Pharmacovigilance Experience in Turkish Pharmaceutical Industry

Neslihan Gülenoğlu Pharm, Pfizer İlaçları Ltd. Şti.
İstanbul
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 developments.
Pharmacovigilance organization / Pfizer INC

Worldwide Safety Organization

Executive Assistant
M. Janik

Vice President
Worldwide Safety
M. Brumfield

Sr. Medical Director
European Drug Safety
K. Sultjaga-Petchel

Director/Group Leader Quality Management, Compliance and Licensing
D. Driscoll

Director/Group Leader Therapeutic Teams
A. Pitwood

Director/Group Leader Medical
P. McLaughlin

Director/Group Leader Regulatory Safety
J. Groth

Director/Group Leader Licensing
A. Garrity

Director/Therapeutic Team Leaders
A. Dickson, C. Benetia, R. Burke, A. Quintana

Lead Medical Directors
A. Gaddes, K. Thacker, J. Armstrong, A. Quintana

Director WWS Outsourcing
L. Raftery

Director CCP
M. Radwaner

Director WWS Training & Documentation
T. Clancaglini

Director Information Resources
M. Ibara

Director/Group Leader Medical Literature
F. Weiss

Director/Group Leader Operations & Project Mgmt
TBD
### Pharmacovigilance Organization / Pfizer INC

<table>
<thead>
<tr>
<th>EDS</th>
<th>Compliance</th>
<th>SEE</th>
<th>Therapeutic/medical</th>
</tr>
</thead>
<tbody>
<tr>
<td>EMEA submission</td>
<td>QC</td>
<td>epidemiology</td>
<td>Case assessments</td>
</tr>
<tr>
<td>Support to EU offices</td>
<td>Data entry</td>
<td>Safety evaluation RM</td>
<td>causality</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PSUR</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Respond to HA</td>
<td></td>
</tr>
</tbody>
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Pharmacovigilance organization / Pfizer Turkey

Medikal Division

Clinical Trials   Medical Support   Medical Support   Regulatory Affairs

Safety / Pharmacovigilance
Procedures

• Global SOPs are in effect
  • AEM01 - Adverse Event Monitoring SOP

  - Standard Adverse Event Report form is used by all countries for reporting Adverse Events to Headquarters.
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 personnel within specific timeframes (2 months of employment)
Training

• Training of all relevant Medical & Marketing employees by Safety Manager on Spontaneous Adverse Event Reporting Responsibilities within 2 months of employment (including sales representatives and employees 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
• Spontaneous 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
Adverse Events

- Serious AEs
- Non-serious AEs
Serious AEs

- Death
- Life Threatening
- Congenital anomaly/Birth defect
- Permanent incapacity/disabilities
- Hospitalization/ prolongation of hospitalization

Any AE considered Serious by the reporting physician investigator or Pfizer personnel
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 Adverse 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.
24/10/2003

Health Authorities

PSUR

CIOMS

Safety Manager

e-AEM system/intranet

Safety Manager
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
  - Monthly 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 developments
Meeting/Seminars

- Inter-company meetings
  - Recent regulatory developments
  - 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 Accessing 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 development and continue throughout the life cycle.
- Includes proactive risk assessment and development of plans to manage risk
- Identify estimate and evaluate risks
- Risk Management Plans / guidelines
- Could become a regulatory requirement at the time of New Drug Application?
EU ACCESSING COUNTRIES

- May 2004

Main problems

- PhV perception - a burden / unwanted activity
- Lack of IT support
- PhV support staff
Regulations / new developments

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

• Increased importance of close follow up of recent EU developments regarding Pharmacovigilance.
THANK YOU