CHAPTER 15

INTRODUCTION TO PHARMACOVIGILANCE

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"The science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems," according to the World Health Organization. Pharmacovigilance is the process and science of monitoring the safety of medicines and taking action to minimise risks and maximise benefits. Drug: A drug is any substance or mixture of substances that is manufactured, sold, or represented for use in: A drug is any substance or mixture of substances manufactured, sold, or represented for use in diagnosing, treating, mitigating, or preventing a disease, disorder, or abnormal physical state, or its symptoms, in humans or animals, or restoring, correcting, or modifying organic functions in humans or animals, or disinfection in food manufacturing, preparation, or storage facilities. Standard terms and definitions in Pharmacovigilance

Adverse Event (or Adverse Experience) - Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

Adverse Drug Reaction (ADR)

All noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions in the pre-approval clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established. The phrase "responses to a medicinal product" implies that there is at least a reasonable possibility of a causal relationship between a medicinal product and an adverse event, i.e. the relationship cannot be ruled out. In the case of marketed medicinal products, WHO Technical Report 498 [1972] contains a widely accepted definition of an adverse drug reaction in the post-marketing setting:

"A noxious and unintended response to a drug that occurs at doses normally used in man for disease prevention, diagnosis, or therapy, or for modifying physiological function."

Unlisted / Unexpected Adverse Drug Reaction

An adverse reaction whose nature or severity differs from that described in the product information (e.g., the Investigator's Brochure for an unapproved investigational medicinal product and prescribing information / Summary of Product Characteristics

(SmPC) for marketed products). Adverse Drug Reactions Listed / Expected ADR whose nature, severity, specificity, and outcome are all consistent with the CCSI data.

Challenge

Administration of a suspect product by any route.

Dechallenge

A suspect product is removed from a patient's therapeutic regimen.

Negative Dechallenge

An adverse experience persists after the suspect product has been removed.

Positive Dechallenge

Withdrawal of the suspect product causes a partial or complete disappearance of an adverse experience.

Rechallenge

Following a positive dechallenge, reintroduce a suspect product suspected of causing an adverse experience.

Negative Rechallenge

When the product is reintroduced, it fails to produce signs or symptoms that are similar to those seen when the suspect product was first introduced.

Positive Rechallenge

When the suspect product is reintroduced, similar signs and symptoms reappear. Serious Adverse Event or Adverse Drug Reaction

A serious adverse event (experience) or reaction is any untoward medical occurrence that at any dose:

- leads to death,
- is life-threatening,
- requires inpatient hospitalisation or prolongation of existing hospitalisation,
- results in persistent or significant disability/incapacity, * is a congenital anomaly/birth defect.