IFPMA

GOOD PHARMACOVIGILANCE PRINCIPLES TO ENSURE BIOTHERAPEUTICS SAFETY

1 PHARMACOVIGILANCE & BIOTHERAPEUTIC MEDICINES DEFINITION

Pharmakon (Greek): medicinal substances
Vigilia (Latin): to keep watch

"The science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem" World Health Organization

Biotherapeutic medicines (or biotherapeutics) are medicines whose active ingredients are or are derived from proteins and other substances produced by living organisms.

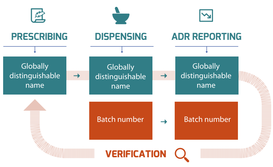
KEY PRINCIPLE 1

- All medicines can cause Adverse Drug Reactions (ADR).
- Biotherapeutics have unique characteristics, due to their biological nature and complex structure that require special ADR tracking.
- Certain rare events undetectable during clinical trials prior to the marketing authorization can lead to ADRs or even decreased efficacy.

2 TRACEABILITY

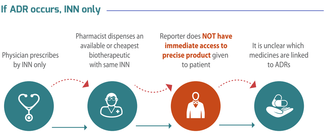
FULL TRACEABILITY THROUGHOUT THE PRESCRIBING, DISPENSING AND ADR REPORTING CHAIN

Accurate identification of biotherapeutics or manufactured batch is one pillar of a good pharmacovigilance (PV) system



IN A MULTISOURCE ENVIRONMENT, DISTINGUISHABLE NAMES ENSURE TRACEABILITY

If ADR occurs, INN only



If ADR occurs, Brand and INN

Prescribing by brand name and distinguishable International Nonproprietary Name (INN) allows physicians rapid access to the precise product dispensed when reporting ADRs

Source: Amgen

KEY PRINCIPLE 2

Each biotherapeutic should have a distinguishable name to clearly differentiate it from other biotherapeutics to ensure clear identification, safe prescription and dispensing to patients, and accurate reporting and analysis of ADR data (i.e., improve traceability). Healthcare professionals should use the distinguishable name when prescribing and dispensing to ensure that any ADRs reported are assigned to the correct biotherapeutic and batch number.

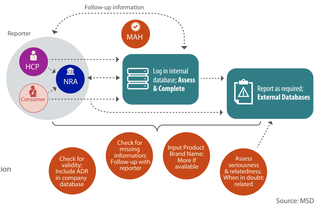
3 ADVERSE DRUG REACTION (ADR) COLLECTION AND SIGNAL DETECTION

REPORTING PATH OF AN ADR FROM REPORTER TO FINAL DATABASE

HCP = Healthcare Professional

NRA = National Regulatory Agency

MAH = Marketing Authorization Holder



Source: MSD

KEY PRINCIPLE 3

PV reporting systems should be:

- easy to use to allow reporting by any parties including patients and HCPs and
- well-structured to facilitate the meaningful analysis of ADR data on biotherapeutics.

Health authorities, NRA, medical researchers and companies to perform analyses at both the product class and individual product level for each biotherapeutic.

4 RISK MANAGEMENT PLAN (RMP) & RISK MINIMIZATION ELEMENTS

The European Medicines Agency (EMA) recently summarized the scope of a RMP as a defined set of PV activities which:

- Aim to characterize the safety profile of the medicine;
- Proactively plan activities to characterize risks and to identify new risks and increase knowledge about the safety profile of the medicine; and
- Plan and implement risk minimization and mitigation and to assess the effectiveness of these efforts.

Considerable effort is needed in not only engaging HCPs, patients and their carers in understanding their role in risk management, but also to explain why risk management is needed and how these safety risks should be considered in the context of their treatment.

KEY PRINCIPLE 4

IFPMA supports pro-active management of potential risks to further mitigate adverse consequences to patients.

For effective RMP, a system for identification of medicines, clear prescribing and recording of the information, and good communication to HCPs, patients and their carers are needed.

5 ROLES & RESPONSIBILITIES

KEY PRINCIPLE 5

HCPs should use distinguishable names when prescribing biotherapeutic medicines. This practice will help maintain the role of the physician in selecting a particular therapy for the patient and provide clarity for the pharmacist about what medicine was prescribed.

- Confusion may lead to automatic substitution and inaccurate attribution of ADRs.
- Ensuring that all biotechnology manufacturers adhere to global standards for manufacturing and PV will protect patient safety and maintain the quality of existing PV practices.

Each MAH of each biological product must have an established PV system to ensure comprehensive monitoring of the product.