IV. NEW AND GLOBAL + OLD APPROACH PRODUCT LEGISLATION:

A. Standard questionnaire to be filled for each sector individually:

***Sector*: Pharmaceuticals**

1. Harmonisation of laws including technical regulations

1.1. Legal basis

References (and copies) of the publication of acts and decrees transposing Directive(s) …….. into the national legislation of your country:

Directive No. 2001/83/EC was transposed by:

1- Regulation on Licensing of Medicinal Products for Human Use: The Regulation was published in Official Gazette No. 25705, dated 19 January 2005. Except for Article 9, it was entered into force on 30 December 2005.

2- Regulation on the Promotion of Human Medicinal Products (transposing the provisions under Title VIII - Advertising - of the abovementioned Directive): The Regulation was published in Official Gazette No. 25268, dated 23 October 2003 and was put into force on 1 December 2003.

3- Regulation on the Monitoring and Evaluation of the Safety of Human Medicinal Products (Pharmacovigilance): (transposing the provisions under Title IX – Pharmacovigilance - of the abovementioned Directive): The Regulation was published in Official Gazette No 25763, dated 22 March 2005 and entered into force on 30 June 2005 (with its guideline).

4- Regulation on the Classification of Human Medicinal Products (transposing the provisions under Title VI - Classification of Medicinal Products - of the abovementioned Directive): The Regulation was published in Official Gazette No. 25730, dated 17 February 2005 and entered into force on 30 June 2005 (with its guideline).

5- Regulation on Packaging and Labelling for Human Medicinal Products (transposing the provisions under Title V- Labelling and Package Leaflet - of the abovementioned Directive): The Regulation was published in Official Gazette No. 25904, dated 12 August 2005 and entered into force on 30 December 2005.

6- Regulation on the Manufacturing Practices for Human Medicinal Products (transposing the provisions under Title IV - Manufacture and Importation - of the abovementioned Directive and of Directive No. 91/356/EC): The Regulation was published in Official Gazette No. 25268, dated 23 October 2003 and put into force as of the same day. It was amended on 30 June 2004 (Official Gazette No. 25508).

Directive No. 78/25/EEC was transposed by;

- The Communiqué concerning the Colouring Substances for Human Medicinal Products: (published in Official Gazette No. 25704, dated 18 January 2005 and entered into force on the date of its publication)

Directive No. 89/105/EC (Transparency Directive) was transposed by;

1- Decree on the Pricing of Medicinal Products for Human Use (published in Official Gazette No. 25373, dated 14 February 2004 and entered in the force on the same day).

It was amended by;

-The Decree Amending the Decree on the Pricing of Medicinal Products for Human Use (published in Official Gazette No. 25433, dated 14 April 2004)

-The Decree Amending the Decree on the Pricing of Medicinal Products for Human Use (published in Official Gazette No. 25651, dated 25 November 2004)

2- Communiqué on the Pricing of Medicinal Products for Human Use (published in Official Gazette No. 25391, dated 3 March 2004 and entered into force on the same day).

Regulation No. 1084/2003/EC was transposed by;

1- Regulation on the Variation of Human Medicinal Products: The Regulation was published in Official Gazette No. 25823, dated 23 May 2005 and entered into force on 30 December 2005 (with its guideline).

Explanatory note: the translation of CTD (Common Technical Document) into Turkish had already finished. However translation of relevant guidelines is still ongoing, as there are more than 240 guidelines.

Date of entry into application of the national measures transposing the Directive:

See above.

If not yet transposed, please indicate the state of play, expected timing, steps to be undertaken, difficulties encountered (if any):

The following Directives (or their certain provisions) have not transposed yet:

Directive No.2001/83/EC (Provisions of Title VII- Wholesale of Medicinal products)

The works on “Draft Regulation on the Warehousing and Distribution of Human Medicinal Products” transposing the provisions of abovementioned Title of the Directive 2001/83/EC are still on going.

Directive No. 2001/20/EC

The internal works on "Draft Regulation on the Conduct of Clinical Trials for Human Medicinal Products had been finalised, it has been sent to EU Commission for review.

1.2. Responsible authority

Name and contact details of the competent authority (government, ministry, department, service) and person(s) in charge of transposing the Directive into national legislation

The competent authority is DG of Pharmaceuticals and Pharmacy of Ministry of Health.

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General Coordinator:
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1.3. Notified bodies

Has your country the intention to notify conformity assessment bodies for the Directive? If so, could you already identify these bodies (name, and contact details) and indicate the conformity tasks (products and modules) that they will be entitled to perform

N/A

2. Implementation

2.1. Participation in Standing Committee and Experts' Group

Name, function and contact details of the representatives (and their alternates, if any) of your country's governmental authorities designated or to be designated to represent your country in the meetings of the standing committee and experts' group established under the Directive:

For medicinal products for human use; General Directorate of Pharmaceuticals and Pharmacy of MoH would like to participate to "Pharmaceutical Committee"

The name of the candidate representative is Pharm. Eda CİNDOĞLU, MSc.

2.2. Implementing structure

Responsible authority central/local:
Name and contact details of the competent authority (government ministry, department, service) and person(s) in charge of implementing the provisions of the Directive in the territory of your country:

The competent authority is DG of Pharmaceuticals and Pharmacy of Ministry of Health.

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The local authorities

There are local health authorities in all of 81 provinces affiliated with the MoH. They realise market controls, collect the required samples from the stated batches of medicinal products from the pharmacies and send to the General Directorate of Pharmaceuticals and Pharmacy for analyses.

Implementation:
- Explain how implementation of the Directive in your country will be ensured (monitoring and control tools: market surveillance and others

Directorate General for Pharmaceuticals and Pharmacy (DG) of MoH carries out market controls for medicinal products.

- Explain how market surveillance is carried out and on which basis

In 2005, 154 market controls were made by the DG upon the complaints and ex-officio. For an effective market control system, the DG has the right to inspect the premises of the manufacturing plants/sites of medicinal products and clinics, which carry clinical trials with inspectors who work at Inspectorate Board of MoH. (GMP, GCP inspections)

Medicinal products for human use are subject to laboratory analyses before marketing authorisation is granted.

Also when there is a complaint or a suspicion or when it is found necessary by the General Directorate of Pharmaceuticals and Pharmacy, the Drug and Cosmetics Control Laboratory of Refik Saydam Hygiene Institute carries the necessary analyses which are stated in the applicants' dossier as finished product specifications.

- Resources available: specify the number and qualification of personnel designated for market surveillance activities (divided in office staff/field personnel)

There are approximately 75 pharmacists, biologists and chemists working at the Official Drug and Cosmetics Control Laboratory in Refik Saydam Hygiene Institute to conduct market controls. This Institute is the central official control laboratory.

The personnel in the local health authorities also deal with the local market control activities.

- Cost: What budget will be provided for market surveillance activities? How will this be financed*?*

The MoH finances the expenditures of the market controls from its budget.

Methods of enforcement:

- What means/methods will be available in your country for enforcing compliance with the Directive(s)?

- Which are the reactive methods available?

- *Rights* of the authority: What are the powers of the authority?

- **Penalties: which will be the penalties applicable to violation of the national implementing measures?**

The legislation defines the necessary means for enforcing compliance with the principles set forth thereof.

For products having a risk to the human health or non-conforming to the provisions of the legislation, the MoH has the power to take all necessary protective measures (including administrative fines, withdrawal from the market and confiscation of the product, closing of the manufacturing place) by considering the level of non-conformity and the principle of proportionality.

All actions are taken and the penalties are applied according to the related provisions of the legislation. There are also provisions in Law No. 5237, Turkish Penal Code, defining the crimes against the public health and their sanctions.

For administrative enforcement, the sanctions are applied in accordance with the provisions of the Decree Law No. 181 on the Administrative Structure and Duties of the MoH, Law No. 1262 on Pharmaceuticals, Law No. 4926 on Fight Against Smuggling, Law No. 2313 on Control of Narcotic Drugs, Law No. 4703 on Preparation and Implementation of Technical Legislation on Products, Law No. 4077 on Consumer Protection, Articles 22 and 23 of Regulation on Licensing of Medicinal Products for Human Use, and Regulation on the Withdrawal of Medicinal Products for Human Use which was published in Official Gazette No. 19196, dated 15/08/1986.

In 2004, 10 medicinal products (on the basis of active ingredients) were withdrawn from the market due to several reasons, like health risk, wrong labeling and incompatibility to its finished product specifications. In 2005, the number was 16.

3. Calibration, metrology, standards, testing, certification, conformity assessment, accreditation and market surveillance

Please provide information on the relevant regimes for the products in this sector:

- **short description and**
- **further evolution.**

N/A