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Introduction to pharmacovigilance
Monitoring the safety of medicines

What is pharmacovigilance?

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- Pharmacovigilance is the science and practices related to the detection, assessment, understanding, and prevention of adverse effects or any other medicine-related problem
- In recent years, the scope of pharmacovigilance has been widened to include:
  - Herbal medicines and dietary supplements
  - Traditional and complementary medicines
  - Blood products
  - Biologics (medicines derived from a biological source or living cells such as antigens or vaccines)
  - Medical devices

What is an adverse event?

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- An Adverse Event (AE) is any negative medical occurrence in a patient treated wit ha medicine, whether or not it is considered to be associated with that product.
- An AE does **not** necessarily have a causal relationship with the treatment.
- AEs can happen:
  - During the use of a product, **or**
  - Following the withdrawal of a product

Adverse events can include: (1)

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- Suspected interactions with other medicines (medicine-medicine interactions)
- Medicines abuse
- Medication errors, such as taking too much of the medicine
- Product technical complaints, such as missing tablets or damaged product
- Events resulting from overdose

Adverse events can include (2)

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- Lack of expected medicine effect
- Worsening of illness after the use of a product
- Birth defects and other events after the use of the medicinal product during pregnancy

What is a serious adverse event?

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- A serious adverse event (SAE) involves:
- Death
- An immediately life-threatening event
- Inpatient hospitalisation or extended hospitalisation
- Significant or persistent disability
- Birth defect or congenital anomaly
- An important medical event that may jeopardise the patient or might require intervention to prevent one of the other outcomes listed above

What are the aims of pharmacovigilance? (1)

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- To improve patient care and safety in relation to the use of medicines and all medical and paramedical (services that support medical work such as nursing, first aid, radiography) interventions
  - For instance, accurate labelling
- Improve public health and safety in relation to the use of medicines
  - For instance, risk management plans, educational materials

What are the aims of pharmacovigilance? (2)

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- Contribute to the assessment of benefit, harm, effectiveness, and risk of medicines, encouraging their safe, rational, and more effective (including cost-effective) use
- Promote understanding, education, and clinical training in pharmacovigilance and its effective communication to the public
  - For instance, sharing information with health authorities and other stakeholders

How did pharmacovigilance come to exist?

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- The World Health Organisation (WHO) established its Programme for International Drug Monitoring in response to the thalidomide disaster, revealed in 1961.
- Subsequent to the thalidomide disaster, systems were developed for the collection of AE reports in a central database to contribute to the work of national regulatory authorities, improve the safety profile of medicines, and help avoid further disasters.