Pharmacovigilance Experience in Turkish Pharmaceutical Industry

Neslihan Gülenoğlu Pharm,
Pfizer İlaçları Ltd.Şti.

23-24 Oct, 2003
Istanbul

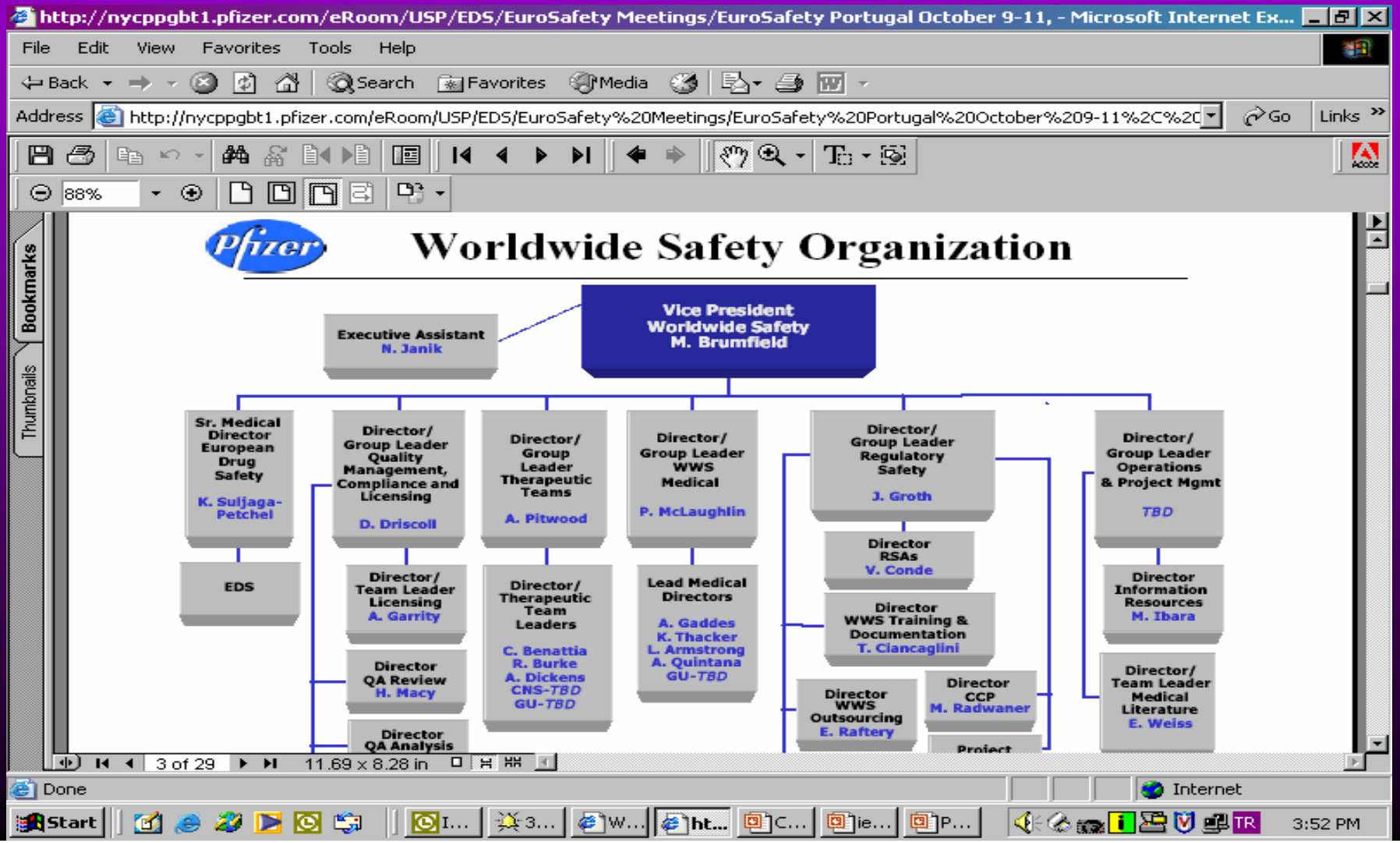
Pharmacovigilance is...

- Legal &
- Ethical responsibility
- Compliance with local regulations
- Compliance with company procedures

Agenda

- Organisation
- Procedures / SOPs
- Training
- Sources of Adverse Events
- Local Practices
- Audits / Performance reports
- Other activities
  - Inter-company meetings
  - International meetings on recent EU developements.

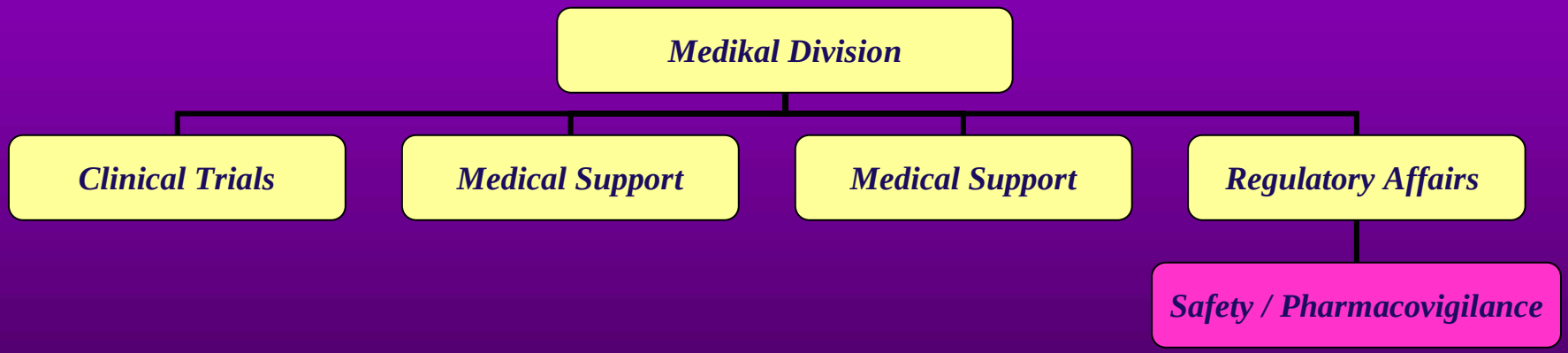
Pharmacovigilance organization / Pfizer INC



Pharmacovigilance organization / Pfizer INC

EDS	Compliance	SEE	Therapeutic /medical
EMEA submission	QC	epidemiolgy	Case assessments
Support to EU offices	Data entry	Safety evaluation RM	causality
		PSUR Respond to HA	

Pharmacovigilance organization / Pfizer Turkey

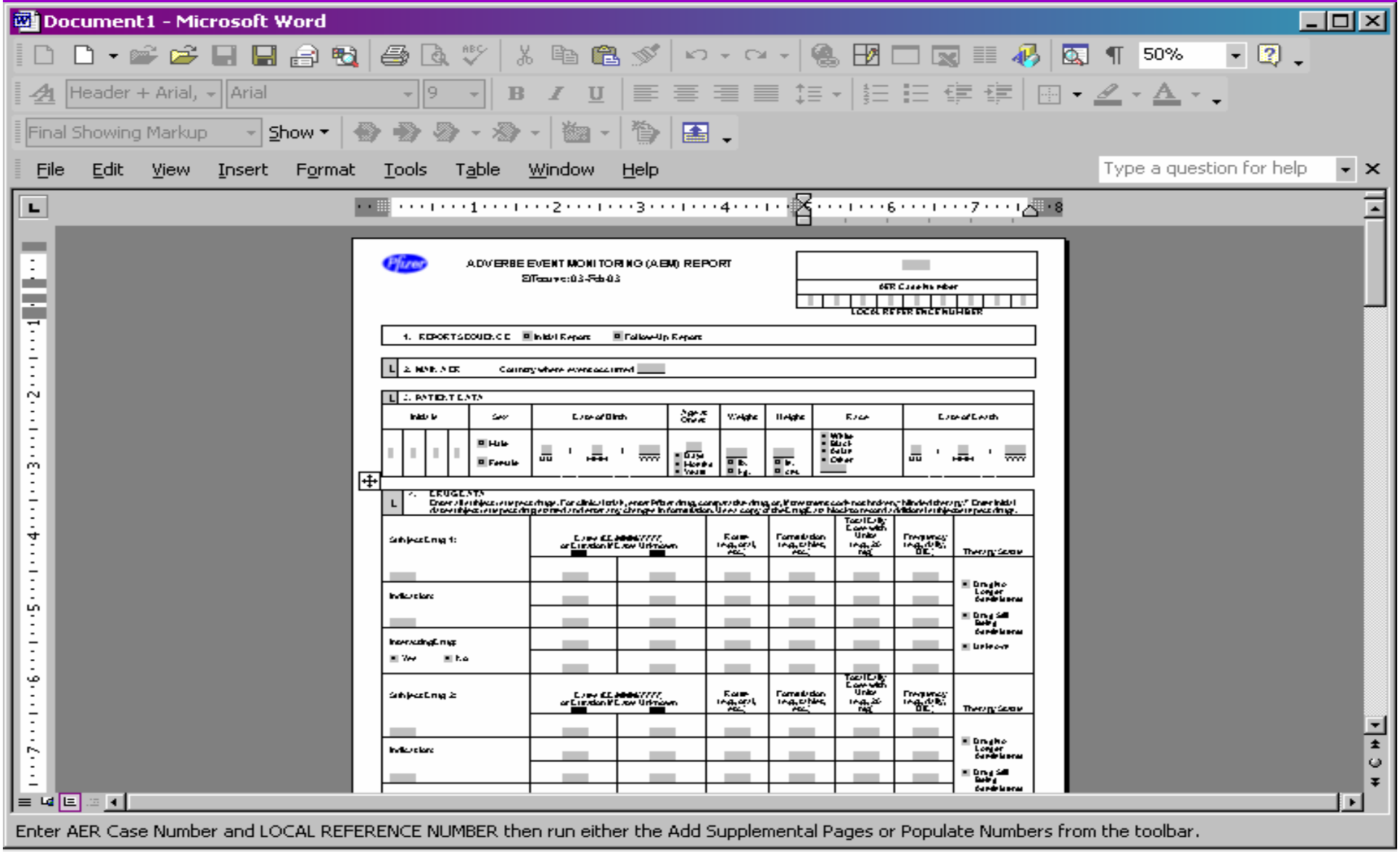


Procedures

- Global SOPs are in effect
  - AEMO1 – Adverse Event Monitoring SOP

  – Standart Adverse Event Report form is used by all countries for reporting Adverse Events to Headquarters.

AEM Report


Document1 - Microsoft Word
ADVERSE EVENT MONITORING (AEM) REPORT
Enter AER Case Number and LOCAL REFERENCE NUMBER then run either the Add Supplemental Pages or Populate Numbers from the toolbar.
Start
4:06 PM

Training

- Global SOPs are in effect
- AEM02 – Safety Training for Spontaneous Reports of Adverse Events

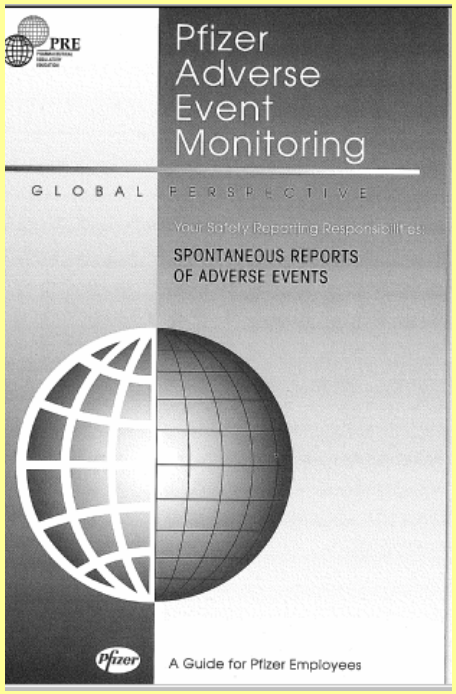
  - Training on Adverse Event Reporting Responsibilities and procedures is mandatory for all medical division personel within specific timeframes (2 months of employement)

Training

- Training of all relevant Medical & Marketing employees by Safety Manager on Spontaneous Adverse Event Reporting Responsibilities within 2 months of employement (including sales representatives and emloyees who may be in direct contact with Physicians, healthcare professionals ex: Operators, security)

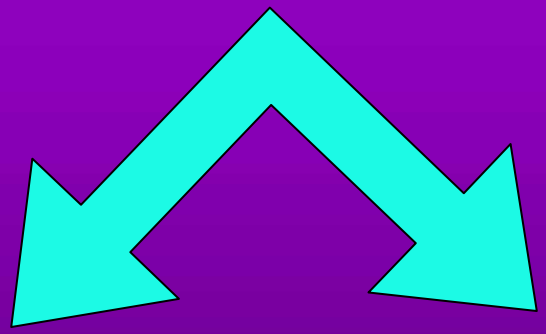
- Trainings are documented and audited via routine local and global audits.

Spontaneous AE Reporting REsponsibilities /



Local Practices

Sources of AEs

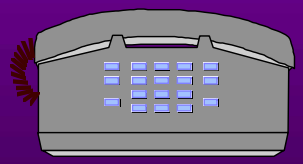


- Clinical Trials

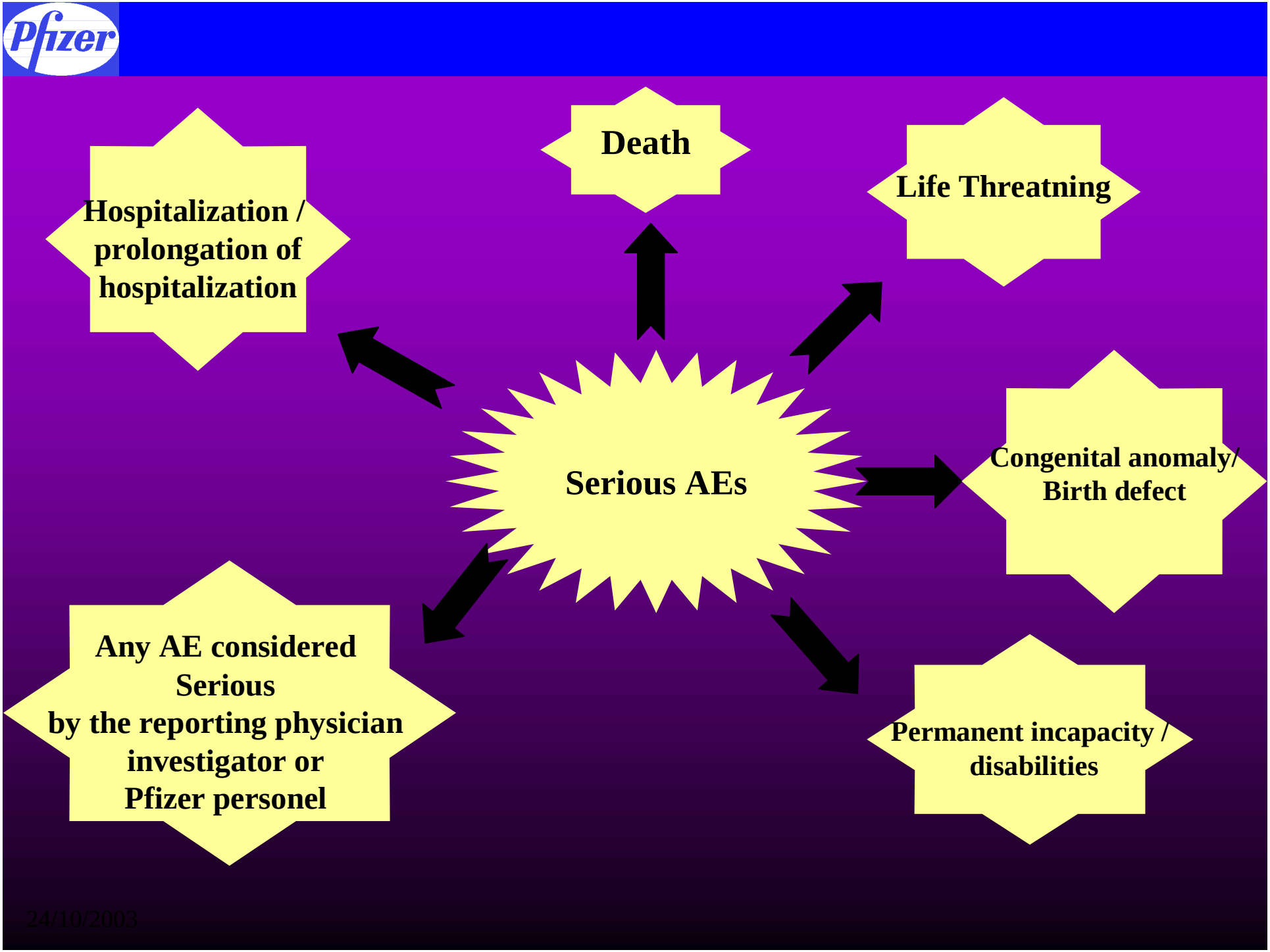
- Spontanous reports
- Publications
- Regulatory Authorities

How Spontaneous reports are received?

- Sales reps (physicians – patients – caregivers)
- Social environment (friends / family)
- Phone, fax, emails, letters from physicians, patients, pharmacists.
- Media (newspaper, TV etc...)
  - examples




Serious AEs
Adverse Events
Non-serious AEs


Death
Life Threatning
Hospitalization / prolongation of hospitalization
Serious AEs
Congenital anomaly/ Birth defect
Any AE considered Serious by the reporting physician investigator or Pfizer personel
Permanent incapacity / disabilities

Reporting Timelines

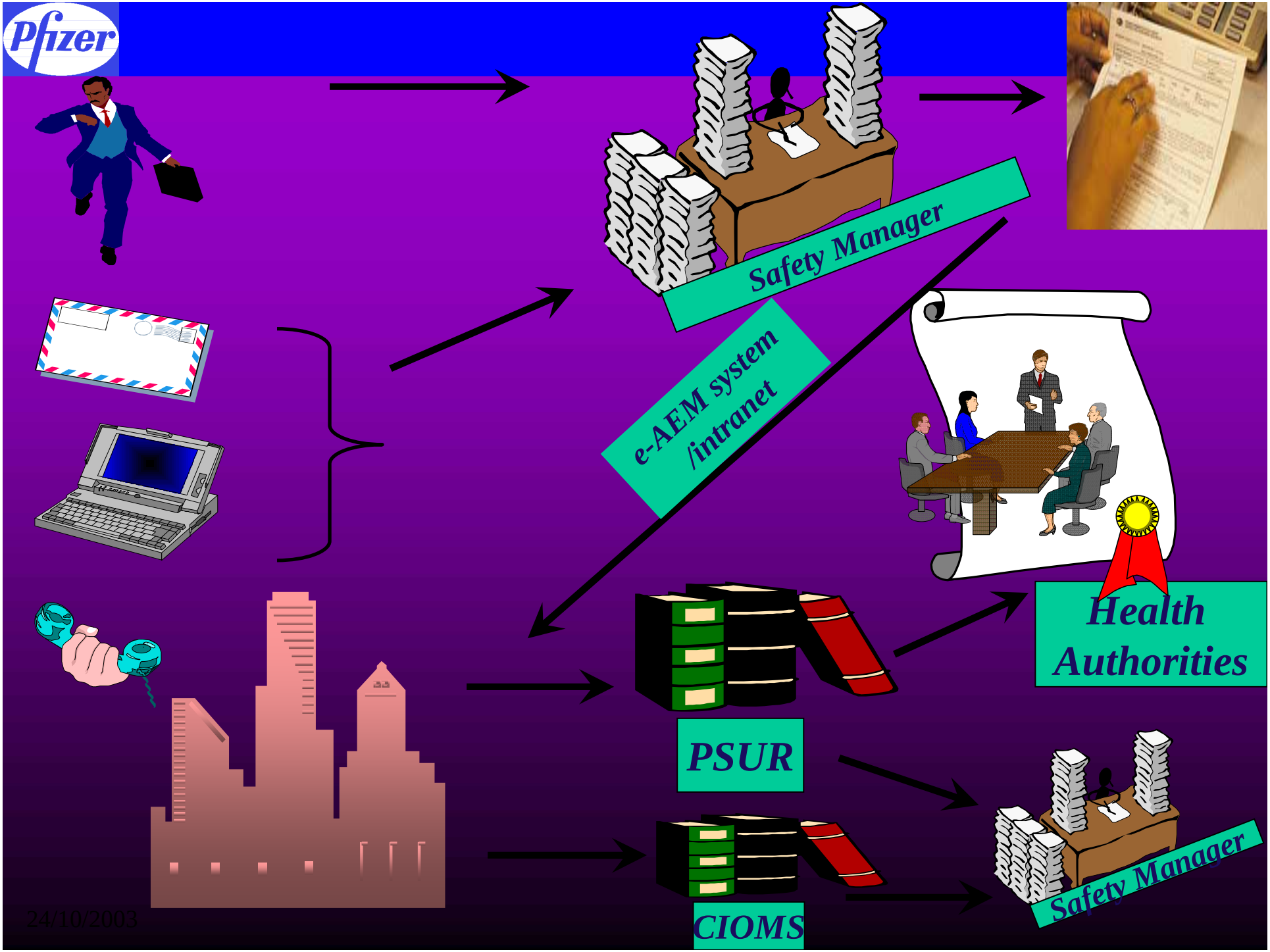
Serious AEs – should be reported to Pfizer HQ within 2 business days of receipt by **any** Pfizer employee.

Non-Serious AEs – should be reported to Pfizer HQ within 10 business days of receipt by **any** Pfizer employee.

Minimum Criteria for reporting AEs

- Description of Advers event: Adverse event term or SAE criteria.
- Name of Pfizer drug
- Identifiable patient

Other follow up information may be submitted later on by Follow up reports.


Pfizer
Safety Manager
e-AEM system
/intranet
Health
Authorities
PSUR
CIOMS
Safety Manager
24/10/2003

Audits

- Audits / Performance reports
  - To review and ensure that AE reporting and training is conducted and documented according to effective SOPs
    - Local reviews conducted by Quality Standards Manager
    - Periodic Audits conducted by Pfizer Corporate Pharmaceutical Regulatory Monitoring Group
  - Monhtly performance reports issued by Worldwide Safety Compliance Group showing performance of Pfizer Turkey in reporting AEs.

Other Activities

- Meetings / seminars
  - Inter-company meetings
  - International meetings / trainings on recent EU developements

Meeting/Seminars

- Inter-company meetings
  - Recent regulatory developements
  - New processes & applications / training
  - Product specific sessions

New EU issues / topics

- e-Submission of Individual Case Reports
- EUDRA VIGILANCE
- New Clinical Trial Directive
  - To be adopted by May 2004
- Risk Management
- EU Accesing Countries
- MedDRA terminology
  - Mandatory for AE reports since Jan 2003
- Good Pharmacovigilance Practices

EUDRA VIGILANCE

- EUDRA VIGILANCE is the European data-processing network and database management system for the exchange, processing and evaluation of Individual Case Safety Reports (ICSRs) related to medicinal products authorised in the European Economic Area (EEA).
- Eudra Vigilance Gateway for the secure electronic transmission of ICSRs in the European Union
- Eudra Vigilance database

EUDRA VIGILANCE

- Operational since Dec 2001 / upgraded March 2003
- Exchange information between EMEA-Regulatory Authorities - Pharm.Companies
- All national authorities connected
- http://eudravigilance.emea.eu.int

RISK MANAGEMENT

- Activities specific to a chemical entity / drug in order to manage known and possible risks
- Should begin at the early stages developement and continue to through out the life cycle.
- Includes proactive risk assessment and developement of plans to manage risk
- Identify estimate and evaluate risks
- Risk Managament Plans / guidelines
- Could become a regulatory requirement at the time of New Drug Application ?

EU ACCESING COUNTRIES

- May 2004

- Main problems
  - PhV perception – a burden / unwanted activity
  - Lack of IT suppport
  - PhV support staff

Regulations / new developements

- MoH efforts for harmonizing Turkish Parmaceutical Regulations with EU regulations
  - Pharmacovigilance regulation is on the way

- Increased importance of close follow up of recent EU developements regarding Pharmacovigilance.

THANK YOU