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Note on Risk Management in Pharmacovigilance

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Opinion Article

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DESCRIPTION

The pharmaceutical science linked to the collection, identification, assessment, monitoring, and avoidance of adverse effects with pharmaceutical goods is known as pharmacovigilance (PV or PhV). The words "pharmacovigilance" come from the Greek words pharmakon (drug) and vigilare (vigilance). As a result, pharmacovigilance is heavily focused on Adverse Drug Reactions (ADR), which are defined as any noxious and unintended response to a drug, such as lack of efficacy (the condition that this definition only applies with the doses normally used for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological disorder function was excluded with the latest amendment of the applicable legislation).

Information obtained from patients and healthcare providers through pharmacovigilance agreements, as well as data obtained from other sources such as the medical literature, is crucial in supplying the data required for pharmacovigilance. In most countries, adverse event data acquired by the licence holder (typically a pharmaceutical corporation) must be submitted to the local drug regulatory body in order to market or test a pharmaceutical product. In the end, pharmacovigilance is concerned with detecting the risks connected with pharmaceutical products and reducing the chance of any harm to patients. To assess their compliance with global laws, regulations, and advice, companies must execute a complete drug safety and pharmacovigilance audit.

A risk management plan is a written document that outlines the risks Adverse Drug Reactions (ADR) and Potential Adverse Reactions (PAR) associated with the use of a drug, as well as how they are addressed (warnings on drug labels or packet inserts about possible side effects that should prompt the patient to inform/see his physician and/or pharmacist, as well as the drug's manufacturer and/or the Food and Drug Administration (FDA), European Medicines Agency. Once the drug HAS been commercialised, the overarching purpose of a risk management plan is to ensure a favourable risk-benefit profile. All new market authorization requests within the European Union must

include this document, which must be provided in a specific format. Risk management plans may also be presented in, although they are not necessary.

A risk management plan's hazards are divided into three categories: identifiable risks, potential risks, and undiscovered risks. The procedures that the Market Authorization Holder, usually a pharmaceutical corporation, will take to mitigate the hazards connected with the use of the drug are also stated in a risk management plan. The majority of these controls are aimed at the product's labelling and healthcare practitioners. Indeed, the hazards identified in a pre-authorization risk management strategy will very certainly be included in the product's post-marketing labelling. Because a drug may be used in ways not previously investigated in clinical trials once it has been approved, the risk management strategy includes a description of this potential "off-label use" as well as the hazards associated with it.

In the United States, the FDA may require a firm to submit a document called a Risk Evaluation and Mitigation Strategy (REMS) for a drug that has a specific risk that the FDA considers needs to be mitigated under certain circumstances. A Risk Evaluation and Mitigation Strategy, while not as comprehensive as a risk management plan, can require a sponsor to perform certain activities or follow a protocol, known as Elements to Assure Safe Use, to ensure that a positive risk-benefit profile for the drug is maintained for the circumstances under which the product is marketed. In most countries, pharmaceutical companies are required by law to conduct clinical trials, which involve testing new treatments on humans before they are made widely available. This happens after a medicine has been pre-screened for toxicity, which may or may not involve animal testing. A representative sample of patients for whom the drug is developed at most a few thousand is normally chosen by the manufacturers or their agents, along with a comparable control group. A placebo or another treatment may be given to the control group, which is often a so-called "gold standard" or the "best" drug available for the ailment.

Clinical studies, on the whole provide a lot of information regarding how effectively a drug works. They give data that should be reliable for bigger groups with similar characteristics to the trial group–age, gender, health status, ethnic origin, and so on even though target clinical populations are often significantly different from trial populations in terms of such characteristics. A clinical trial's variables are established and controlled, but it can never tell the actual effect of a drug's effects in all conditions. Nothing, in fact, could tell the actual cause, but a clinical study must tell enough; "enough" is established by legislation and current judgments about the acceptable balance of benefit and harm. When a medicine is approved for usage, it may be used in patients who were not included in the clinical studies (children, the elderly, pregnant women, patients with co-morbidities not found in the clinical trial population, etc.) Among order to maintain a good risk/benefit balance in all known populations utilising the drug, a new set of warnings, precautions, or contraindications (where the drug should not be used at all) for the product's labelling may be essential.