SFDA Pharmacovigilance System

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Executive Director of Vigilance & Crisis Management Department
Pharmacovigilance in
Saudi Arabia: Rules and Responsibilities
Riyadh 15/5/2011
Drug Regulations Strategic Imperatives

1. Design IND application approval process
2. Design NDA approval process
3. Re-engineer current drug approval process
4. Establish cosmetics listing database and regulation
5. Establish post-marketing surveillance program
6. Develop port of entry inspection presence
7. Support implementation of an agency wide communication plan
8. Updating of existing guidelines and regulations
9. Establish department for licensing of pharmaceutical institutions
Established

Saudi Food & Drug Authority (SFDA)

National Pharmacovigilance Center (NPC)
Pharmacovigilance In KSA

• The National Pharmacovigilance Centre (NPC) was announced to be functioning in March 2009.
Kick-off for pharmacovigilance in Saudi Arabia

Sten Olsson

Saudi Arabia officially launched its national pharmacovigilance programme by organizing a symposium in the capital city Riyadh from 30-31 March 2009, under the theme 'Drug Safety, a Global

No. 92

Sten Olsson presents a copy of the book Drug Benefits and Risks from the UMC to the new centre in Saudi Arabia, represented by Saleh Bawazeir (left) and Ghazi Saeed (middle).
Organizational Structure

Pharmacovigilance & Crisis Management Directorate

National Pharmacovigilance Center (NPC)
- Data entry
- Signal detection
- Risk analysis
- PSURs
- Inspection

Cosmovigilance
- Data entry
- Risk analysis and Signal detection

Crisis Management
- Drugs
- Cosmetics

Medication Error
Objectives

- Improve patient safety in relation to the use of medicines.
- Detection of ADRs at an early stage.
- Detection of increase in frequency of known ADRs.
- Prevention of adverse drug events, if possible.
- Promotion of understanding, education and training in Pharmacovigilance.
- Encouraging rational and more effective use of medicines.
- Liaison with international centers.
Strategy

Strategic plan was to establish NPC including the following:

• To build an infrastructure for NPC:
  – Staffing, qualifications, and expertise.
  – PV Guidelines
  – Reporting channels
  – Database
  – Connecting large hospitals to reporting system
  – Advisory committee
  – To enhance awareness and reporting culture
Staffing, Qualifications, and Expertise.

- **Staffing**
  - 10 employees
  - 2 PhD
  - 4 Masters degree
  - 4 Bachelor degree

- **Postgraduate education**
  - 4 PharmD
  - 1 Master of Clinical Pharmacology
  - 1 Master of Clinical Epidemiology
Staffing, Qualifications, and Expertise.

• **Training**
  - Fellowship at US. FDA
  - Pharmacoepidemiology
  - Pharmacovigilance
  - Risk management
  - Signal detection
  - MedDRA coding
PV Guideline:

- Roles of MAHs.
- Roles of QPPV.
- ICSRs.
- PSURs.
Reporting Channels

- Online Reporting Form
- Paper-based Reporting Form
- Verbal Reporting & Other reporting means
  - Telephone
  - Fax
  - E-mail
  - Prepaid Mail
Paper-Based Reporting Forms

If in doubt fill the form out!
### I. Reaction Information

<table>
<thead>
<tr>
<th>1. Patient Initials (first, last)</th>
<th>1a. Country</th>
<th>2. Date of Birth</th>
<th>2a. Age</th>
<th>3. Sex</th>
<th>4-6. Reaction Onset</th>
<th>8-12 Check All Appropriate to Adverse Reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Day</td>
<td>Month</td>
<td>Year</td>
<td>Day</td>
<td>Patient Died</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Involved or Prolonged Inpatient Hospitalization</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Involved Persistence or Significant Disability or Incapacity</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Life Threatening</td>
</tr>
</tbody>
</table>

7 + 13 Describe Reaction(s) (including relevant tests/lab data)

Narrative: *

### II. Suspect Drug(s) Information

<table>
<thead>
<tr>
<th>14. Suspect Drug 1 of 1 (include generic name)</th>
<th>20. Did Reaction Abate After Stopping Drug?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>□ Yes □ No □ NA</td>
</tr>
</tbody>
</table>

15. Daily Dose(s)

16. Route(s) of Administration

17. Indication(s) for Use

18. Therapy Dates (from/to)

19. Therapy Duration

21. Did Reaction Reappear After Reintroduction?

□ Yes □ No □ NA

### III. Concomitant Drugs and History

22. Concomitant Drug(s) and Dates of Administration (exclude those used to treat reaction)

23. Other Relevant History (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)
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  <senderorganization>B. Braun Melsungen AG</senderorganization>
  <senderdepartment>Corporate Drug Safety</senderdepartment>
</sender>
Adverse Drug Reaction reporting form (ADR) for healthcare professionals
Form no. (ADR-1)

A. Patient Details  
B. Suspected Products  
C. concomitant drugs used  
D. Adverse Drug Reaction Description  
E. Relatedness  
F. Seriousness of the case Check all that apply  
G. Preventability Information (Check all that apply)  
H. Reporter Details  

Report's and patient's identity are held in strict confidence by SFDA and protected to the fullest extent of the law, information provided by the reporter will be strictly protected and will not be used in any way against him.
**A. Patient Details**

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name (optional)</td>
<td></td>
</tr>
<tr>
<td>Date of Birth</td>
<td>Greg Hijri (mm/dd/yyyy)</td>
</tr>
<tr>
<td>Medical Record No.</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>(Choose)</td>
</tr>
<tr>
<td>Weight</td>
<td></td>
</tr>
<tr>
<td>Height</td>
<td></td>
</tr>
<tr>
<td>Patient Location in the Hospital</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td>Male/Female</td>
</tr>
</tbody>
</table>

**B. Suspected Products**

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Type</td>
<td>Drug/Vaccine/Herbal/Cosmetic/Diagnostics/Other</td>
</tr>
<tr>
<td>Product name</td>
<td>Generic Name/Trade Name</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Select</td>
</tr>
<tr>
<td>Dose</td>
<td>(Choose)</td>
</tr>
<tr>
<td>Dosage Form</td>
<td>Select</td>
</tr>
<tr>
<td>Route</td>
<td>Select</td>
</tr>
<tr>
<td>Frequency</td>
<td>(Choose)</td>
</tr>
<tr>
<td>Batch number</td>
<td></td>
</tr>
<tr>
<td>Purpose of use</td>
<td></td>
</tr>
<tr>
<td>Start Date</td>
<td>Greg Hijri (mm/dd/yyyy)</td>
</tr>
<tr>
<td>End Date</td>
<td>Greg Hijri (mm/dd/yyyy)</td>
</tr>
<tr>
<td>Action</td>
<td>Drug withdrawn/</td>
</tr>
</tbody>
</table>

Who Reports to The NPC?

- Healthcare Providers
  - Pharmacists
  - Nurses
  - Doctors

- Public
  - Citizens, residents.
  - Different disciplines and backgrounds.

- Drug Industries
  - QPPV
What Can Be Reported to NPC?

All suspected ADRs that might be related to use of medicines, vaccines, herbal products and cosmetics.
<table>
<thead>
<tr>
<th>Case Number</th>
<th>Country</th>
<th>First_RECEIVED</th>
<th>Last_RECEIVED</th>
<th>Onset</th>
<th>First Key Product</th>
<th>First Adverse Event</th>
<th>Deadline</th>
<th>Editor</th>
<th>Step</th>
</tr>
</thead>
<tbody>
<tr>
<td>US-00041</td>
<td>United States</td>
<td>08-04-2010</td>
<td>08-04-2010</td>
<td>05-02-2010</td>
<td>TRAMADOL HYDROCHLORIDE</td>
<td>coma</td>
<td></td>
<td></td>
<td>Evaluation</td>
</tr>
<tr>
<td>US-00025</td>
<td>United States</td>
<td>01-05-2010</td>
<td>01-05-2010</td>
<td>02-02-2006</td>
<td>Unknown</td>
<td>Nephrogenic Fibrosing Dermopathy</td>
<td></td>
<td></td>
<td>Evaluation</td>
</tr>
</tbody>
</table>
Signal Detection Tool

Select Criteria

Run name: 2010Q3 Vigibase Generic by Year (S)

Generic Name (Abridged)

WHO-DD Hierarchy Level:
- ATC5
- ATC4
- ATC3
- ATC2
- ATC1

PT

MedDRA Hierarchy Level:
- PT
- HLT
- HLGT
- SOC

Select WHO-DD Terms
Select Available Values
Select Saved List

Trade/Generic Lookup

Select MedDRA Terms
Select Available Values
Select Saved List

Limit to: EBGM > 0.0

Show Advanced

View Results Table  Choose Graph  Clear All
Connecting Large Hospitals to Reporting System

62 PV Coordinators have been recruited

Northern region = 5
Western region = 19
Southern region = 8
Central region = 18
Eastern region = 12
Awareness of Healthcare Professionals and Public

45 workshops have been conducted

>5000 HCP have received training about PV and ADR reporting
# Completed Workshops

<table>
<thead>
<tr>
<th>Regions</th>
<th>No. of workshops</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central</td>
<td>15</td>
</tr>
<tr>
<td>Western</td>
<td>16</td>
</tr>
<tr>
<td>Northwestern</td>
<td>4</td>
</tr>
<tr>
<td>Eastern</td>
<td>6</td>
</tr>
<tr>
<td>Southern</td>
<td>4</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>45</strong></td>
</tr>
</tbody>
</table>
Reporting reward

10 ADRs / Quality Reports = 1 Accredited CME hour
## Type of Reports (Oct 2009-April 2011)

<table>
<thead>
<tr>
<th>Reports type</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADRs</td>
<td>1266</td>
<td>85%</td>
</tr>
<tr>
<td>Herbal (traditional) products</td>
<td>17</td>
<td>1%</td>
</tr>
<tr>
<td>Cosmetics</td>
<td>16</td>
<td>1%</td>
</tr>
<tr>
<td>Medication errors</td>
<td>63</td>
<td>4.5%</td>
</tr>
<tr>
<td>Product quality</td>
<td>123</td>
<td>8.5%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1486</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>
ADR Reports By Type Of Reporter

<table>
<thead>
<tr>
<th>Type Of Reporter</th>
<th>Number of reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician</td>
<td>172</td>
</tr>
<tr>
<td>Pharmacist</td>
<td>286</td>
</tr>
<tr>
<td>Other HCP</td>
<td>228</td>
</tr>
<tr>
<td>MAH</td>
<td>743</td>
</tr>
<tr>
<td>Public</td>
<td>57</td>
</tr>
</tbody>
</table>
Type of Reports by Seriousness

- Serious: 61%
- Non-serious: 39%
<table>
<thead>
<tr>
<th>SOC Name</th>
<th>AE Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Congenital, familial and genetic disorders</td>
<td>1</td>
</tr>
<tr>
<td>Endocrine disorders</td>
<td>2</td>
</tr>
<tr>
<td>Social circumstances</td>
<td>4</td>
</tr>
<tr>
<td>Pregnancy, puerperium and perinatal conditions</td>
<td>5</td>
</tr>
<tr>
<td>Surgical and medical procedures</td>
<td>5</td>
</tr>
<tr>
<td>Reproductive system and breast disorders</td>
<td>7</td>
</tr>
<tr>
<td>Ear and labyrinth disorders</td>
<td>12</td>
</tr>
<tr>
<td>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</td>
<td>12</td>
</tr>
<tr>
<td>Hepatobiliary disorders</td>
<td>25</td>
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<tr>
<td>Immune system disorders</td>
<td>30</td>
</tr>
<tr>
<td>Infections and infestations</td>
<td>42</td>
</tr>
<tr>
<td>Metabolism and nutrition disorders</td>
<td>48</td>
</tr>
<tr>
<td>Renal and urinary disorders</td>
<td>51</td>
</tr>
<tr>
<td>Blood and lymphatic system disorders</td>
<td>53</td>
</tr>
<tr>
<td>Eye disorders</td>
<td>59</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td>64</td>
</tr>
<tr>
<td>Vascular disorders</td>
<td>97</td>
</tr>
<tr>
<td>Cardiac disorders</td>
<td>105</td>
</tr>
<tr>
<td>Investigations</td>
<td>110</td>
</tr>
<tr>
<td>Injury, poisoning and procedural complications</td>
<td>132</td>
</tr>
<tr>
<td>Psychiatric disorders</td>
<td>147</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td>180</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td>238</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>312</td>
</tr>
<tr>
<td>Other</td>
<td>440</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td>454</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td>498</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>3133</strong></td>
</tr>
</tbody>
</table>
ADR Reports By SOC

- General disorders and administration site conditions
  - Skin and subcutaneous tissue disorders
  - Other
- Nervous system disorders
- Gastrointestinal disorders
- Respiratory, thoracic and mediastinal disorders
- Psychiatric disorders
- Injury, poisoning and procedural complications
- Investigations
- Cardiac disorders
- Vascular disorders
- Musculoskeletal and connective tissue disorders
- Eye disorders
- Blood and lymphatic system disorders
- Renal and urinary disorders
- Metabolism and nutrition disorders
- Infections and infestations
- Immune system disorders
- Hepatobiliary disorders
- Neoplasms benign, malignant and unspecified (incl cysts...)
- Ear and labyrinth disorders
- Reproductive system and breast disorders
- Surgical and medical procedures
- Pregnancy, puerperium and perinatal conditions
- Social circumstances
- Endocrine disorders
- Congenital, familial and genetic disorders

Total of 3133 AE
PV Advisory Committee

- Multidisciplinary team
- Provide independent evaluation of safety concerns
Activities of PV Advisory Committee

- 17 meetings

Actions taken ranged from labeling update to revoking of drug marketing authorization

Examples of actions taken:
- Withdrawal of Sibutramine
- Suspension and then withdrawal of Rosiglitazone
Actions taken ranged from labeling update to submission of risk management plan.
Success Stories

Saudi Arabia revokes obesity drug licence

Saudi Arabia suspends Glaxo diabetes drug

Arvandia

Saudi FDA cancels the Registration of Aupent Product

Reuters

The Saudi FDA has announced that Aupent & 10mg & 5mg syrup is no longer available in the market due to its hazards.

Accordingly, the drug products are banned from the market and the public is advised to seek alternative drugs for patients who need it.
If you suspect an ADR..

Do not assume someone else will report it!

Be vigilant by reporting to Saudi-Vigilance.
Thank You
www.sfda.gov.sa/npc