SCREENING CHAPTER 01
FREE MOVEMENT OF GOODS

AGENDA ITEM: VETERINARY MEDICINAL PRODUCTS

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

NATIONAL LEGISLATION - I

- Council Directive 2001/82/EC on Medicinal Products:
  - Law No. 3285 on Animal Health Control
  - Regulation on Authorisation of Veterinary Medicinal Products (OG. No.24915/2002)
  - Regulation on Private Veterinary Laboratories (23821/1999)
  - Communiqué on the Principles of Taking Samples from Veterinary Health Products Including Vaccines, Sera, Dilution Liquids and Biological Substances (No. 2000/44) (24259/2000)
  - Communiqué on the Principles to be adopted in the Importation of Veterinary Biological Products (No. 2002-37)
  - Instructions on Prospectus Preparation (No. 2003/22)

Technical studies are continuing regarding above mentioned pieces of legislation in order to align with the Council Directive 2001/82/EC.

NATIONAL LEGISLATION - II

- Council Directive 98/8/EC on Biocidal Products

Technical studies are continuing in order to align with Council Directive 98/8/EC within the framework of a Twinning Project coordinated by the MoH.

- Council Directive 78/25/EEC on Colouring Matters
  94/36/EC and Annex to Directive 95/45/EC Relating to Foodstuffs

Communiqué on Colouring Matters Used in Human and Veterinary Medicinal Products (25704/2005)

- Council Directive 84/539/EEC on Electro-medical Equipment Used in Veterinary Medicine

No corresponding national legislation.

NATIONAL LEGISLATION - III

- Council Directive 86/609/EEC on Experimental Animals

  ✓ Regulation on the Procedures and Principles for the Protection of Animals used for experimental or other scientific purposes, breeding establishments for experimental animals and the establishment, operation and inspection of laboratories performing the experiments (24464/2004).

  ✓ Technical studies are continuing in order to align with Council Directive 86/609/EEC.

NATIONAL LEGISLATION - IV

- Commission Directives 91/412/EEC and 2003/94/EC on Good Manufacturing Practice

  ✓ Studies have been conducted under the Twinning Project TR02/IB/AG-01 between Turkey and Germany entitled "Support for the Alignment of Turkey with the EU Veterinary Acquis-No.02.03.05" (13-11-2003 / 31-10-2005).

  ✓ GMP workshops were organised with the participation of all relevant Ministries (the MARA, the MoH, the MoEF).

  ✓ A common GMP monitoring authority in Turkey does not exist.

NATIONAL LEGISLATION - V

- Council Directive 88/320/EEC on Good Laboratory Practice (GLP)

  ✓ The Regulation on Principles of Good Laboratory Practice and Certification of Test Laboratories (24796/2002).

  ✓ Studies have been conducted under the Twinning Project TR02/IB/AG-01 between Turkey and Germany entitled “Support for the Alignment of Turkey with the EU Veterinary Acquis-No.02.03.05” (13-11-2003 / 31-10-2005).

  ✓ GLP workshops were organised with the participation of all relevant Ministries (the MARA, the MoH, the MoEF).

  ✓ A Twinning Project with Slovakia, for which the MARA is among the beneficiaries, is being implemented under the coordination of the MoH.

NATIONAL LEGISLATION- VI

- Council Regulation 90/2377 (EEC) on the Establishment of Maximum Residue Limits (MRL)

  ✓ Communiqué No. 2002/30 on Maximum Residue Limits of Veterinary Pharmaceuticals in Food of Animal Origin (OG. 24739/2002). This Communiqué is based on relevant EU legislation and is updated and subsequently re-published annually
  (amended by the Communiqué No. 2004/4).

ADMINISTRATIVE STRUCTURE

Administrative units responsible for veterinary medicinal products are under the General Directorate of Protection and Control (GDPC) of the Ministry of Agriculture and Rural Affairs (MARA).

The responsibilities of the Departments of Veterinary Pharmaceuticals and Veterinary Laboratory Services regarding veterinary medicinal products include:

- Authorisation
- Sales and distribution channels
- Control of manufacturing premises and laboratories
- Follow up of complaints
- Imports
- Export
- Pricing

NATIONAL PROCEDURE FOR VETERINARY BIOLOGICAL PRODUCTS

DOMESTIC PRODUCTION

• Granting of Operation Licences to Manufacturing Sites and Facilities
- Fulfilment of technical and hygienic requirements

• Granting of Production Pre-licences to Products to be Manufactured
The Commission for Production Pre-licences decides upon evaluation of : - General Information
- Authorisation Dossier (Production and control information of products)
Good Manufacturing Practice (GMP), European Pharmacopie, Code of Federal Regulation (9CFR) Manual of Standards for Diagnostic Tests and Vaccines (OIE)
- Stability Studies

• Granting of Sales Authorization to Manufactured Products depends on positive results of sampling, quality control, immunity, safety, sterility tests

• Placing on the Market of Products with Sales Authorization
- Working Permit is granted to Distribution Units by MARA
- Distribution to the market is performed by warehouses with working permit and private veterinary practitioners

PROCEDURES FOR IMPORTS OF VETERINARY BIOLOGICAL PRODUCTS

- Granting of Authorisation to Imported Products

  The Commission for Importation Pre-licences decides upon evaluation of:

  - General Information (Authorization, Free Sales Certificate, GMP Certificate, etc.)
  - Authorization Dossier (Production and control information of products)
  - Good Manufacturing Practice (GMP), European Pharmacopie, Code of Federal Regulation (9CFR)

    Manual of Standards for Diagnostic Tests and Vaccines (OIE)
  - Stability Studies

- Granting of Authorisation for Actual Importation
  - Control Certificate
  - Entry of the Product into Customs

- Granting of Sales Authorisation to Products to be Imported

  Depends on positive results of sampling, quality control, immunity (when required), safety, sterility tests

- Placing on the Market of Imported Products with Sales Authorisation
  - Working Permit is granted to Distribution Units by MARA
  - Distribution to the market is performed by warehouses with working permit and private vets

NATIONAL PROCEDURE FOR VETERINARY PHARMACEUTICALS

DOMESTIC PRODUCTION

- Granting of Operation Licences to Manufacturing Premises
  - Fulfilment of technical and hygienic requirements

- Granting of Authorisation to Domestic Products
  The National Commission on Authorisation of Vet. Pharmaceuticals evaluates
  - Certificate of Business Permit
  - General Information
  - Authorisation Dossier

- Authorisation is granted according to quality control analyses of pharmaceuticals.

PROCEDURES FOR IMPORTS OF VETERINARY PHARMACEUTICALS

- Granting of Authorisation to Imported Products

Requirements in addition to information included in authorisation dossiers of domestic pharmaceuticals are:

- Certificate of Authority
- Original Formulation
- Free Sales Certificate
- GMP Certificate of the Manufacturing Premises

- Application for authorisation is evaluated by the National Commission on Authorisation of Veterinary Pharmaceuticals.

- Authorisation is granted according to quality control analyses of pharmaceuticals.

MARKET SURVEILLANCE

The market surveillance activities of veterinary medicinal products are carried out through following ways:

- **Regular Controls**

Regular Controls are carried out by:

Central Organisation
General Directorate of Protection and Control
- Department of Veterinary Pharmaceuticals
- Department of Veterinary Laboratories

Provincial/District Organisation
Provincial Directorates
- Animal Health Department

- **Controls Based on Notifications and Complaints**

THANK YOU FOR YOUR ATTENTION