Basic Pharmacovigilance Training for ICA Foundation

Product Safety and Quality: Reporting Obligations

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What is Pharmacovigilance (PV)?

Pharmacovigilance = Drug Safety

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]

Definition of Pharmacovigilance (WHO, 2002), www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/

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.

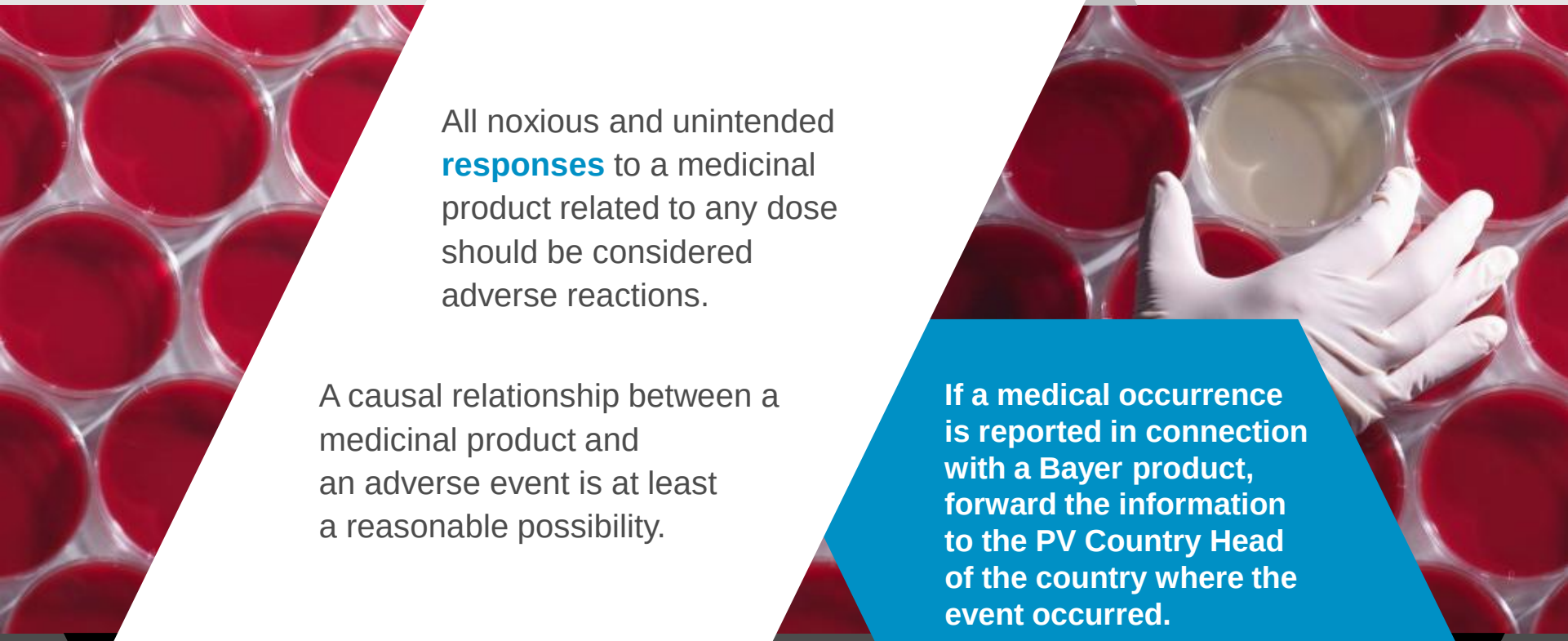
Examples

- 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.

Quality Complaints

Product Technical Complaints (PTC) and Usability Issue (UI)

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

Case Reports in Special Situations

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

Reporting of case information

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.

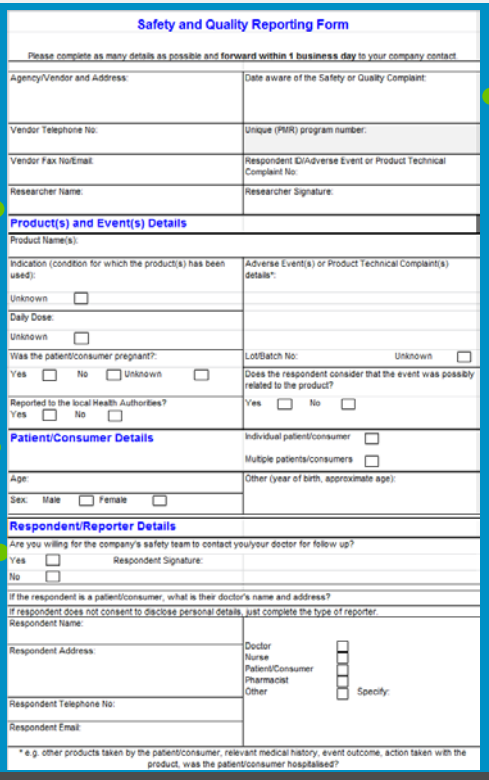
How to report product safety/quality issues?

Report form / Reporting website

Product and Event Details

Patient/ Consumer Details

Reporter details (who told you)



Safety and Quality Reporting Form

Please complete as many details as possible and **forward within 1 business day** to your company contact.

Agency/Vendor and Address:	Date aware of the Safety or Quality Complaint:
Vendor Telephone No:	Unique (PMR) program number:
Vendor Fax No/Email:	Respondent ID/Adverse Event or Product Technical Complaint No:
Researcher Name:	Researcher Signature:

Product(s) and Event(s) Details

Product Name(s):

Indication (condition for which the product(s) has been used): Unknown ☐	Adverse Event(s) or Product Technical Complaint(s) details*:
Daily Dose: Unknown ☐	
Was the patient/consumer pregnant?: Yes ☐ No ☐ Unknown ☐	Lot/Batch No: Unknown ☐
Reported to the local Health Authorities? Yes ☐ No ☐	Does the respondent consider that the event was possibly related to the product? Yes ☐ No ☐

Patient/Consumer Details	Individual patient/consumer ☐ Multiple patients/consumers ☐
Age:	Other (year of birth, approximate age):
Sex: Male ☐ Female ☐	

Respondent/Reporter Details

Are you willing for the company's safety team to contact you/your doctor for follow up?

Yes ☐ Respondent Signature:

No ☐

If the respondent is a patient/consumer, what is their doctor's name and address?

If respondent does not consent to disclose personal details, just complete the type of reporter.

Respondent Name:	
Respondent Address:	Doctor ☐ Nurse ☐ Patient/Consumer ☐ Pharmacist ☐ Other ☐ Specify:
Respondent Telephone No:	
Respondent Email:	

* e.g. other products taken by the patient/consumer, relevant medical history, event outcome, action taken with the product, was the patient/consumer hospitalised?

The date you received the report.

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

http://pharma.bayer.com/en/treatment-care/report-a-side-effect/

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

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Fax: +49 30 468 96765

E-mail: GPV.CaseProcessing@bayer.com

Web: http://pharma.bayer.com/en/treatment-care/report-a-side-effect/

Thank you!