SCREENING CHAPTER 01
FREE MOVEMENT OF GOODS

AGENDA ITEM: PHARMACEUTICALS

Country Session: The Republic of TURKEY
20 – 24 February 2006

GENERAL PRINCIPLES

- A medicinal product can only be placed on the market in Turkey when a marketing authorisation has been issued by the General Directorate of Pharmaceuticals and Pharmacy of Ministry of Health (MoH).
- Marketing authorisations are granted on the basis of the criteria QUALITY, SAFETY and EFFICACY.
- Applications must be in a standart format which is described in the legislation.

HUMAN CODE – 2001/83/EC

- Regulation on Licensing of Medicinal Products for Human Use published in the OG No. 25705, dated 19 January 2005. The Regulation entered into force as of 30 December 2005, except for Article 9.

- Article 9 regulates the abridged application procedure and entered into force in 1 January 2005 without prejudice to the Patent Law.

  - subparagraph (a),

    1- regulates informed consent,
    2- regulates well established medicinal use, which is also 10 years,
    3- regulates the application to essentially similar products whose data exclusivity period have expired.

DATA EXCLUSIVITY PERIOD

- The data exclusivity period foreseen in this sub-paragraph shall apply;
  - ✓ to original products, which have been licensed in a state within the Customs Union Area as from 1 January 2001 for the first time and for which no generic marketing authorisation application was made in Turkey prior to 1 January 2005,
  - ✓ to original products which shall be licensed in a state within the Customs Union Area after 1 January 2005 for the first time.
- The data exclusivity period is 6 (six) years beginning from the first marketing authorization date within the Customs Union Area.
- Products that have patent protection in Turkey shall have 6 (six) years of data exclusivity period limited to the patent duration in Turkey.

DATA EXCLUSIVITY

- However, when the medicinal product is intended for a different therapeutic indication from that of the other medicinal products marketed or is to be administered by different routes or by different doses, the results of appropriate toxicological and pharmacological tests and/or appropriate clinical trials must be provided.

- In the case of new medicinal products containing known constituents not hitherto used in combination for therapeutic purposes, the results of toxicological and pharmacological tests and clinical trials relating to that combination must be provided.

- Yet, it is not necessary to provide references relating to each individual constituent.

LICENSING PERIOD

ARTICLE 15 OF THE LICENSING REGULATION;

- The Ministry shall finalize the complete license application within 210 days. However, the periods stemming from the extraordinary situations and the activities of organisations, which are beyond the control of the MoH, are not included in this period.

- The cases where the 210 day period shall be stopped are clearly indicated in this Article.

VALIDITY PERIOD OF THE MARKETING AUTHORISATION

ARTICLE 21 of the Licensing Regulation, states that the marketing authorisations are valid for a period of 5 (five) years.

For the renewal of marketing authorisations, the applicant shall submit the necessary pharmacovigilance data as well as the final form of the file concerning the quality, safety and efficacy at least 3 (three) months prior to the end of the validity period of the marketing authorisations.

- **ARTICLE 31** which regulates the "entry into force" provision states that, except for Article 9 and Provisional Article 1 of second subparagraph, the Regulation shall enter into force on 30 December 2005.

  Currently, the Regulation is fully in force with all its provisions.

ANNEX I OF THE LICENSING REGULATION:

- is prepared according to the Directive No.2003/63/EC which obliges the applicant to prepare its application in Common Technical Document (CTD) format after 30 December 2005.

- Based on this Article, 130 applications filed after this date in the old format were rejected by General Directorate of Pharmaceuticals and Pharmacy.

THE REGULATION ON THE MANUFACTURING PRACTICES FOR HUMAN MEDICINAL

PRODUCTS TRANSPOSING DIRECTIVE NO. 2001/83 (TITLE IV) AND DIRECTIVE NO. 91/356/EC was published in the OG No. 25268, dated 23 October 2003 and put into force on the same day.

Some articles have been amended and published in OG No. 25508, dated 30 January 2004 and was put into force on the same day.

ARTICLE 6 of the Regulation states that after inspections and verifications of documentation the manufacturing authorisation shall be given within 90 days following the application.

ARTICLE 7 of the Regulation states that any application for changes in the manufacturing authorisation of domestically manufactured and imported pharmaceuticals shall be finalised within 90 days.

According to provisions of **ARTICLES 11 AND 12**, the holder of the marketing authorisation shall have a qualified person at his disposal and his/her duties are stated in **ARTICLES 12 AND 15** (b).

MARKET SURVEILLANCE

- General Directorate of Pharmaceuticals and Pharmacy carries out inspections with the Inspectorate Board of MoH including the unannounced inspections when it is necessary.
- In the case of complaints and when necessary, before a new marketing authorisation is issued, Refik Saydam Hygiene Institute Official Medicines Control Laboratory carries out the required tests on samples which the medicinal products have to comply with according to the pharmacopae standards.

THE REGULATION ON THE MONITORING AND EVALUATION OF THE SAFETY OF HUMAN MEDICINAL PRODUCTS TRANSPOSING HUMAN CODE 2001/83 (TITLE IX – PHARMACOVIGILANCE) was published in the OG No. 25763, dated 22 March 2005 and put into force on 30 June 2005 with its guideline.

- TÜFAM - Turkish Adverse Drug Reactions Monitoring Center which is also a Member of WHO Uppsala Monitoring Centre carries out the duties stated in the Regulation.

- Marketing authorisation holder must have a qualified person responsible for Pharmacovigilance activities at her/his disposal.

THE REGULATION ON LICENSING OF MEDICINAL PRODUCTS FOR HUMAN USE TRANSPOSING HUMAN CODE 2001/83 (TITLE X – MEDICINAL PRODUCTS DERIVED FROM HUMAN BLOOD AND PLASMA) also includes the medicinal products from human blood and plasma.

ARTICLE 26 states the special provisions concerning this group of medicinal products.

THE REGULATION ON THE CLASSIFICATION OF HUMAN MEDICINAL PRODUCTS TRANSPOSING HUMAN CODE 2001/83 DIRECTIVE (TITLE VI-CLASSIFICATION OF MEDICINAL PRODUCTS) was published in OG No. 25730, dated 17 February 2005 and entered into force on 30 June 2005 with its guideline.

THE REGULATION ON PACKAGING AND LABELING FOR HUMAN MEDICINAL PRODUCTS TRANSPOSING HUMAN CODE 2001/83 (TITLE V-LABELLING AND PACKAGE LEAFLET) was published in OG No. 25904, dated 12 August 2005, and entered into force on 30 December 2005.

THE REGULATION ON THE PROMOTION OF HUMAN MEDICINAL PRODUCTS TRANSPOSING HUMAN CODE 2001/83/EC (TITLE VIII-ADVERTISING) was published in OG No. 25268, dated 23 October 2003, and entered into force 1 December 2003.

THE REGULATION ON THE VARIATION OF HUMAN MEDICINAL PRODUCTS TRANSPOSING REGULATION 1084/2003/EC was published in OG No. 25823, dated 23 May 2005, and entered into force on 30 December 2005 with its guideline.

THE COMMUNIQUÉ CONCERNING THE COLOURING SUBSTANCES FOR HUMAN MEDICINAL PRODUCTS TRANSPOSING DIRECTIVE 78/25/EEC was published in OG No. 25704, dated 18 January 2005, and entered into force at the same day of publication.

The provisions of this Regulation are enforced by the MoH and the Ministry of Agriculture and Rural Affairs.

DECREE ON THE PRICING OF MEDICINAL PRODUCTS FOR HUMAN USE TRANSPOSING THE DIRECTIVE 89/105 was published in the OG No. 25373, dated 14 February 2004 and put into force on the same date (amended by the Decrees published in the OG No's. 25433 and 25651, dated 14 April 2004 and 25 November 2004, respectively).

With the 14 February 2004 Decree, equal treatment for imported and domestically produced pharmaceuticals in terms of reference pricing system has been attained.

General principle of pricing of the pharmaceuticals:

1- Reference price is based on the lowest available price of the product in five reference Member States (France, Greece, Italy, Portugal and Spain).

2- The originator company can price the original product up to 100% of the reference price. The generic product can be priced at a maximum of 80% of the reference price.

3- Price Evaluation Commission has been established, which meets every 3 months, the coordinator is MoH while the other members are from the Ministry of Finance, the State Planning Organization, the Undersecretariat of Treasury, the Ministry of Labour and Social Security.

4- Reimbursement Commission has been established, which meets every 6 months, the coordinator is the Ministry of Finance, while the other members are from the MoH, the State Planning Organization, the Undersecretariat of Treasury and from Social Security Institutions.

5- With a new categorisation under this Decree, profit margins have been redesigned to reflect commensurate profit margins for defined levels of price for both the wholesalers and pharmacies.

THANK YOU FOR YOUR ATTENTION