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Pharmacovigilance

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Pharmacovigilance has been defined by the World Health Organization (WHO) as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem.

In line with this general definition, objectives of pharmacovigilance are:

• Preventing harm from adverse reactions in humans arising from the use of authorised medicinal products within or outside the terms of marketing authorisation or from occupational exposure.

• Promoting the safe and effective use of medicinal products, in particular through providing timely information about the safety of medicinal products to patients, healthcare professionals and the public.

Pharmacovigilance is therefore an activity contributing to the protection of patients' and public health. Pharmacovigilance involves the collection of data on Adverse Reactions which must then be analysed and evaluated to create meaningful safety information. The process of signalling involves looking at the adverse reaction data for patterns that suggest new safety information. This article provides a brief introduction to the definition and purpose of signals and some of the key methodologies employed to generate them.

Pharmacovigilance Signals

The term is most commonly associated with drugs during the post-marketing phase, although it may also be used during pre-marketing clinical trials.

Signals are information that arises from one or multiple sources (including observations and experiments), which suggests a new potentially causal association, or a new aspect of a known association, between an intervention and an event or set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verificatory action.

This could be a problem which has never previously been suspected to be associated with the product; or a known event which is now occurring within a patient group for whom it has not been documented before or perhaps occurring with greater frequency than anticipated. The signal may be generated from

qualitative analysis of spontaneous reports or quantative analysis through data mining and statistical activities.

Signal Management

The process of signal management is a set of activities which aim to determine:

- whether there are new risks associated with a particular drug
- whether risks associated with a particular drug have changed

Sources for the detection of signals can come from:

- spontaneous reporting
- active monitoring systems
- interventional studies (clinical trials)
- non-interventional studies (pharmacoepidemiology studies)
- non-clinical studies (e.g. animal toxicology studies)
- systematic reviews (i.e. thorough review of the published literature)
- meta-analyses (i.e. mathematical pooling of all the clinical trial data)
- Monitoring adverse drug reaction databases
- Published articles
- Ongoing benefit-risk monitoring

The process for managing signals within pharmaceutical companies and regulatory authorities / pharmacovigilance centres must systematically address the following steps

- Signal detection
- Validation and Confirmation
- Analysis
- Prioritisation
- Assessment
- Recommending action

All steps taken and recommendations made must be accurately tracked and documented at every stage. There are resulting legal obligations which must be fulfilled in an accurate and timely manner but the ultimate goal is to confirm or refute whether there is some new issue with the safety of a medicine so that action might then be taken to reduce the risk.

Note: This article cannot constitute any form of professional advice, article is for understanding of subject only. Author is working profesional of pharma organization and active person in

pharmacovigilance and medical affairs field. Author is also working for national antibiotic resistance survillance program in India.

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