Basic Pharmacovigilance Training for ICA Foundation

Product Safety and Quality: Reporting Obligations

Bayer AG, Pharmaceuticals
Muellerstr. 178, D-13353 Berlin, Germany
GPV.CaseProcessing@bayer.com

V2.0 – June 2018
Pharmacovigilance (PV) is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem (WHO)\(^1\)

Why is Pharmacovigilance so important?

- PV is responsible for collecting and reporting of Safety and Quality related information regarding Bayer products for human use.
- PV ensures maximum safety and the most favorable benefit-risk-ratio for medicinal products.
- Consumer, patients and healthcare professionals play an important role in the reporting process of safety and quality related information.
- Pharmacovigilance relies on the support from everybody, also from You!
What is an Adverse Event?

Definition

Any untoward **medical occurrence** in a patient or clinical investigation subject administered a pharmaceutical product or medical device, and which does not necessarily have a causal relationship (association) with this treatment.

**Examples**
- Unfavorable and unintended sign (e.g. an abnormal laboratory finding)
- Symptom
- Disease permanent or temporally associated with the use of a medicinal product
- New medical condition
- Death of a patient

Reportable whether or not considered related to the medicinal product, serious or non-serious, known or unknown.
What is an Adverse Reaction?

Definition

All noxious and unintended responses to a medicinal product related to any dose should be considered adverse reactions.

A causal relationship between a medicinal product and an adverse event is at least a reasonable possibility.

If a medical occurrence is reported in connection with a Bayer product, forward the information to the PV Country Head of the country where the event occurred.
A **PTC** is a report about an obvious or suspected quality defect of the drug or the medical device related to the drug. A PTC can also be a suspected counterfeit.

A **Usability Issue** is a report about a use error or customer satisfaction issue by the user of a medical device or combination products.

**Examples**

**Product Related**
- A missing row in an untouched pill blister
- Pill is in an unfamiliar color, taste, or shape

**Package Related**
- Label and content are different products
- Package shows stains from water spotting

**Medical Device Related**
- The release button of my autoinjector does not release
- Software failure with electronic supported pill dispenser
Pharmaceutical companies are legally obliged to collect reports without Adverse Events (AE) in special situations:

- Lack of Drug effect
- Drug exposure during conception, pregnancy, childbirth, breastfeeding
- Medication error
- Off-label use
- Overdose (accidental or intentional)
- Drug abuse or misuse
- Drug dependency
- Occupational exposure
- (Intentional) Product use issue
- Unexpected therapeutic benefit
- Suspicion of transmission of an infectious agent via a Bayer product
Please inform Bayer PV about any case, where a patient/consumer is potentially at medical risk while using a Bayer product. Bayer needs to have the information for any issue where the Bayer product and some medical occurrence was brought in connection.

Please tell us...

- Which company product is suspected to have caused an Adverse Event/PTC?
- What happened? → Adverse Event/PTC (include all relevant information, e.g. dates, dosage, indication, etc.)

If you can, try to obtain also the following information:

- Who reported the case? → Identifiable reporter
- Who experience an AE? → Identifiable patient

What does “Identifiable” mean?

- An identifier for a reporter can be their profession, country, city etc.
- An identifier for a patient can be their gender, age, age group etc.
How to report product safety/quality issues?

Report form / Reporting website

Alternatively you can also report in multiple languages via the Bayer AE-reporting website:

What to do with a case report?

Please report

- Adverse Event / Adverse Reaction
- Product Technical Complaint / Usability Issue
- Cases in Special Situations without AE

… must be **reported within one business day.**

Select the reporting channel which is most suitable for you

Bayer AG, Pharmaceuticals
Pharmacovigilance
Muellerstr. 178
D-13353 Berlin, Germany

Fax: +49 30 468 96765

E-mail: GPV.CaseProcessing@bayer.com

Thank you!