

FARMAKOVİJİLANANS ve FARMAKOVİJİLANANS  
UYGULAMALARI  
**(Pharmacovigilance and  
implementation)**

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23-24 Ekim 2003  
İstanbul

(23-24 October 2003 – ISTANBUL)

**Sevgi ÖKSÜZ**

**farma**team

# FARMAKOVİJİLANS DÜNYASINA HOŞGELDİNİZ

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**WELCOME to  
PHARMACOVIGILANCE WORLD**

**farma**team

# PHARMACOVIGILANCE

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Pharmacovigilance is the science and activities;

- relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems.

# PHARMACOVIGILANCE

## *New concerns of PV*

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- Herbals
- Traditional and complementary medicines
- Blood products
- Vaccines
- Medical devices

# PHARMACOVIGILANCE

*traditionally*

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- Collecting ADRs /AEs
  - Causality assessment
  - Risk assessment
  - Data analysis
  - Benefit/risk
  - Signals
  - Alerts
  - Measures
-

## PHARMACOVIGILANCE

### *other relevant issues*

- 
- ❑ substandard medicines – counterfeit drugs
  - ❑ medication errors
  - ❑ lack of efficacy
  - ❑ off-label use
  - ❑ acute and chronic poisoning

## PHARMACOVIGILANCE

### *other relevant issues*

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- ❑ assessment of drug-related mortality
  - ❑ abuse and misuse of medicines
  - ❑ interactions with chemicals / other medicines / food

# PHARMACOVIGILANCE

## *Specific aims*

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- to improve patient care and safety
- to improve public health and safety
- to contribute to the assessment of benefit/risk, rational use
- to promote understanding, education, clinical training in PV-communication



# PHARMACOVIGILANCE

## *during drug development*

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- ✓ Pre-clinical
- ✓ Clinical (Phase I, II, III)

# PHARMACOVIGILANCE

## *during drug development*

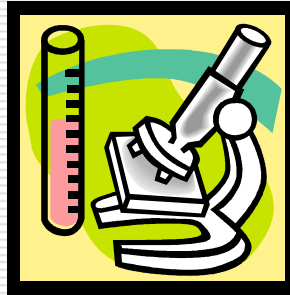
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- ✓ Post marketing
  - Spontan reporting
  - Clinical trials
  - Company sponsored studies
  - Drug utilization studies
  - Literature information
  - Pharmacoepidemiologic studies

# DRUGS

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EFFICACY

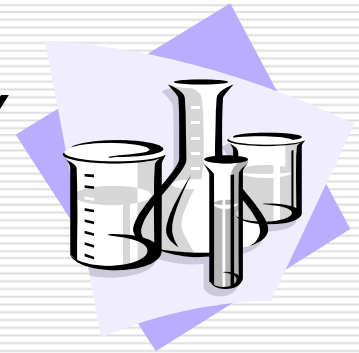


SAFETY



??????

QUALITY



# PHARMACOVIGILANCE

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Very dynamic

# PHARMACOVIGILANCE

*looking to the future....*

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Globalization - Harmonization

Internet - sales and information

Self medication

# PHARMACOVIGILANCE

## *Future*

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Patient reporting

Ethics

Special patient groups (children)

Pharmacogenetics

Pharmacoeconomy

# PHARMACOVIGILANCE

## *QA of data*

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- ❖ QA arrangements
- ❖ Data management
- ❖ Audits

# PHARMACOVIGILANCE

## *methodology-technical issues*

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- Terminology
- e-transfer of data
- compatability of different systems



# PHARMACOVIGILANCE

## *in relation to regulatory work*

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### **Compliance**

- Regulations/guidelines  
(national, harmonized)
- Inspections
- Good pharmacovigilance practise

# PHARMACOVIGILANCE

## *Two examples*

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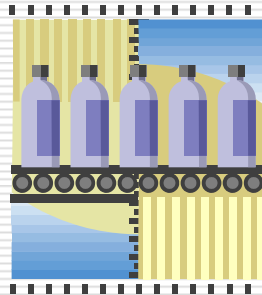
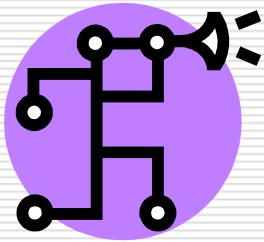
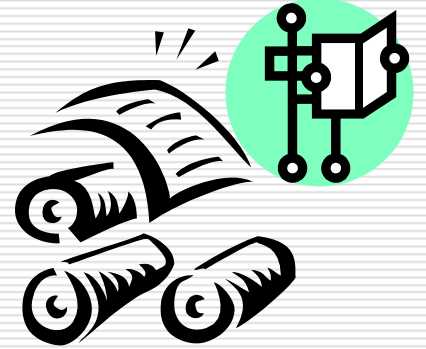
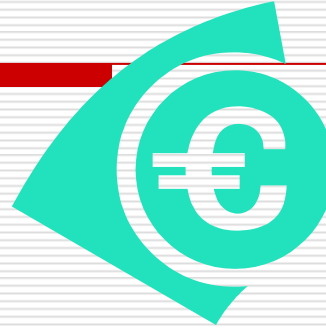
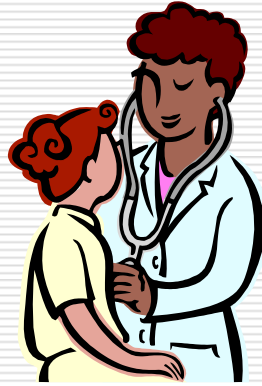
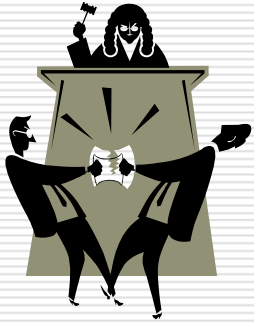
Thalidomide

l- tryptophan – EMS (eosinophilia  
myalgia syndrome)

# PLAYERS

*complications*

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# MORE farmacovigilance....

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- Risk assessment
- Risk management

**Risk perception???**

# PHARMACOVIGILANCE **more and more...**

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- Crisis planning
- Crisis management

# PHARMACOVIGILANCE

## *International work*

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WHO

CIOMS

EU

ICH

National Authorities

ISOP

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# PHARMACOVIGILANCE

## *Why important ?*

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- Public Health
- Pharmacoeconomics
- Ethics

*as consequence....*

# PHARMACOVIGILANCE

## *Why important ?*

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Regulatory authorities requires more...

New studies, new regulations, new technologies, new expenditures...



# PHARMACOVIGILANCE

## *Why important ?*

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Outcome might be;

- a valuable drug unnecessarily out
- withdrawal of the product
- some variation of the registration
- image of company and drug diminished
- .....

# PHARMACOVIGILANCE

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Be prepared for the worst case,



# PHARMACOVIGILANCE

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