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Editorial

Editorial Note on Pharmacovigilance

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EDITORIAL NOTE

Pharmacovigilance (PV or PhV), also known as drug safety, is the pharmacological science relating to the collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products. The etymological roots for the word "pharmacovigilance" are: pharmakon (Greek for drug) and vigilare (Latin for to keep watch). As a such, pharmacovigilance heavily focuses on adverse drug reactions, or ADRs, which are defined as any response to a drug which is noxious and unintended, including 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 new amendment of the applicable legislation). Medication errors such as overdose, and misuse and abuse of a drug as well as a drug exposure during pregnancy and breastfeeding, are also of interest, even without an adverse event, because they may result in an adverse drug reaction.

Information received from patients and healthcare providers via pharmacovigilance agreements (PVAs), as well as other sources such as the medical literature, plays a critical role in providing the data necessary for pharmacovigilance to take place. In fact, in order to market or to test a pharmaceutical product in most countries, adverse event data received by the license holder (usually a pharmaceutical company) must be submitted to the local drug regulatory authority. (See Adverse event reporting below.)

Ultimately, pharmacovigilance is concerned with identifying the hazards associated with pharmaceutical products and with minimizing the risk of any harm that may come to patients. Companies must conduct a comprehensive drug safety and pharmacovigilance audit to assess their compliance with worldwide laws, regulations, and guidance.

One of the fundamental principles of adverse event reporting is the determination of what constitutes an Individual Case Safety Report (ICSR). During the triage phase of a potential adverse event report, it is important to determine if the "4 elements" of a valid ICSR are present:

- an identifiable patient
- an identifiable reporter
- a suspect drug,
- an adverse event.

If one or more of these four elements is missing, the case is not a valid ICSR. Although there are no exceptions to this rule there may be circumstances that may require a judgment call. For example, the term "identifiable" may not always be clear-cut. If a physician reports that he/she has a patient X taking drug Y who experienced Z (an AE), but refuses to provide any specifics about patient X, the report is still a valid case even though the patient is not specifically identified. This is because the reporter has first-hand information about the patient and is identifiable (i.e. a real person) to the physician. Identifiability is important so as not only to prevent duplicate reporting of the same case, but also to permit follow-up for additional information.

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