

Drug Safety

Pharmacovigilance
("PV")

Pharmacovigilance-CSL

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Pharmacovigilance

- Collection
- Detection
- Assessment
- Monitoring
- Prevention

of adverse effects with
pharmaceutical products.

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Goal

minimize the risk of
any harm that may
come to patients

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ADR

(old definition)

adverse drug reactions, which are defined as any response to a drug which is noxious and unintended

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New Definition of Adverse Reaction

(broader in scope)

Noxious and unintended effects resulting not only from the authorised use of a medicinal product in normal doses, but also from medicinal errors and uses outside the terms of the marketing authorisation (off-label use), as well as the misuse and abuse of the medicinal product.

http://www.pmlive.com/pharma_intelligence/changes_to_pharmacovigilance_legislation_in_europe_426142
Misuse: Fehlgebrauch = absichtliche Verwendung außerhalb der GI,
Beispiel Erythropoetin bei Doping
Abuse: Exzessive Verwendung außerhalb der GI

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Sources of information

- healthcare providers
- patients
- medical literature
- clinical trials
- other, e.g. Social Media

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AE

Adverse event (AE) is a side effect occurring with a drug. By definition, the causal relationship between the AE and the drug is unknown.

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ADR

Adverse drug reaction is a side effect (non intended reaction to the drug) occurring with a drug where a positive (direct) **causal** relationship between the event and the drug is thought, or has been proven, to exist.

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Responsible

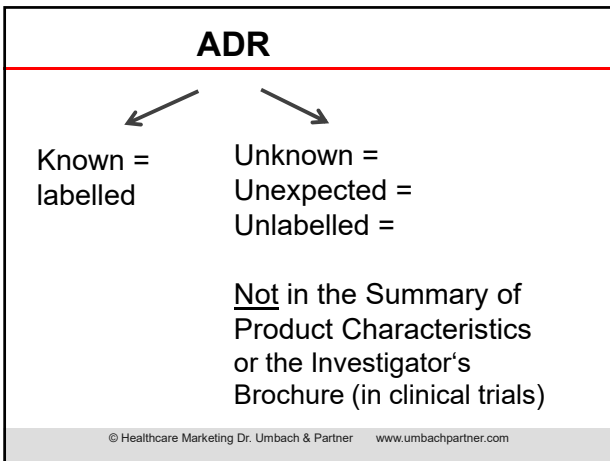
Authorities

In Europe: EMA (European Medicines Agency)
In Germany: Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) / Paul-Ehrlich-Institut (PEI)

In the companies

QPPV: Qualified Person for Pharmacovigilance
In Germany: Stufenplanbeauftragter der Firma laut § 63a Arzneimittelgesetz (AMG)

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Serious adverse drug reactions

Patient outcome is one of the following:

- Death
- Life-threatening
- Hospitalization (initial or prolonged)
- Disability
- Congenital anomaly
- Requires intervention to prevent permanent impairment or damage

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"Severe" vs "Serious"

Schwerwiegend

A common headache may be severe, if it causes intense pain, but it is not usually serious.

A subarachnoid hemorrhage leading to a headache is a serious condition.

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Reporting ADRs to Authorities

Non-serious

PSUR = Periodic Safety Update Report /
 PBRER = Periodic benefit-risk evaluation report

Serious

15 days (Expedited Report)

In clinical studies: 7 days

For details, see European and national legislation

Note: Many drug companies require internal reporting within 24 hours

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Tolerability vs Safety

Metamizol = Novaminsulfon (Novalgin®)

Efficacious and well tolerated analgesic drug

In rare cases: Agranulocytosis
 Serious side effect



Not approved in Sweden and other countries

Non-opioid pyrazolone derivative

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Reality: "Underreporting"

Formblatt im
 Deutschen Ärzteblatt

Bericht über unerwünschte
 Arzneimittelwirkungen

Hinweis: Weiteres Formular
 "for Suspect Reaction" vom
 Council for International
 Organisations of Medical
 Science (CIOMS) Guidelines

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