Basic Pharmacovigilance Training

provided by

BayerPharma AG
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Consumer, patients and healthcare professionals play an important role in the reporting process of safety related information.

To enable Bayer to provide up-to-date safety information on Bayer products, your support is pivotal to continued patient and drug safety.
Definitions
An adverse drug reaction (ADR) is any untoward medical occurrence in a patient administered a pharmaceutical product, which is suspected to have a causal relationship with this treatment.

Spontaneous reports from consumers and healthcare professionals should be regarded as suspected ADRs.
Lack of Efficacy (Lack of Drug Effect)

Failure to produce the expected pharmacological action for an approved indication.

Example:
A patient received an oral contraceptive and became pregnant.
Central questions

- What information should be reported?
- How is the information reported?
- To whom should I report?
What information should be reported?
What information should be reported?

Any information

✖️ on an ADR or lack of efficacy connected with the use of a Bayer product.
What information should be reported?

Any information on ADRs occurring

- in the course of the use of a drug
- from drug overdose whether accidental or intentional
- from drug abuse / misuse / non-approved use
- from drug withdrawal
- in the infant of a nursing mother
- possibly as a result of exposure of the mother or the fetus during pregnancy.
What information should be reported?

Any information

- even if no ADR has been observed,
  - from drug overdose whether accidental or intentional
  - from drug abuse / misuse / non-approved use
  - from drug administration during pregnancy.
What information should be reported?

**Serious ADRs**

Any ADR occurring at any dose which fulfills one of the following criteria:

- results in death
- is life-threatening
- requires inpatient hospitalization or prolongation of existing hospitalization
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect
- is an important medical event.
What information should be reported?

**Minimum information required for a case:**

1. An identifiable patient
2. An identifiable reporter
3. A suspect drug
4. A suspect ADR

"Identifiable"

- Patient/reporter does not need to be identified at time of report but is identifiable if some effort is taken.
What information should be reported?

Product Technical Complaints

Please also report any information regarding the **product quality** of a Bayer product you become aware of.

Examples are

- wrong product (label and contents are different products)
- correct product but wrong strength
- faulty packaging, e.g. wrong or missing batch number or expiry date.
How is the information reported?
How is the information reported?

Adverse Events

Document any Adverse Event on the ADR Short Report Form.
Inform about any exposure to a Bayer product during pregnancy.
How is the information reported?

ADR Short Report Form

- Who has experienced the event? (PATIENT)
- What event has the patient experienced? (EVENT)
- Which Bayer drugs were involved? (DRUG)
- Who has reported the event? (REPORTER)
How is the information reported?

ADR Short Report Form

<table>
<thead>
<tr>
<th>Local case ID:</th>
<th>Date of receipt of information: 20 June 2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial report</td>
<td>Follow-up report</td>
</tr>
</tbody>
</table>

Give information on the patient who has experienced the Adverse Event.

<table>
<thead>
<tr>
<th>Initials</th>
<th>Gender</th>
<th>Age [years]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>male</td>
<td></td>
</tr>
<tr>
<td></td>
<td>female</td>
<td></td>
</tr>
</tbody>
</table>

Which Adverse Event(s) has the patient experienced?

1. 
2. 
3. 
4.

<table>
<thead>
<tr>
<th>Date:</th>
<th>Date:</th>
<th>Date:</th>
<th>Date:</th>
</tr>
</thead>
</table>

Was the patient hospitalized? Yes No

Did the patient die? Yes No

Describe details of the Adverse Event(s).
To whom should I report?
To whom should I report?

Report at your earliest convenience to:

Names: Bayer Pharma AG
       Global Pharmacovigilance,
       Muellerstr. 178, D-13353 Berlin, Germany

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