SCREENING CHAPTER 01
FREE MOVEMENT OF GOODS

AGENDA ITEM: MEDICAL DEVICES

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

NATIONAL LEGISLATION

- **Regulation on Active Implantable Medical Devices** was published in the OG dated 12 March 2002 to transpose the Directive 90/385/EEC and entered into force on 31 December 2003,
- **Regulation on Medical Devices** was published in the OG dated 13 March 2002 to transpose the Directive 93/42/EEC and entered into force on 31 December 2003,
- **Regulation on In Vitro Diagnostic Devices** was published in the OG dated 14 October 2003 to transpose the Directive 98/79/EC and entered into force on 14 April 2005.

The process of exchange of opinion with the European Commission is continuing.

HARMONISED STANDARDS

- 90 % of the European harmonised standards referred to by MDDs were transposed by Turkish Standards Institute (TSE),
- After finalising the harmonisation, a list of their reference numbers will be published in the OG.

CONFORMITY ASSESSMENT BODIES

- The criteria for the approval of the NBs under MDDs are determined via a Communiqué published in the OG dated 14.11.2003,
- There is no designated notified body in Turkey, but two potential CABs applied to MoH,
- The Project on Support to the Turkish CABs and the MIT in the implementation of some NA Directives to improve the infrastructure of the Refik Saydam Hygiene Institute (RSHI) is effective.

VIGILANCE SYSTEM

- MoH has been collecting the vigilance reports since December 2004.
- 36 reports were received and the corrective (and other) actions were taken.
- A web-based vigilance system will be operational by the first quarter of 2006.

MARKET SURVEILLANCE - I

- Law No. 4703, on the Preparation and Implementation of Technical Legislation on Products (Published in the OG No. 24459, dated 11.7.2001)
- Implementing Regulation of Law No.4703 on the Market Surveillance
- Turkish Penal Code No. 5237
- Principal Law on Health Services No. 3359
- Law No. 181 on the Organisation and Missions of the MoH
- Three regulations on medical devices

MARKET SURVEILLANCE - II

- Central and provincial offices of MoH with 100 inspectors are in charge of implementing the provisions of the MDDs,
- At the beginning of February 2005, an inspector's manual was prepared based on Law No.4703, two Regulations of MDs, classification of MDs, procedures of inspection including taking samples,
- Afterwards, inspectors were trained according to the manual, New Approach principles, MDDs and their practical implementation,
- A web-based registration system was established for registration of manufacturers and their products.

MARKET SURVEILLANCE - III

- The MoH has developed its Market Surveillance Strategy.
- RSHI and its laboratories as the main test laboratory for testing of samples from three kinds of medical devices
- 63 investigations in 2005;
  - ✓ 6 MDs which were found to be non-compliant were temporarily prohibited from being placed on the market,
  - ✓ 57 products were found to be in compliance with MDRs.

PARTICIPATION IN THE COMMITTEES

Participation to the Medical Devices Expert Group meetings held in Brussels

THANK YOU FOR YOUR ATTENTION