Overview and regulation of Individual Case Safety Reports (ICSRs)

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Pharmacovigilance in Saudi Arabia: Rules and Requirement
15 May 2011
Outline

- Definition of Adverse Drug Events (ADE) and Reporting Requirement
- Serious Events, unexpected events and Serious unexpected Events
- Minimum requirement
- Expedited reporting in Saudi Arabia.
- Expedited reporting internationally.
- Reporting methods and timeline.
- Take home messages.
Adverse Drug Events

- All serious Adverse Drug Events (ADEs)
- **ADEs:** An injury resulting from the use of a drug as a result of:
  - *Intrinsic nature of a medication*
  - *Harm resulting from medication errors*
  - *under-use (Misuse) of medicines or*
  - *failure to prescribe a medicine when indicated*
Serious ADR

• an ADR that is
  – Result in death
  – Life-threatening
  – Require hospitalization
  – Prolong hospitalization
  – Cause disability
  – Cause congenital anomaly
  – Requires intervention to prevent permanent injury
Unexpected ADR

One that is not mentioned in the product’s Summary of Product Characteristics (SPC)

Serious Unexpected ADR

An ADR which is both serious and unexpected
Minimum Requirement for an acceptable ICSR (Case Definition)

1. Identifiable patient
2. Suspect Drug(s)
3. Event(s)
4. Identifiable reporter
PV Guideline:

- Expedited reporting in Saudi Arabia and internationally.
Expedited Reporting in KSA

• ICSRs requiring expedited reporting promptly and no later than 15 calendar days from receipt.

• All ICSRs must be submitted as CIOMS form (only for the generics companies).

• NPC only accepts ICSRs in xml. format. (only for the multinational companies)

• Non-serious ADRs should only be reported in accordance with PSURs.
Expedited Reporting International

- Timeline: 15 days.

- All serious unexpected suspected adverse reactions (SUSARs) that occur outside Saudi Arabia.

- Expected serious and non-serious ADRs should only be reported in accordance with PSURs.
Reporting Timeline

1. Report with 15 calendar days
2. Local
   - Yes: Serious
   - No: Expected
     - Yes: Report with 15 calendar days
     - No: Report with 15 calendar days
3. Serious
   - Yes: PSUR
   - No: ADE
Reporting Methods

**Multinational companies**
Through NPC email
*xml ONLY*  
*(ICH E2b)*

**Generics companies**
Fax / Email / Airmail
*pdf. ONLY*  
*(CIOMS)*
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    <senderdepartment>Corporate Drug Safety</senderdepartment>
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# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

<table>
<thead>
<tr>
<th>1. PATIENT INITIALS (first/last)</th>
<th>2. DATE OF BIRTH</th>
<th>2a. AGE</th>
<th>3. SEX</th>
<th>4-6. REACTION ONSET</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day</td>
<td>Month</td>
<td>Year</td>
<td>Day</td>
<td>Month</td>
</tr>
</tbody>
</table>

- 6-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
  - □ PATIENT DIED
  - □ INVOLVED OR PROLONGED INFANT HOSPITALIZATION
  - □ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
  - □ LIFE THREATENING

*7 + 13 DESCRIBE REACTION(S) (including relevant test/lab data)*

**Narrative:** *

## II. SUSPECT DRUG(S) INFORMATION

<table>
<thead>
<tr>
<th>14. SUSPECT DRUG for 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>

<table>
<thead>
<tr>
<th>15. DAILY DOSE(S)</th>
<th>16. ROUTE(S) OF ADMINISTRATION</th>
<th>21. DID REACTION REAPPEAR AFTER REINTRODUCTION?</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>□ YES □ NO □ NA</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>17. INDICATION(S) FOR USE</th>
<th>18. THERAPY DATES (from/to)</th>
<th>19. THERAPY DURATION</th>
</tr>
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## III. CONCOMITANT DRUGS AND HISTORY

<table>
<thead>
<tr>
<th>22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)</th>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)</th>
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<tbody>
<tr>
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Special follow-ups

- Pregnancies
- Deaths
- Treatment failures
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<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>
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<tr>
<td>SA.000033</td>
<td>Saudi Arabia</td>
<td>08-05-2010</td>
<td>08-05-2010</td>
<td></td>
<td>CEFTRIDINE (CEPHRADINE)</td>
<td>anaphylactic shock</td>
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<td>Saudi Arabia</td>
<td>15-05-2010</td>
<td>15-05-2010</td>
<td>01-03-2010</td>
<td>Unknown</td>
<td>muscle pain</td>
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<td></td>
</tr>
<tr>
<td>SA.000038</td>
<td>Saudi Arabia</td>
<td>15-05-2010</td>
<td>16-05-2010</td>
<td>06-02-2010</td>
<td>CIPROFLOXACIN</td>
<td>macular erythema</td>
<td></td>
<td>Coding</td>
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</tr>
<tr>
<td>SA.000040</td>
<td>Saudi Arabia</td>
<td>15-05-2010</td>
<td>16-05-2010</td>
<td>06-02-2009</td>
<td>MOXIFLOXACIN</td>
<td>erythematous skin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SA.000076</td>
<td>Saudi Arabia</td>
<td>18-05-2010</td>
<td>18-05-2010</td>
<td></td>
<td></td>
<td>Comulsion</td>
<td></td>
<td>Coding</td>
<td></td>
</tr>
<tr>
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<td>skin eruption</td>
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<td>18-05-2010</td>
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<td></td>
<td>pt developed hyperkalaemia</td>
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<td>18-05-2010</td>
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<td></td>
<td></td>
<td>pt came to the hospital with</td>
<td></td>
<td>Coding</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>severe GI bleeding high INR,</td>
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<td></td>
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<td>he admitted to ICU then</td>
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<td>transferred to IMI, pt use</td>
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<td>warfarin which prescribed</td>
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<td></td>
<td>for him from SFH &amp; PSSC</td>
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<td>high INR 5.7</td>
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<tr>
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<td>Loss of consciousness</td>
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<tr>
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<td>18-05-2010</td>
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<td>rash all over body including</td>
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<td></td>
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<td>abdomen, back and left eye</td>
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<tr>
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<td>between tramadol and diazepam</td>
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<tr>
<td>SA.000082</td>
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<td>18-05-2010</td>
<td>18-05-2010</td>
<td></td>
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<td></td>
<td></td>
<td>Coding</td>
<td></td>
</tr>
</tbody>
</table>
How to Communicate with Saudi-Vigilance

You can approach The NPC either by:

1. Calling The NPC at +966-1-2759222 Ext. 2353, 2340
2. Fax to +966-1-2057662
3. Via The NPC’s e-mail address: npc.drug@sfda.gov.sa
Take Home Messages

• What do we need from MAHs
  – Follow the PV guidelines which can be found at: [www.sfda.gov.sa/Ar/Drug/Topics/drug_reg/](http://www.sfda.gov.sa/Ar/Drug/Topics/drug_reg/)
  – Comply with expedited reporting requirements
  – Submission of serious cases only.
  – Comply with ICSRs specifications
  – Comply with required methods of ICSRs submission:
    • Multinational companies (xml) file only.
    • Generics companies CIOMS form (PDF).
It’s time to **join hands** & share a **common goals** to deliver **safe drugs** to protect our **patients**.
Thank You
www.sfda.gov.sa/npc