

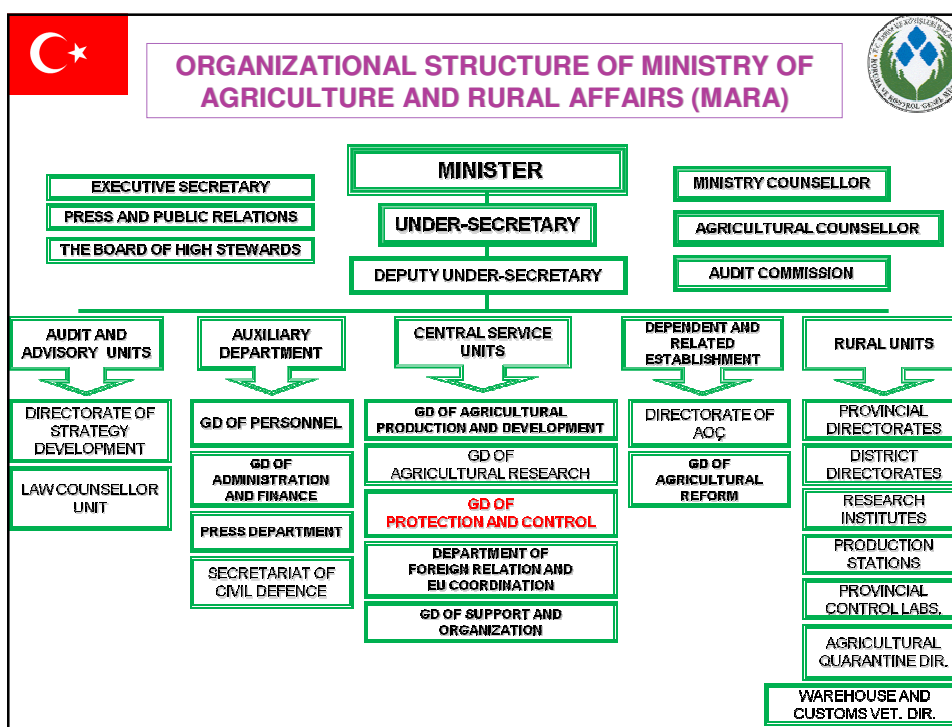


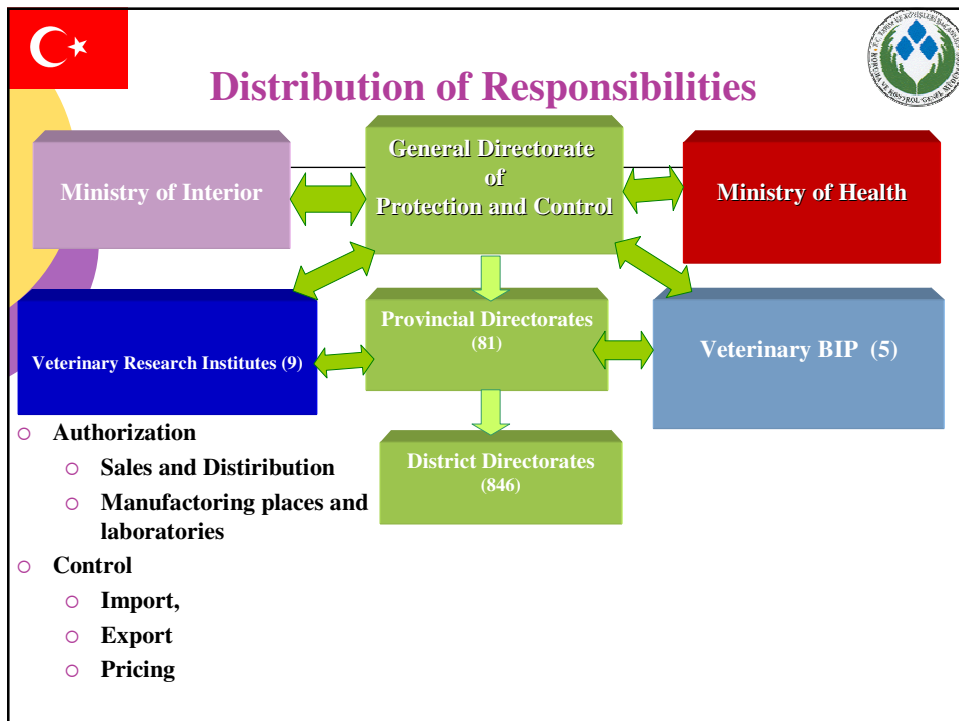
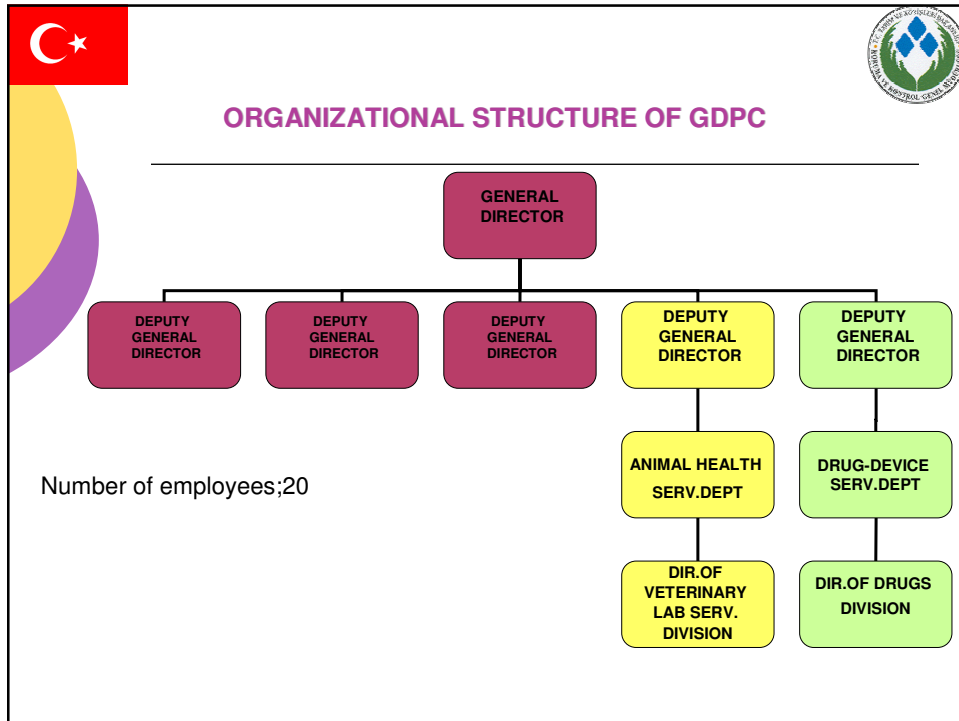
REPUBLIC OF TURKEY
MINISTRY OF AGRICULTURE AND RURAL AFFAIRS
GENERAL DIRECTORATE PROTECTION AND CONTROL



COUNTRY REPORT
 By
H.Haluk AŞKAROĞLU

**IPA- Intraductry Meeting on the participation of Candidate
 and Potential Candidate Countries in the European Medicines
 Agency Activities, 1-2 February 2010, London -UK**







Pharmacovigilance System

- **Authorized Products on Web (www.kkgm.gov.tr)**
- **Vaccination Monitoring System established on VIS**
- **Controls Methods ;**
 - **Routine Control ,**
 - **Up on Complaint**
 - **Storages for Veterinary Medicinal Products**
 - **Manufacture Places**
 - **Animal Husbandaries**
 - **Places of Sales**



Pharmacovigilance System

- **Inspections are carried out by;**
 - **General Directorate of Protection and Control,**
 - **Provincial Directorates of MARA,**
 - **Institute Experts**
- **Quality Controls of Pharmaceuticals**
 - **Pendik Veterinary Control and Research Institute**
- **Quality Controls of Veterinary biological Products**
 - **Bornova Veterinary Control and Research Institute**



NATIONAL PROCEDURE FOR VETERINARY DOMESTIC PRODUCTION



- To grant the **Operation Licences** to Manufacturing Sites
 - The technical and hygienic conditions should meet the requirements
- To grant the **Pre-Licences** to the products to be manufactured
 - The National Commission For Production Pre-Licences evaluate the dossiers and meet every 3 months for decision.
- To grant **The Sales Authorization** to the manufactured products,
 - Sampling,
 - Quality Control;
 - Efficacy
 - Safety
 - Sterility



Veterinary Medicinal Products



	Veterinary Biological Products	Veterinary Pharmaceutical Products
Importing Firms	33	44
Imported Authorized Products	413	702
Domestic Manufacturing Firms	11	54
Domestic Authorized Products	108	1522



Alignment with in the EU

- **Not fully aligned with EU legislation**
- **In Two Years**
 - Establishment of Risk Analysis Method for Import and Domestic products,
 - Preparation of Marketing Authorization Directive aligned with EU Legislation
 - Renewal of all Marketing Authorization dossiers
 - Continious of GMP Legislation preparation,
 - Continious of Full alignment studies.



Challenges

- **Lack of GMP authority.**
- **Weaknesses of market surveillance system,**
- **Lack of qualified personnel,**
- **Lack of inspector,**
- **Insufficient bioequivalence studies for Pharmaceuticals**



Turkey

Simply to feel good. Holidays in Turkey. The lively culture of Istanbul welcomes you. The magical lighting of the Hagia Sophia greets your eyes with an unforgettable promise. Capture the city and discover the attractive shopping possibilities and, be sure to rest in the comfortable atmosphere of one of the innumerable hotels. We will welcome you with all this and more. www.reiseland-tuerkei.info

Generalkonsulat der Republik Türkei, Abteilung Kultur | Bender Straße 37, 60329 Frankfurt am Main, Tel.: 069 2332-8164, Fax: 069 233761

Turkey
what a feeling!