30, 2009 and will be put in effect in July 2013. A revision in the field of cosmetics is also required in accordance with the regulation mentioned in Turkey as well and the studies with respect are still continuing.

4.2.3.6. Foods for Special Medical Purposes

The Communiqué on Foods for Special Medical Purposes harmonizing the Commission Directive on Foods for Special Medical Purposes of March 25, 1999 and No: 1999/21/EC was published in the Official Gazette of December 24, 2001 and No: 24620 and put into effect. As it has been required during the implementation, studies with this regard are still continuing in the Pharmacy and Pharmaceuticals Directorate General, which is responsible for the implementation of this communiqué.

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5 The Official Gazette of October 12, 2006 No: 26317; The Official Gazette of April 26, 2009 No: 27211; The Official Gazette of March 27, 2010 No: 27534
4.2.4. Negotiation Process for the Free Movement of Goods

The General Affairs Council of the EU, upon the participation of new countries in the EU with the fifth generation expansion of the EU, decided not to start negotiations on this chapter until the commitments (the issue of Customs Union with Greek Cypriot Administration of Southern Cyprus) with regard to the Additional Protocol signed on July 29, 2005 are fulfilled by Turkey on December 11, 2006. This chapter is one of the 8 headlines suspended.

However, towards the end of 2007, Portugal took steps in the direction of issues highly possible to be turned into opening benchmarks in terms of this chapter during its presidency.

The coordination of this chapter is carried out by the UFT and the relevant studies with regard to the preparation of opening-closing benchmarks and Position Papers are executed by the Ministry of EU.

4.2.4.1. Opening Benchmarks of Free Movement of Goods

5 opening benchmarks have been determined for this chapter:

**Benchmark 1-** Turkey addresses the barriers to trade contrary to Articles 5 and 7 of Decision 1/95 of the EC-Turkey Association Council and in particular:

- Removes import permits or license requirements, as well as disproportionate requirements for certificates, for the products covered by Decision 1/95 of the Association Council, other than used motor vehicles, and with particular reference to alcoholic beverages,
- Submits to the Commission a plan for removing import permits on used motor vehicles.

**Benchmark 2-** Turkey completes the internal screening of measures contrary to articles 28-30 of the Treaty (regarding quantitative restrictions on imports and exports between Member States), provides a plan for their removal and introduces the mutual recognition clause in its legal order.

**Benchmark 3:** Turkey presents an action plan with milestones for the remaining alignment of implementation in the areas of horizontal procedural measures as well as pharmaceuticals. This benchmark is directly related to the Ministry of health.
**Benchmark 4**- Turkey presents to the Commission a comprehensive strategy with milestones for the upgrade of administrative capacity necessary for the implementation of the EC legislation on market surveillance.

**Benchmark 5**- Turkey has fulfilled its obligations of full, non-discriminatory implementation of the Additional Protocol to the Association Agreement.

**4.2.4.2. Screening Report**

The introductory screening meetings were held on December 16-20, 2006 and the detailed screening meetings were carried out on December 20-24, 2006.

With regard to the pharmaceuticals the followings were stated by the European Commission in the Screening Report:

- Turkey has fulfilled legislation studies required; however the alignment is still partial,

- Certain legislation drafts (delivery, clinical researches) are prepared,

- There are some amendments in the Implementing Regulation on Data Exclusivity; however this does not include abridged applications,

- Data exclusivity has been limited to six years for original products since January 1, 2005 on condition that the licence concerned is granted as of January 1, 2001 in countries under the scope of CU and there is no application for generic licenses before January 1, 2005 in Turkey,

- Apart from the current situation and the studies carried out, there is no indication that Turkey has an intention to align its legislation with the Acquis Communitaire,

- Regulations with regard to pricing and reimbursement of medicinal products are in compliance with the EU.
4.2.4.3. Action Plan of the Undersecretariat of Foreign Trade

The UFT, the coordinator of the Free Movement of Goods, conducted certain studies with regard to the opening benchmarks in 2007 and prepared an Action Plan.

The summary of the plan;

- The requirement of alignment with regard to medicinal products for human use is the requirement of ACDs No:1/95 and 2/97 and the legislation determined under the scope of the ACD No:2/97 was to be aligned by January 1, 2001,

- The issues with regard to data exclusivity is included in the Implementing Regulation on Licensing published on January 19, 2005,

- Turkey underwent into an inspection in terms its Implementing Regulation on Technical Barriers to Trade based on a complaint from a EU sector in December 2003,

- Within this scope, Turkey acts contrary to mutual and multilateral commitments in terms of transparency, pricing, reimbursement and data exclusivity,

- During this process effective solutions could be found due to effective efforts by Turkey; however the problems with regard to data exclusivity are still continuing,

- Therefore, the subject matter is mainly focused on the failure to implement data exclusivity between 2001 and 2005,

- The Commission has still the opinion that the criteria applied for the evaluation and licensing of generic applications do not comply with the CU rules and Turkish domestic law.

4.2.4.4. Approach of the Ministry of Health

Even though the UFT mentions that the subject matter is focused on the issue of data exclusivity; the Ministry of Health (PPDG) has favoured to submit a general plan in terms of
medicinal products for human use as it is indicated the benchmark concerned. Accordingly, the position of the Ministry of Health by March 25, 2010 is as follows:

<table>
<thead>
<tr>
<th>LEGISLATION HARMONIZATION STUDIES CARRIED OUT SO FAR</th>
<th>DIRECTIVES</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Implementing Regulation on Licensing Medical Devices for Human Use, the Official Gazette of January 19, 2005 and No: 25705</td>
<td>2001/83/EC</td>
</tr>
<tr>
<td>The Implementing Regulation on Commercial Activities of Medical Devices for Human Use, the Official Gazette of October 23, 2003 and No: 25268</td>
<td>2001/83/EC, Chapter VIII</td>
</tr>
<tr>
<td>The Implementing Regulation on Surveillance of Safety of Medical Devices for Human Use, the Official Gazette of March 22, 2005 and No: 25763</td>
<td>2001/83/EC, Chapter IX</td>
</tr>
<tr>
<td>The Implementing Regulation on Categorization of Medical Devices for Human Use, the Official Gazette of February 17, 2005 and No: 25730</td>
<td>2001/83/EC, Chapter VI</td>
</tr>
<tr>
<td>The Implementing Regulation on Packaging and Labelling of Medical Devices for Human Use, the Official Gazette of August 12, 2005 and No: 25904</td>
<td>2001/83/EC, Chapter V</td>
</tr>
<tr>
<td>The Implementing Regulation on Manufacturing Plants of Medical Devices for Human Use, the Official Gazette of October 23, 2003 and No: 25268</td>
<td>91/356/EC</td>
</tr>
<tr>
<td>The Implementing Regulation on Medical Devices for Human Use Already Licensed or Applied for License, the Official Gazette of May 23, 2005 and No: 25823</td>
<td>1085/2003/EC</td>
</tr>
<tr>
<td>The Communiqué on Colorants Used for Veterinary Medical Devices and Medical Devices for Human Use, the Official Gazette of January 18, 2005 and No: 25704</td>
<td>78/25/EC</td>
</tr>
<tr>
<td>The Decision on Pricing Medicines for Human Use, the Official Gazette of February 14, 2004 and No: 25373</td>
<td>89/105/EC</td>
</tr>
<tr>
<td>The Communiqué on Pricing Medicines for Human Use, the Official Gazette of March 03, 2004 and No: 25391</td>
<td></td>
</tr>
<tr>
<td>The Communiqué on Clinical Researches, the Official Gazette of December 23, 2008 and No: 27089</td>
<td>2001/20/EC</td>
</tr>
<tr>
<td>(The State Council granted a motion for stay of execution in accordance with the Decision of its 10th Department of November 13, 2009 and No: 2009/3991 E. Studies for a new implementing regulation by PPDG are still continuing.)</td>
<td>2005/28/EC</td>
</tr>
</tbody>
</table>

LEGISLATION DELAYED SO FAR

<table>
<thead>
<tr>
<th>DIRECTIVE</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Implementing Regulation on Warehousing and Distribution of Medicinal Products (its draft is available)</td>
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</tbody>
</table>
4.2.4.5. Relevant Legislation in 2008 National Programme

2008 National Programme for medicinal products for human use is as follows:

<table>
<thead>
<tr>
<th>EU Legislation in Effect</th>
<th>Draft Turkish Legislation</th>
<th>Scope</th>
<th>Date of Publication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Directive No 2004/27/EC</td>
<td>Amendment of the Implementing Regulation on the Licensing of Medicinal Products for Human Use</td>
<td>To harmonise data exclusivity, which is currently implemented in compliance with the Directive no 2001/83/EC, with the data exclusivity-related provisions of the Directive no 2004/27/AT</td>
<td>It will be published within the framework of full membership perspective</td>
</tr>
<tr>
<td>Directive No 2004/24/EC</td>
<td>Implementing Regulation on the Simplified Licensing of Traditional Herbal Medicinal Products</td>
<td>To audit the traditional use of the products whose traditional use is authenticated bibliographically or through expert evidence and to prevent public health from their adverse effects by defining them as products containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations.</td>
<td>The Implementing Regulation, which had been projected to be published in 2009, was published in the Official Gazette no. 27721 of 6 October 2010 and entered into force as the “Implementing Regulation on Traditional Herbal Medicinal Products”.</td>
</tr>
<tr>
<td>Directive No 2001/83/EC</td>
<td>Implementing Regulation on the Warehousing and Distribution of Medicinal Products</td>
<td>To provide the safety and quality of authorised/permitted medicinal products for human use and veterinary medicinal products in order to protect public health and to ensure the withdrawal of defective, fake or ruined products when necessary. To establish the methods and principles regarding the proper implementation of purchase, sale, storage, distribution and relevant procedures regarding the said products.</td>
<td>Despite the 2009 projections, no regulations have been conducted.</td>
</tr>
<tr>
<td>Directive No 2001/83/ EC</td>
<td>Law Amending the Law no. 1262 on Pharmaceuticals and Medical Preparations</td>
<td>Licensing of advertising for non-prescription medicinal products for human use.</td>
<td>It will be published within the framework of full membership perspective</td>
</tr>
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<td>------------------------</td>
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</tbody>
</table>
| Regulation No 141/2000 | Implementing Regulation on Orphan Drugs | Patients with rare diseases should have the right to equal treatment like any other patients. Therefore, within the scope of the encouragement of the drug industry to research, develop and place on the market the drugs for rare diseases, to establish the licensing methods and principles of the orphan drugs meeting the following benchmarks:  
• intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition,  
• intended for the diagnosis, prevention or treatment of a serious or chronic condition,  
• without incentives it is unlikely that the marketing of the product would generate sufficient return to justify the necessary invest. | It will be published within the framework of full membership perspective |
| Regulation No 847/2000 | Implementing Regulation on the Designation of a Medicinal Product as Orphan Medicinal Product and the Determination and Implementation of the Criteria for the Definitions of the Concepts ‘Similar Medicinal Product’ and ‘Clinical Superiority’ | • To identify the drugs which are used for the diagnosis, prevention and treatment of rare diseases or conditions,  
• To classify these drugs through their evaluation based on their production costs and frequency of use,  
• To determine the production and usage responsibilities brought by the “similar” or “clinically superior” concepts  
• To encourage the producers to develop and introduce these drugs | It will be published within the framework of full membership perspective |
4.2.4.6. Opening Benchmark for the Free Movement of Goods Chapter which Indirectly Concern the Ministry of Health

**Benchmark 1-** Turkey addresses the barriers to trade contrary to Articles 5 and 7 of Decision 1/95 of the EC-Turkey Association Council and in particular:

- Removes import permits or license requirements, as well as disproportionate requirements for certificates, for the products covered by Decision 1/95 of the Association Council, other than used motor vehicles, and with particular reference to alcoholic beverages,
- Submits to the Commission a plan for removing import permits on used motor vehicles.

Within the scope of Customs Union (CU) established between Turkey and the EU, import permit or licenses are of great importance in terms of the removal of the measurements with equivalent effect such as customs duty.

The Undersecretariat of Foreign Trade, which is responsible for the coordination of MSD Chapter, addressed this issue in March 2007 within the scope of the studies for an action plan aiming at tackling the problematical issues with the participation of all related agencies. Turkey requests extra import certificates for the products within free circulation in the EU, therefore this has been interpreted as Turkey’s violation of CU liabilities by the EU. Article 7 of the Decision 1/95 of the EC-Turkey Association Council which is the basis of import licenses, provide foundation for the protection of public safety, human and animal health and phytosanitary although it is stated that the documents required by certain agencies are inconsistent with the EU implementations.

**Benchmark 2-** Turkey completes the internal screening of measures contrary to articles 28-30 of the Treaty (regarding quantitative restrictions on imports and exports between Member States), provides a plan for their removal and introduces the mutual recognition clause in its legal order.

Within the scope of the Commission Interpretative Communication No 2003/C 265/02 it is stated that the Turkish products within the non-regulated area (not regulated by any legislation) should not be treated the same as the products from the Member States. Pursuant to the Decision 1/95 of the EC-Turkey Association Council, the EU has the opinion that
Turkey should also conduct a similar implementation and should realise the mutual recognition principle.

**Benchmark 4-** Turkey presents to the Commission a comprehensive strategy with milestones for the upgrade of administrative capacity necessary for the implementation of the EC legislation on market surveillance.

With the contributions from relevant agencies the “National Strategy Paper on Market Surveillance” has been prepared under the coordination of the Undersecretariat of Foreign Trade and it was published in April 2010. The said document has also been submitted to the European Commission.

**Benchmark 5-** Turkey has fulfilled its obligations of full, non-discriminatory implementation of the Additional Protocol to the Association Agreement.

Within the scope of the Ankara Agreement creating an association between Turkey and the EU, the Additional Protocol to CU was signed by Turkey on 29 July 2005 upon the fifth enlargement of the EU. The Protocol consists of 16 articles and includes the following issues:

Under the title “Contracting Parties” it is stated that 10 new Member States including the “Republic of Cyprus” which joined the EU in 2004 shall be parties and shall adopt all agreements and protocols signed between Turkey and the EU. In the document it is stated that the individually mentioned countries which are considered as parties shall be represented by the Council of the European Union and “25 countries represented by the Council of the European Union and the EC is the one part” and “the Republic of Turkey” is the other part.

Under the title “Territory of Application” it is indicated that Ankara Agreement shall apply to the territory to which the Treaty establishing the European Community applies. Turkey has also published a Declaration following the signing of the Additional Protocol:

1. Turkey remains committed to finding a political settlement of the Cyprus issue and has clearly demonstrated its resolve in this regard. Accordingly, Turkey will continue to support the efforts of the UN Secretary-General towards achieving a comprehensive settlement which will lead to the establishment of a new bi-zonal partnership State. A just
and lasting settlement would greatly contribute to peace, stability and harmonious relations in the region.

2. The Republic of Cyprus referred to in the Protocol is not the original partnership State established in 1960.

3. Turkey will thus continue to regard the Greek Cypriot authorities as exercising authority, control and jurisdiction only in the territory south of the buffer zone, as is currently the case, and as not representing the Turkish Cypriot people and will treat the acts performed by them accordingly.

4. Turkey declares that signature, ratification and implementation of this Protocol neither amount to any form of recognition of the Republic of Cyprus referred to in the Protocol; nor prejudice Turkey’s rights and obligations emanating from the Treaty of Guarantee, the Treaty of Alliance, and the Treaty of Establishment of 1960.

5. Turkey reaffirms that its existing relationship with the Turkish Republic of Northern Cyprus remains unchanged by becoming a party to the Protocol.

6. Pending a comprehensive settlement, the position of Turkey on Cyprus will remain unchanged. Turkey expresses its readiness to establish relations with the new partnership State which will emerge following a comprehensive settlement in Cyprus.

4.2.4.7. Considerations required to be mentioned with regard to the Chapter

1. The considerations with regard to the Market Surveillance are within the Closing Benchmark for “Consumer and Health Protection”.

2. The considerations discussed by the Customs Union Joint Committee, which was established by the Decision 1/95 to provide the well functioning of CU and to provide the information and opinion exchange between the parties, are important in terms of the determined benchmarks.
4.3. RIGHT OF ESTABLISHMENT AND FREEDOM TO PROVIDE SERVICES
(Chapter 3)

4.3.1. Scope of the Chapter

Right of Establishment and Freedom to Provide Services is one of the four fundamental freedoms of the single market. Within the scope of this Chapter, Member States are liable to ensure that right of establishment and freedom to provide services are not hindered by legislation throughout the EU. Within this framework, in order to facilitate the practice of certain occupations, special rules should be established with regard to the mutual recognition of occupational qualifications and diplomas. In terms of certain occupations, a harmonised curriculum should be followed in order to provide automatic recognition of the occupational qualification concerned.

4.3.2. Studies Conducted by the Ministry of Health for this Chapter

In this chapter, occupational qualifications and their mutual recognition by the Member States is of great importance. Within the framework of this Chapter, the EU divides the occupation groups in two and applies two different systems for each.

The first group are the occupations for which minimum training requirements, curriculum and training hours are clearly defined and uniform implementation is obligatory for all Member States. These occupations are physician, nurse, midwife, pharmacist, dentist, veterinary and architect. “Automatic recognition” of occupational qualification system is implemented for these occupations for which a standardised training is obligatory at EU level.

“Implementing Regulation on the Establishment of Minimum Training Requirements for Physician, Nurse, Midwife, Dentist, Veterinary, Pharmacist and Architect Training Programmes” was prepared by the Higher Education Council (YÖK) with the contributions from the Ministry of Health and published in the Official Gazette no. 26775 of 02.02.2008. By the time this Implementing Regulation has entered into force, harmonisation with the EU training curriculum and minimum training periods regarding the occupations such as physician, nurse, midwife, pharmacist and dentist which are under the responsibility of the Ministry of Health have been ensured.
The second group of occupations under this Chapter are the ones for which minimum training standards have not yet been regulated to practice in the EU. The Member States are free to make their own internal regulations and to establish minimum requirements for the practice of the occupation if they are to make these regulations.

Within this scope, 26 health occupations which are currently practiced in Turkey and not regulated legally have been regulated by the Law no. 6225 of 06 April 2011.

As the Additional Protocol was not implemented during the EU Summit in December 2006 (because the additional protocol was not implemented to include Greek Cypriot Administration of Southern Cyprus), negotiations have been suspended for Right of Establishment and Freedom to Provide Services.

4.4. INTELLECTUAL PROPERTY (Chapter 7)

4.4.1. Scope of the Chapter

Legislation with regard to copyright and industrial property rights are included in the Intellectual Property Law Chapter.

Copyright includes regulations aiming at the protection of the creators of intellectual and art works which are considered as works of science and literature, music, fine arts or cinema.

Industrial property rights have a broad area including trademark, patent, design, utility model, biotechnology products and supplementary protection certificate.

4.4.2. Current Situation with regard to the Chapter

With respect to the Intellectual Property Law Chapter, introductory screening meeting was held in 6-7 February 2006 and the detailed screening meeting was held in 2-3 March 2006 in Brussels. An opening benchmark was introduced in the screening report declared by the Commission as a result of the screening meetings in 19 October 2006.

As an opening benchmark, Turkey has been requested to draw up an action plan for the harmonisation with the acquis and administrative capacity building. The action plan drawn up
with the contribution of the related agencies and institutions has been submitted to the Commission.

Negotiation Position Paper, which is Turkey’s commitment paper with regard to the Chapter, was submitted to the Commission on 6 May 2008 and the Common Position Paper was adopted. This chapter was opened to negotiation in 17 June 2008.

Five closing benchmarks (one political, four technical benchmarks) have been determined in the EU Common Position Paper:

1. Turkey has to fulfil its obligation of full non-discriminatory implementation of the Additional Protocol to the Association Agreement (political benchmark),

2. Turkey has engaged successfully in a dialogue on intellectual property rights issues according to the terms of reference submitted by the Commission to Turkey on 3 April 2008,

3. Turkey makes sure that enforcing bodies dispose of sufficient administrative capacity to enforce the rights concerning the fight against piracy and counterfeit,

4. Turkey provides a satisfactory track record of investigations, prosecutions and judicial treatment of violations and an improved performance concerning the effective enforcement of Intellectual Property Law, including a substantial reduction in the volume of counterfeited and pirated goods exported to the EU.

5. Turkey completes the alignment with the Community acquis concerning the community exhaustion of rights and the introduction of supplementary protection certificates, and ensures that these rights will be enforced by accession.

4.4.3. Studies Conducted by the Ministry of Health for this Chapter

Two of the above mentioned closing benchmarks concern the Ministry of Health. These are:

- Establishment of a dialogue mechanism in the area of Intellectual Property Rights, and
• Completion of the alignment with the Community acquis concerning the community exhaustion of rights and the introduction of supplementary protection certificates and to ensure that these rights will be enforced by accession.

4.4.3.1. Dialogue Mechanism

In the EU Common Position Paper, the Commission has determined the establishment of a dialogue mechanism concerning intellectual property rights as a closing benchmark. It is indicated that, “Turkey has engaged successfully in a dialogue on intellectual property rights issues according to the terms of reference submitted by the Commission to Turkey on 3 April 2008”. Terms of Reference (ToR) text includes the considerations with regard to the operation of the dialogue mechanism which is planned to be established between the EU and Turkey.

Following the review of the ToR text by the related agencies, the amendments recommended by Turkey have been sent to the Commission and the “Intellectual Property Rights Working Group” proposed as an alternative for the dialogue mechanism has been established. The Working Group held its first meeting on 18 May 2011.

4.4.3.2. Supplementary Protection Certificate

Council Regulation No 1768/92 of 18 June 1992 concerning the Creation of a Supplementary Protection Certificate for Medicinal Products provides maximum five years of protection following the exhaustion of the legal duration (20 years) of the basic patent of medicines. It is aimed to compensate the time lost during the phase of licensing with supplementary protection certificate. Supplementary protection certificate is implemented for the medicinal products which are protected by a basic patent in force in the country in question and which obtained license in accordance with the licensing legislation.

In Turkey's Programme for Alignment with the Acquis (2007-2013) it is stated that with regard to the supplementary protection certificate, harmonization shall be ensured in the framework of full membership perspective to the EU legislation.
Turkish Patent Institute is responsible for the alignment of the EU Regulation. However, on account of the fact that supplementary protection certificate is implemented for medicinal products, it directly concerns the Ministry of Health.

Alignment with the EU legislation concerning supplementary protection certificate is determined as a benchmark in the negotiations held within the scope of Intellectual Property Law Chapter.

The expansion of the supplementary protection certificate implementation in terms of first Licensing dates prior to the date of full membership is disapproved.

The negotiation position of the Ministry of Health with regard to supplementary protection certificate is that its harmonisation shall be ensured in the framework of full membership, not retroactively.

4.5. ENVIRONMENT (Chapter 27)

4.5.1. Scope of the Chapter

The environment policy of the EU supports sustainable development and aims at the protection of the environment for the current and next generations. The acquis in this area consists of long legal texts more than two hundred, including water and air quality, waste management, the protection of environment, industrial pollution control and risk management, chemicals and genetically modified organisms (GMO) as well as noise and forestry.

4.5.2. Current Situation with regard to the Chapter

With regard to the Environment Chapter, the Screening Report prepared by the European Commission was approved by the Council of the European Union and communicated to Turkey in 3 October 2007 by Portuguese Presidency. The screening report mentions two opening benchmarks. The said benchmarks are as follows:

1. Turkey presents to the Commission its comprehensive strategy for the gradual well coordinated transposition, implementation and enforcement of the acquis in this chapter,
including plans for building up the necessary administrative capacity at national, regional and local level and required financial resources, with an indication of milestones and timetables. (Explanatory note and draft strategy of approximately 1500 pages)\(^6\)

2. Turkey fulfils its obligations as regards the implementation of applicable environment acquis in line with the relevant EC-Turkey Association Council decisions. (5 Implementation Reports for regulation)

With a view to meeting the first opening benchmark, a Strategy Paper of 400 pages for 69 EU legislations has been prepared under the coordination of the Ministry of Environment and Urban Planning with the contributions from related agencies and institutions including the Ministry of Health. This Strategy Paper includes the following:

- Horizontal Legislation,
- Air Quality,
- Waste Management,
- Water Quality,
- Protection of the Environment,
- Industrial Pollution Control and Risk Management
- Chemicals Management,
- Genetically Modified Organisms,
- Noise Management.

With a view to meeting the second opening benchmark, Implementation Notes for 5 EU legislation within the scope of CU have been prepared under the coordination of the Ministry of Environment and Urban Planning. The said legislation is listed below:

- Directive on Hazardous Chemicals,
- Directive on Animals used for Experimental Purposes,
- Directive on Packaging and Packaging Waste,
- Directive on the Quality of Petroleum and Diesel Oil,

\(^6\) The preparation studies for the said strategy have been conducted under the coordination of the Ministry of Environment and Urban Planning. The Ministry of Health made contributions within the scope of “bathing waters” and “biocidal products”.
• Directive on Sulphur Content of Liquid Fuels.


Consequently, during the 2009 Swedish Presidency, the letter requesting Turkey’s Negotiation Position Paper was communicated to Turkey. The working groups in Turkey, consisting of the representatives from related ministries/public agencies (including the Ministry of Health) have drawn up the negotiation position paper under the chairmanship of the Ministry of Environment and Urban Planning which is responsible for the chapter concerned and under the coordination of the Ministry for EU Affairs and they communicated the Paper to the European Commission. The following are mentioned in Turkey’s Negotiation Position Paper:

• The current situation of the harmonisation with the EU acquis,

• The institutional structure to be established for full alignment and implementation, the studies to be conducted and the alignment schedule planned.

The said Negotiation Position Paper has been based on the “Strategy Paper” prepared which had been drawn up within the scope of the first opening benchmark. The European Commission has published the Common Position Paper in reply to the Negotiation Position Paper. During the Swedish Presidency, negotiations with the EU were opened on the 27. Environment Chapter, at the Intergovernmental Participation Conference on 21 December 2009.

Six closing benchmarks have been determined by the Common Position Paper of EU prepared in reply to the Negotiation Position Paper for the temporary closure of the Environment Chapter:

7 The said Negotiation Position Paper has been prepared based on the “Strategy Paper”, drawn up within the scope of the first opening benchmark.
1. Turkey adopts legislation aimed at implementing EU’s horizontal and framework environmental legislation,

2. Turkey passes legislation aimed at implementing the EU acquis in the field of water quality, and makes further progress,

3. Turkey adopts legislation in the field of industrial pollution control and risk management,

4. Turkey continues its alignment with the acquis in the remaining sectors of this chapter including nature protection and waste management and demonstrates that it will be fully prepared for the EU requirements at the date of accession,

5. Turkey continues capacity building of the administrative bodies including inspection services and ensures these structures are in place,

6. Turkey has to fulfil its obligation concerning the Additional Protocol.

In order to fulfil the said closing benchmarks, the studies of the relevant agencies and institutions continue under the coordination of the Ministry of Environment and Urban Planning.

4.5.2. Studies Conducted by the Ministry of Health for this Chapter

The Ministry of Health makes contribution to the studies of the Ministry of Environment and Urban Planning, the coordinator of this Chapter. The contribution from the Ministry of Health is summarised below in terms of Directives.


Within the framework of the Directive 98/83/AT, “Implementing Regulation on Water Intended for Human Consumption” was published in the Official Gazette no. 25730 of 17.02.2005 and entered into force. Moreover, the Twinning Project on “Strengthening the Ministry of Health to Harmonise and Implement Legislation in the Field of Biocidal Products
and Water” which was started in 2006 and finished in 2008 with a budget of €1,5 million has been conducted.

Environmental Health Department of the General Directorate of Primary Health Care under the Ministry of Health is responsible for the harmonisation with the EU legislation with regard to drinking water and water intended for human consumption. The Department is also responsible for providing the physical quality control of waters and facilities. Furthermore, the Ministry of Health is responsible for conducting the monitoring, auditing, reporting procedures and sanction implementations with regard to drinking water and water intended for human consumption.

Refik Saydam Hygiene Centre and Regional Hygiene Institutes are responsible for the analysis and reporting procedures with regard to drinking water and water intended for human consumption.

Provincial Health Directorates, on the other hand, are responsible for determining water sample collection sites, conducting sampling and monitoring, taking necessary measurements for the detection of inconveniences, handling information, reporting and sanction procedures.

The Ministry of Health continues its studies aiming at the establishment of a database for monitoring drinking water and the establishment of mechanisms for the management of the cases which do not comply with the requirements. The Ministry plans to activate the whole system.

4.5.2.2. Studies within the scope of the Council Directive 76/160/EEC on the Quality of Bathing Water

The said Directive was published in the Official Gazette of 9 January 2006 by the Ministry of Environment and Urban Planning via “Implementing Regulation on the Quality of Bathing Water” and transposed to the national legislation.

The Ministry of Health has conducted the twinning project on “Strengthening the Ministry of Health to Harmonise and Implement Legislation in the Field of Biocidal Products and Water”
with a view to ensuring the complete and efficient implementation of the said Implementing Regulation.

Directive 2006/7/EC concerning the management of bathing water quality will repeal the Directive 76/160/EEC mentioned above as of 2015 and the harmonisation with the Directive 2006/7/EC will be conducted by the Ministry of Health and the Ministry of Environment and Urban Planning. According to the National Programme 2008, the said harmonisation study is projected to take place following the year 2011. Therefore, the Ministry of Health had suggested a twinning project within the scope of IPA 2010 and the said project have been approved by the European Commission. The project will initiate in early 2012 and is planned to be accomplished within the first quarter of 2014.

4.5.2.3. Directive 98/8/EC concerning the Placing of Biocidal Products on the Market

The Implementing Regulation on Biocidal Products was published in the Official Gazette no. 27449 (4th rep.) of 31.12.2009 and entered into force. The said Implementing Regulation has been prepared as an outcome of the twinning project on “Strengthening the Ministry of Health to Harmonise and Implement Legislation in the Field of Biocidal Products and Water”.

Moreover, the Ministry of Health provides support for the studies of the Ministry of Environment and Urban Planning with regard to environment.

4.5.2.4. The Part with regard to Environment concerning the Ministry of Health in Turkey 2010 Progress Report

The Progress Report states that the legislation on biocidal products, included under the direct responsibility of the Ministry of Health for harmonisation, has been adopted however the capacity is insufficient for effective implementation.

Within this framework, “Competent Authorities Meetings” are held with the participation of EU Member States’ competent authorities to discuss the implementations regarding the placing on the market of biocidal products regulated under the Directive 98/8/EC. The General Directorate of Primary Health Care is considered to provide participation for the said meetings at certain intervals.
4.6. JUSTICE, FREEDOM AND SECURITY (Chapter 24)

4.6.1. Scope of the Chapter

Chapter 24 “Justice, Freedom and Security” includes issues such as border control, visas, external migration, asylum, the fight against illegal trafficking of narcotics, money laundering, organised crime, terrorism, fraud and counterfeiting and police and judiciary cooperation, Schengen acquis which provides customs cooperation and the removal of border control.

4.6.2. Studies Conducted by the Ministry of Health for this Chapter

4.6.2.1. Migration and Asylum

Within the scope of “Migration and Asylum”, one of the most important issues under this Chapter, the Ministry of Health provides technical support for the “Establishment of Country of Origin Information Systems” and “Support for the Development of an Action Plan to Implement Turkey’s Asylum and Migration Strategy and Establishment of Return Centres for Illegal Migrants” projects which are conducted by the Ministry of Interior and Turkish National Police. The final meetings of the projects were held in October 2010 and June 2011.

Also, “Establishment of Reception, Screening and Accommodation Centres for the Asylum Seekers and Refugees Twinning Project” continues. Within this scope, in addition to the said Projects, the studies for the establishment of standards of health care services to be provided during irregular migration, in return centres and reception/accommodation centres continue under the responsibility of the Ministry of Health.

On the other hand, the Ministry contributes to a study for the preparation of a Draft Law including asylum and migration issues. Within the scope of this Draft Law which is lately named as “Foreigners and International Security Law” includes accommodation and travelling of foreigners within the country, passport and visa procedures and procurement of health services.
4.6.2.2. Integrated Border Management

“Integrated border management”, which is very important in terms of Turkey’s security, is one of the opening benchmarks of this Chapter. Within this scope, the Ministry of Health provides participation in the preparation studies for “Draft Law on Border Security/Protection Organisation”.

4.6.2.2.1. Integrated Border Management Action Plan Phase – I

The objective of the Project is to determine suggestions with regard to legal and administrative structuring for the establishment of a border security organisation which is able to implement EU Integrated Border Management Strategy in Turkey. The project also aims at developing and strengthening Turkey’s legal, administrative and technical capacity to align its border management system with EU Integrated Border Management Strategy. To this end, a Border Security organisation is planned to be established under the Ministry of Interior.

Within the scope of project implementation, a high level of coordination and cooperation should be ensured between the participating agencies and Integrated Border Management Coordination Board. The Department of Borders and Maritimal Health and the Department of EU Coordination represents the Ministry of Health in the “Task Force” established for the implementation of the project. The Project was initiated on 17 May 2010. The Project will be implemented for 18 months and will be accomplished on 11 November 2011.

4.6.2.2.2. Integrated Border Management Action Plan Phase – II

Finland Border Protection Unit provides support for the Turkish National Police and the Ministry of Health in improving risk management systems for effective border control. Moreover, a proposal for a special “risk management model” is being developed for the future border management implementations. It was initiated on 11 January 2011 and is planned to be accomplished by 2012.
4.6.2.2.3. Strengthening Integrated Board Management in West Balkans and Turkey Twinning Project:

The project was initiated in 2009. It is being implemented in coordination with International Organisation for Migration. Within the scope of the project, training activities are being provided in stakeholder countries for the personnel of the agencies which have the responsibility of border control and protection.

EU HARMONISATION STUDIES AND MARKET SURVEILLANCE

Even though market surveillance is a new concept, introduced to our lives through the Customs Union (CU) established between Turkey and EU in 1996, it is not very different from the past and current market surveillance procedures conducted by competent agencies and institutions. On the other hand, the EU harmonisation has brought different approaches to market surveillance as well as to other certain practices. This necessitated an efficient share of responsibilities and power between the producers and consumers of the product, institutions making regulations concerning the product and agencies evaluating the compliance of the product in the modernised world.

It is useful to review market surveillance within the legislation systematic which the EU considers as the “New and Global Approach”. From this point of view, there are four important parties within the scope of the system: Competent public authorities, producers, conformity assessment bodies and consumers. Within the framework of the new system, the competent public authorities make the relevant technical regulation (the Directive), establish the harmonised standards for the product and conduct efficient market surveillance in order to determine if the products on the market have been produced in compliance with the relevant technical regulation and/or standards for the safety of the consumer. In the system, basically producers are responsible for the products they have produced. Producers make production either in accordance with the relevant directives or the voluntary standards which have been prepared with regard to the product. Conformity assessment bodies or notified bodies evaluate the conformity of the product with the technical regulations or the voluntary standards and grant CE mark if the product is in conformity. When the consumer has a problem with a
product, he/she submits the case to a competent public institution. In the EU, the following regulations have been made in order to operate this whole system:

- Conformity assessment procedures and modular approaches have been improved,
- Implementing institutions and the criteria for granting CE mark have been determined,
- The standards for quality assurance system and the requirements for the conformity assessment bodies have been generalised,
- The establishment and improvement of accreditation systems have been supported,
- The quality infrastructure (such as calibration and metrology, testing laboratories, certification and examination institutions, accreditation institutions) differences between industry sectors have been minimised.

As it is seen, market surveillance is one of the important elements of new and global approach.

WHAT IS MARKET SURVEILLANCE?

Market surveillance basically includes the activities carried out by competent public authorities to ensure that products are produced in compliance with legal requirements or safe during the placing on the market or distribution of the products or during the time when the products are on the market.

Market surveillance has two aspects: monitoring and auditing. There are differences between market monitoring and market auditing in terms of the parties taking role in these activities.

Market monitoring is basically a phase in which all actors of the market take place actively as well as public bodies. At this stage, the duty of consumers, users, competing producers, distributors, conformity assessment bodies, notified bodies and NGOs is to submit their complaints, notifications and evaluations regarding the incompliance of the products on the market with technical regulations and unsafety thereof to the relevant public authorities. This information shall be taken into consideration by the public authority conducting market surveillance.
Market auditing is a process in which only the public authority is active even though the public authority benefits from the facilities of other testing, examination and/or certification institutions. Within this scope, the competent public bodies control depots and stores, audit production sites regularly if necessary or conducts random and sudden visits to these sites in order to determine if products are in compliance with legislations and if they are safe. Moreover, the competent authority may require the producer to provide information and documents demonstrating compliance with the relevant technical regulation; it controls if the marks demonstrating compliance are attached to the product and used properly; it takes samples from the product or the production line when necessary, in order to determine if they comply with the relevant legislation through laboratory analysis. Sanctions for unsafe products which are stated in the legislation shall be imposed.

**MARKET SURVEILLANCE WITHIN THE SCOPE OF THE EU HARMONISATION**

Within the scope of the EU harmonisation, market surveillance has been brought to the agenda by Decision 1/95 of the EC-Turkey Association Council which establishes CU between Turkey and the EU and determines its methods and principles and by Decision 2/97 of the EC-Turkey Association Council which establishes EU legislation list to be harmonised by Turkey. In addition, the Cabinet Decree no. 97/9196 has regulated the agencies to conduct the harmonisation of the EU regulation determined by Decision 2/97 of the EC-Turkey Association Council. The Cabinet Degree also states that the said harmonisation process shall be conducted by the Undersecretariat of Foreign Trade.

Within this framework, DTM is responsible for the general coordination of and the required legislative infrastructure for technical legislation harmonisation studies. The legislation regarding product safety which is the precondition for the free movement of goods in the single market; the legislation regulating general provisions for the use and attachment of CE marking; the legislation concerning the conformity assessment of products are included within the scope of the legislation which will prepare the infrastructure. These issues establish the legal basis for the transposition of the EU’s New and Global Approach to domestic legislation.

Within this scope the Undersecretariat of Foreign Trade has published the Law no. 4703 on the Preparation and Implementation of the Technical Legislation on the Products (Framework
Law) and its Implementing Regulations. One of the Implementing Regulations in question is the Implementing Regulation on Market Surveillance.

Basically, the Framework Law establishes the duties of authorised bodies, producers and conformity assessment bodies in placing on the market of only the products which are in conformity with the technical regulation and are safe.

The Framework Law focuses on the market surveillance concept which is distributed within the Turkish legislation. It also provides the evaluation of conformity of the production with technical rules by the conformity assessment bodies and notified bodies which do not exist in the current legislation. The Law also regulates the implementations in case unsafe products are detected on the market and it provides Turkey to be a member of the mutual notification mechanism developed by the EU with a view to determining if the draft legislation in Turkey will form technical barriers to trade in the in the areas which are not covered by EU common legislation.

On the other hand, the Implementing Regulation on Market Surveillance which was prepared based on the Framework Law regulates product safety principles, obligations of producers and distributors in placing on the market of products, market surveillance methods and principles, powers and responsibilities of authorised bodies, measurements to be taken in case of an unsafe product, the establishment of Market Surveillance Coordination Board and the working methods and principles of the said Board. The Implementing Regulation also includes the products within the Classical Approach group which are regulated as equally detailed as the products within the scope of New Approach.

Within the scope of the current regulations, only “safe” products may be placed on the market in Turkey. Safe product is defined as “any product which, within the duration of use and under normal conditions of use, does not present any risk or only acceptable risks and consistent with a high level of protection of persons in terms of essential requirements.” Within this scope, products in compliance with technical legislation are considered as “safe” and the responsibility belongs to public, producer, conformity assessment bodies and distributors. Public bodies are responsible for conducting market surveillance by controlling the labels, markings, packaging and certificates and for testing and analysing when necessary.
MARKET SURVEILLANCE IN TURKEY

Market surveillance is conducted by various institutions in Turkey. Within this scope, the products and the agencies and institutions responsible for its market surveillance are given below:

<table>
<thead>
<tr>
<th>Agency and Institution</th>
<th>Products and Goods</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Ministry of Industry and Trade</td>
<td>Machinery, explosives for civil use, motor vehicles, elevators, household appliances, gas burning devices, pressure equipments, measuring instruments, electrical material, textile products, shoes, other machinery and forestry tractors</td>
</tr>
<tr>
<td>The Ministry of Health</td>
<td>Cosmetics, detergents, toys, medical devices</td>
</tr>
<tr>
<td>The Ministry of Agriculture and Rural Affairs</td>
<td>Foodstuff, feedstuff, fertiliser</td>
</tr>
<tr>
<td>The Ministry of Public Works and Settlement</td>
<td>Construction materials</td>
</tr>
<tr>
<td>The Telecommunication Authority</td>
<td>Radio and telecommunications terminal equipments</td>
</tr>
<tr>
<td>The Ministry of Labour and Social Security</td>
<td>Personal protective equipments</td>
</tr>
<tr>
<td>The Undersecretariat of Maritime Affairs</td>
<td>Recreational crafts, naval equipments</td>
</tr>
<tr>
<td>The Tobacco, Tobacco Products and Alcoholic Beverages Market Regulatory Board</td>
<td>Tobacco and tobacco products, alcohol</td>
</tr>
<tr>
<td>The Energy Market Regulatory Authority</td>
<td>Fuel</td>
</tr>
<tr>
<td>The Ministry of Environment and Urban Planning</td>
<td>Hazardous Substances</td>
</tr>
</tbody>
</table>

Most of the abovementioned agencies and institutions have published their own market surveillance regulations based on the Law no. 4703 and the Implementing Regulation on Market Surveillance. Within the implementation phase, the agencies and institutions conduct market surveillance procedures based on the Law no. 4703 as well as the legislation regulating the products in question and other related legislation.
A new systematic structure has been established by means of the implementation of a market surveillance system in harmony with the EU. Currently, auditing studies focused on product safety and based on risk analysis are being conducted ex officio or upon accidents, complaints or notifications.

A general evaluation of market surveillance in Turkey is as follows:

- Legislation pillar of the system have been completed substantially both by the market surveillance regulations conducted by agencies and by the technical legislative alignment with regard to the products,
- Lately, important developments have been realised with regard to infrastructure. Within this scope, Turkish Accreditation Agency has entered into a Mutual Recognition Agreement with the EU. 14 Turkish notified bodies have been registered by the European Commission⁸,
- A substantial support for infrastructure has been provided through EU projects. An inventory of public and private laboratories available in Turkey has been prepared.
- Consumers and NGOs started to follow up the developments and consumer awareness and expectations have risen,
- Through the new regulations, all parties have started to comprehend the philosophy of the new system (CE marking, market surveillance, notified bodies, etc.).

More specifically the progress made is as follows:

- Many agencies responsible for market surveillance have developed their own market surveillance strategies,
- “National Market Surveillance Paper” has been prepared,
- Certain agencies have started to work on a Guidebook which will help auditors to conduct the auditing studies under transparency and which will bring a uniform implementation.
- The establishment of informatics infrastructure has been initiated promptly. Within this scope, web sites and complaint lines have been established.

⁸ Within this scope, the “Turkish Standards Institution” has been assigned as the notified body for toys; “Meyer International Conformity Assessment Services Co. Ltd.”, “Szutest Technical Control and Certification Services Co. Ltd.” and Kalitest Documentation and Training Services Ltd. Company have been assigned as the notified bodies for medical devices.
• The Market Surveillance Coordination Board consisting of the representatives from related agencies and institutions holds regular meetings and works on problems and solutions.

• Moreover, the Circular on the “Market Surveillance and Product Safety Evaluation Board” was published in the Official Gazette no.27879 of 19 March 2011. The meetings of the Board will be held at ministerial level.

Clearly, significant steps have been taken with regard to market surveillance; however there are still a number of problems:

• although the activities conducted by agencies and institutions have increased, they are not adequate yet,

• personal rights, status and terms of reference of auditors vary between the agencies, therefore auditors expect improvement in their personal rights and status,

• auditing is conducted on documents and markings,

• sampling and testing option is rarely used,

• within this scope, mostly penal administration is conducted; punishment of fine, withdrawal and disposal penalties are rarely implemented,

• although the agencies started to allocate a budget share for market surveillance, the budget is not adequate,

• the inadequate budget affects market surveillance activities negatively,

• agencies have different approaches and regulations with regard to meeting laboratory expenses and taking samples.

MARKET SURVEILLANCE DURING NEGOTIATION PROCESS

The EU is in preparation of establishment of opening benchmarks for Free Movement of Goods Chapter which is the first chapter within the scope of negotiations held during Turkey’s EU accession process.

The fourth opening benchmark within the scope of the said Chapter is expected to be “Turkey presents to the Commission a comprehensive strategy with milestones for the upgrade of administrative capacity necessary for the implementation of the EC legislation on market surveillance”.

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Within this scope, with the contributions from relevant agencies the “National Strategy Paper on Market Surveillance” has been prepared under the coordination of the Undersecretariat of Foreign Trade and it was published in April 2010. The said document has also been submitted to the European Commission.

Similarly, the EU decided to open Consumer and Health Protection Chapter for negotiations at the Intergovernmental Conference in December 2007 and established the closing benchmarks through a Common Position Paper.

Within the scope of the said chapter, “Turkey should revise its legislation on general product safety, further amend its legislation on consumer protection and also demonstrate that adequate administrative structures and enforcement capacity, such as the necessary means to participate in the Community's Rapid Alert System (RAPEX), will be put in place.” has been set as a closing benchmark.

MARKET SURVEILLANCE FROM THE POINT OF THE MINISTRY OF HEALTH

Within the framework of the abovementioned considerations the developments with regard to market surveillance may be listed as follows:

- Firstly, the Ministry conducted technical legislation harmonisation studies for the relative product groups within the scope of the harmonisation list established by Decision 2/97 of the EC-Turkey Association Council and the assignment by the Cabinet Decree no. 97/9196.
- The Framework Law published by the Undersecretariat of Foreign Trade and the Implementing Regulations under the Framework Law have established the basis for particularly the product groups requiring CE marking (toys, medical devices).
- The Ministry of Health have conducted studies to establish a market surveillance infrastructure through the EU-supported projects of which the Ministry is a direct or
indirect beneficiary. The said infrastructure has been supported by certain projects. Also, information support has been established through a number of projects.9

- The Ministry of Health is represented in the Market Surveillance Coordination Board.
- Prof. Dr. Recep AKDAĞ, the Minister of Health was one of three Ministers who participated in the Market Surveillance Coordination Board, held at ministerial level on 15 October 2010.
- The Implementing Regulation on the Methods and Principles of the Market Surveillance to be Conducted by the Ministry of Health was published in the Official Gazette no. 26563 of 25 June 2007 and entered into force.
- Ministry of Health, Market Surveillance Coordination Commission which has been established within the scope of the Implementing Regulation meets regularly and more frequently when necessary.
- A database is needed for monitoring the activities with a view to ensuring the efficient operation of market surveillance. The information regarding unsafe products collected through this database will be communicated to RAPEX, the EU rapid alert system for all unsafe products.
- The studies of the Ministry on a market surveillance strategy continue precisely with the participation of senior level staff.
- The operation of market surveillance in the Ministry of Health is as indicated in the following table.

**Market Surveillance Coordination Commission**

The Commission has been established to coordinate the market surveillance activities of the Ministry of Health. Under the chairmanship of the undersecretary or a deputy undersecretary delegated by the undersecretary, the Commission consists of the following: General Director of Curative Services, General Director of Primary Health Care Services, General Director of

9 (1) "Support to the Quality Infrastructure in Turkey” Project (Undersecretariat of Foreign Trade), (2) Support to Turkish Conformity Assessment Bodies Project – RSHC laboratories have been supported with regard to medical devices and detergents. (3) Twinning Project on Capacity Building for the Ministries in Turkey with regard to Market Surveillance Activities – This project has been conducted together with Slovakia and support has been insured concerning medical devices. (4) Administrative Capacity Building to Strengthen Product Safety System in Turkey Project (UFT), (5) Strengthening of Quality Infrastructure in Turkey Project (UFT), (6) “Safety of Toys Project” within the framework of Leonardo da Vinci Programme (7) “Project on Strengthening of the Technical Infrastructure of Auditors of the Ministry of Health concerning safety of toys within the framework of Market Surveillance” within the framework of MATRA Programme (8) “Capacity Building and Accreditation of Toys Laboratory Project” within the framework of MATRA Programme.
Pharmacy and Pharmaceuticals, General Director of Health Education, President of Refik Saydam Hygiene Centre, First Legal Advisor to the Ministry, the Head of the Department of EU Coordination and Head of the Department of Data Processing or the representatives to be delegated by them.

The Commission, meeting quarterly, have the following duties:

- To determine the market surveillance policy of the Ministry,
- To determine the personnel, personnel training and equipment and financing requirements and to make suggestions with a view to meeting these requirements for the effective and efficient organisation of market surveillance,
- To solve the problems faced during the execution of market surveillance activities and to ensure implementation unity,
- To monitor and evaluate the auditing activities conducted by the units; to determine the faults and take necessary measurements,
- To give decision for the establishment of the sub-committees under the Commission in order to conduct the technical studies when necessary.

General Directorate of Pharmacy and Pharmaceuticals

Market surveillance activities with regard to cosmetics and medical devices are conducted by the Department of Market Surveillance under the General Directorate of Pharmacy and Pharmaceuticals.
Cosmetics

Market surveillance activities with regard to cosmetics are conducted by the Department of Market Surveillance under the General Directorate of Pharmacy and Pharmaceuticals.

Provincial Health Directorates conduct market surveillance activities with regard to cosmetics based on the central organisation. When unsafe and nonconforming products are found during the audit, necessary measurements shall be taken by the central organisation.

Market surveillance of cosmetic products is conducted in two methods:

- Audit of Product Information File: The General Directorate of Pharmacy and Pharmaceuticals demands the file. The audit is conducted at the General Directorate or at the address which had been declared in the product notification.
- Sensory Analysis of the Market: Following the evaluation of the possible risks of the notified products and the evaluation of the complaints from the market, the audit is conducted at the stores and depots by analysing the package information of the cosmetic products. The audit is conducted by the Provincial Health Directorates or the Ministry. When unsafe and/or nonconforming products are found during the audit, samples should be taken and sent for analysis.

Also, during the audits, corrective measurements and sanctions should be imposed for the correction of the nonconforming products.

Medical Devices

Market surveillance activities with regard to medical devices are conducted by the Department of Market Surveillance under the General Directorate of Pharmacy and Pharmaceuticals.

10 areas have been determined for market surveillance activities with regard to cosmetics and each of these areas have their own within. The auditing activities demanded by the Ministry are conducted at the Provincial Health Directorates by trained and certified personnel.
Market surveillance with regard to medical devices is conducted in the following methods: sensory analysis, auditing of documents and marking control. When necessary, samples are taken for analysis. When the suspicions cannot be alleviated for imported products, the producer, notified body or competent authority should be contacted to obtain necessary information.

Different from the other product groups for which the Ministry of Health is Responsible, market surveillance for medical devices is conducted together with Notified Bodies, Warning System, and Registry/Notification System in an integrated manner as well as the audit activities conducted in the field.

**General Directorate of Primary Health Care Services**

Ministry of Health, General Directorate of Primary Health Care Services is responsible for the market surveillance activities with regard to toys, chemicals and sanitary products.

**Toys**

Market surveillance activities with regard to toys are conducted by the Environmental Health Department of the General Directorate of Primary Health Care.

In provinces, surveillance activities with regard to products are conducted by 637 personnel who work for the environmental health units and who have passed the auditor exam.

Control of internal market and importation control take place in the market surveillance activities with regard to toys. The Undersecretariat of Foreign Trade is responsible for the importation control of toys. The Ministry of Health conducts surveillance activities with regard to toys based on the central organisation, through its auditors in Provincial Health Directorates. As consequence of market surveillance, necessary measurements are taken and the central organisation imposes sanctions.

Scientific findings, legislation, complaints and notifications from consumers and producers, complaints and notifications from other public authorities and NGOs regarding the non-conformance and unsafety of a product, market surveillance outcomes, information gathered
while investigating the causes of an accident and importation product safety data shall be taken into consideration while market surveillance activities are being conducted.

**Chemicals and Sanitary Products**

Market surveillance activities with regard to chemical products (detergents, air aromatising products, auxiliary chemical products used for pool water, strong acids and bases) and sanitary products (toothbrushes, interdental brushes, tampons, sanitary pads and breast pads, diapers, feeding bottles, teats, sippy cups, sippy cup lids, breast pumps, silicone breast protectors) are conducted by the Environmental Health Department of the General Directorate of Primary Health Care.

Surveillance activities with regard to chemicals and sanitary products are conducted through the environmental health units in provinces, nevertheless these activities may also be supported by other units under Provincial Health Directorates.

Surveillance activities with regard to chemicals and sanitary products are conducted at stores where they are sold. During surveillance, within the scope of the legislation on chemicals and sanitary products, it is investigated if the product notification has been conducted and the labelling information is adequate and samples are taken for analysis if necessary.

Moreover, complaints from consumers and/or competing firms over chemicals and sanitary products are evaluated. When necessary, corrective measurements are imposed, the product is recalled or withdrawn or administrative penalties are imposed. Surveillance activities are conducted by provincial health directorates; however sanctions are imposed by the central organisation of the Ministry within the scope of relative regulations.

**Refik Saydam Hygiene Centre**

When necessary, the products are analysed by Refik Saydam Hygiene Centre and regional directorates affiliated with the Ministry. RSHC laboratories also conduct importation control analyses of the products for which surveillance activities are conducted by the Ministry of Health and the toys for which surveillance activities are conducted by the Undersecretariat of Foreign Trade.
**European Union Coordination Department**

The EU Coordination Department ensures the inter agency communication regarding market surveillance. Besides this inter agency coordination task, the Department of EU Coordination has a general responsibility for conducting market surveillance-related affairs such as organising Coordination Commission meetings, coordinating the participation to the EU committees when necessary and receiving support for other technical issues.

**General Directorate of Health Education**

Certification of market surveillance trainings is conducted by the General Directorate of Health Education.

**Department of Administrative and Financial Affairs**

Information Technologies Unit under the Department of Administrative and Financial Affairs is responsible for the establishment of a market surveillance infrastructure in the Ministry and for the technical operation of this infrastructure. The improvement and operation shall be conducted together by relative units.

**LATEST DEVELOPMENTS**

**Developments in Turkey**

In line with the experiences gained, the EU has considered updating of the New Approach policy necessary. Within this scope, the Regulation (EC) No 765/2008 including market surveillance has entered into force as of 1 January 2010. The Regulation sets up more significant rules (the obligation of the Member States to notify their market surveillance authorities and powers thereof, the organisation of market surveillance authorities and the procedure of market surveillance process, adequate human resources and final resources) for market surveillance.
Within the scope of the studies with regard to the abovementioned Regulation (EC) No 765/2008, the Undersecretariat of Foreign Trade continues the updating activities concerning the Law no. 4703.

The fact that the said Regulation mentions more significant considerations regarding market surveillance, made an alteration of market surveillance activities in Turkey. The “Annual Report for Market Surveillance” became more important.

**Developments in the Ministry**

The coordination of market surveillance activities had been conducted by the Department of EU Coordination, however it was assigned to the General Directorate of Pharmacy and Pharmaceuticals in April 2010. Due to the decision adopted by the Market Surveillance Coordination Commission in May 2011, the task of coordination of inter agency communication was assigned to the Department of EU Coordination again. The activities regarding the operation will continue to be the duty of the General Directorate of Pharmacy and Pharmaceuticals and the General Directorate of Primary Health Care.

Moreover, the Department of Market Surveillance was established under the General Directorate of Pharmacy and Pharmaceuticals June 2011.

**Studies for Amendment of the Implementing Regulation**

In the Market Surveillance Coordination Commission meeting held in 28 October 2008, the “Implementing Regulation on the Methods and Principles of the Market Surveillance” was decided to be amended by the Ministry of Health within the framework of the experience gained and the opinions which were mentioned in the former Commission meetings. The studies continue.

**Personal Rights and Status of Auditors**

The Ministry of Health has conducted the studies of the working group, established within the scope of the “National Strategy Paper on Market Surveillance”. The working group has prepared a draft text including the amendments in the Law no. 4703 aiming at the
improvement of personal rights and status of the personnel and has transferred its studies to the Undersecretariat of Foreign Trade.

**Participation in the EU Joint Action Projects**

With regard to this subject, the Ministry of Health conducts the studies of the working group, established within the scope of the “National Strategy Paper on Market Surveillance”. The studies continue aiming at ensuring all market surveillance authorities to participate in and benefit from the EU Joint Action Projects.

**Accident/ Injury Database**

With regard to this subject, the Ministry of Health conducts the studies of the working group, established within the scope of the “National Strategy Paper on Market Surveillance”. The establishment of a database is envisaged. Following the pilot implementation of the database, it is planned to be shared with other agencies and institutions.

*Within the scope of all the above considerations, The Market Surveillance Strategy of the Ministry of Health (2011- 2013) is maintained meticulously through the senior-level studies. Following the strategy studies, an Action Plan will be established and the accomplishment of targets and strategic goals will be followed-up closely.*