# General Directorate of Pharmaceuticals and Pharmacy: Overview

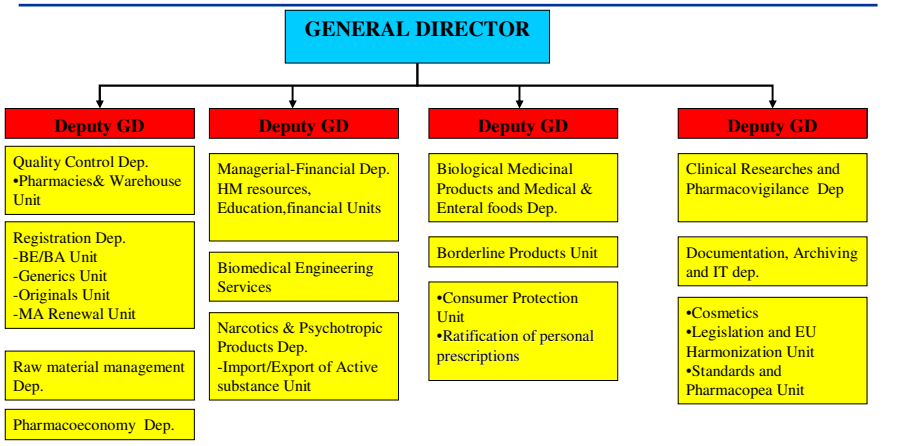
Turkish Drug Regulatory Authority

**Pharm. (M.Sc.) Yasemin KARABEY**
**Head of Legislation and EU Harmonization Department**

## General Directorate of Pharmaceuticals and Pharmacy (GDPP)

- The national authority
  - Human
    - Medicinal Products
    - Medical Devices
    - Cosmetics
- In the body of Ministry of Health
- Function
  - Regulation
  - Evaluation
  - Monitoring

# Organisation of GDPP






# Pharmacovigilance

- TÜFAM - Turkish Adverse Drug Reactions Monitoring Center a Member of WHO Uppsala Monitoring Centre
- In line with EU (2001/83 EC)
- Spontaneous reports
  - PhV contact points
  - Official website of GDPP
  - Directly (fax, mail etc.)
- Post marketing safety data (includes pharmacoepidemiology)
- Decisions taken by other national authorities
- Published scientific studies
- Electronic data bases
- PSURs (latest version of 2001/83 EC)
- 12 Pharm., 1 MD,
- Hot topic: PhV Inspection

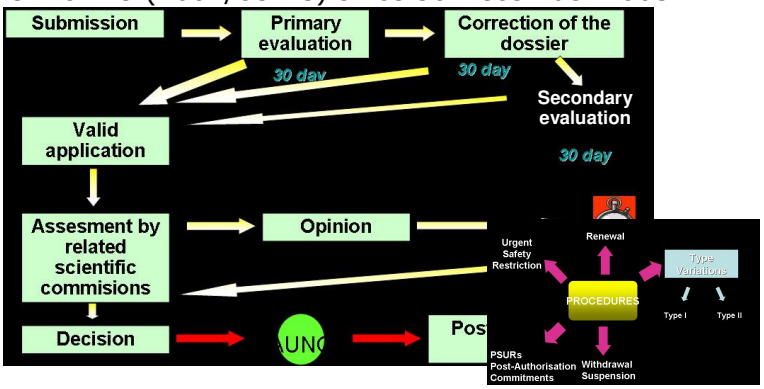
# Inspection

- First GMP regulation was put in to force 1984
- Guidance on GMP published 1994 (final revision May 2009)
- The Regulation On The Manufacturing Practices For Human Medicinal 2003
- In line with EU (2001/83)
- Inspectorate Board of MoH
- Market surveillance
  - Routine controls
  - Assessments of complaints,
  - Withdrawals,
  - Virological analysis for every batches of bio-orginated drugs
- Official Medicines Control Laboratory (Refik Saydam Hygiene Institute)
- Hot topic: SİTE MASTER FILE



# Authorisation of Human Medicinal Products

- In line with EU (2001/83 EC) since 30 December 2005

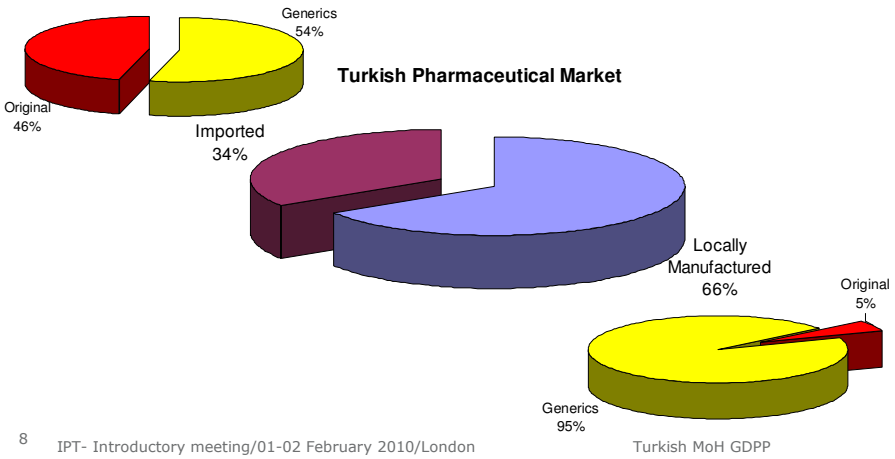


## Authorisation of Human Medicinal Products

- e-Submissions (June 2008)
  - Post marketing activities (variations, vigilance etc.)
  - Pricing applications
  - Notifications for cosmetics



## Pharmaceuticals Industry in Turkey



## Level of implementation of the acquis communautaire

Human Code 2001/83, has already been transposed into several turkish legislation.

1. Regulation on Licensing of Medicinal Products for Human Use Published in the Og No. 25705, Dated 19 January 2005.
2. The Regulation On Packaging And Labeling For Human Medicinal Products Transposing Human Code 2001/83 (Title V- Labelling And Package Leaflet)
3. The Regulation On The Manufacturing Practices For Human Medicinal
4. The Regulation On The Monitoring And Evaluation Of The Safety Of Human Medicinal Products Transposing Human Code 2001/83 (Title IX – Pharmacovigilance
5. 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)



## Level of implementation of the acquis communautaire

5. The Regulation On The Classification Of Human Medicinal Products Transposing Human Code 2001/83 Directive (Title VI- Classification Of Medicinal Products)
6. The Regulation On The Promotion Of Human Medicinal Products Transposing Human Code 2001/83/EC (Title VIII- Advertising)
8. The Regulation On The Variation Of Human Medicinal Products Transposing Regulation 1084/2003/EC
9. The Communiqué Concerning The Colouring Substances For Human Medicinal Products Transposing Directive 78/25/EEC
10. Decree On The Pricing Of Medicinal Products For Human Use Transposing The Directive 89/105

## Other documents

- Translated ICH Guidelines
- Original versions of ICH Guidelines
- QAs, Reflection Papers published by EMA



## Optimum utilization from IPA program

- Regular attendance
  - Legal proceedings (visa, approval)
  - Proposed solution: Invitation for all foreseen meetings of a participant
- More technical/scientific WPs/Commitees then telematics
- Increased number of participants
- More training courses and workshops

# Thank you for your attention!

yasemin.karabey@iegm.gov.tr

www.iegm.gov.tr