PHARMACOVIGILANCE & BIOThERAPEUTIC MEDICINES DEFINITION

If ADR occurs, Brand and INN
If ADR occurs, INN only
Physician prescribes

Each MAH of each biological product must have an established PV system to ensure comprehensive monitoring of the product. The European Medicines Agency (EMA) recently summarized the scope of a RMP as a defined set of PV activities which:

- Are a fundamental part of the EU-led measures to ensure patients' safety and healthcare systems' sustainability;
- Are an integral part of a biotherapeutic medicine's risk management, but also to explain why risk management is in not only engaging HCPs, patients and their carers in not only engaging HCPs, patients and their carers in,

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.

RISK MANAGEMENT PLAN (RMP) & RISK MINIMIZATION ELEMENTS

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