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Fact Sheet

Pharmacovigilance and CIOMS

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World Health Organization

WHO Definition:

Pharmacovigilance (PV) is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.

WHO established its Programme for International Drug Monitoring in response to the thalidomide disaster detected in 1961.

Pharmacovigilance plays an important part in the drug development process, through the clinical trial phases (I – IV) and following post-marketing approval.

CIOMS

CIOMS:

The Council for International Organisations of Medical Sciences (CIOMS), was founded by the World Health Organisation (WHO) and United Nations Education, Scientific and Cultural Organisation (UNESCO) in 1949. The aim of CIOMS is to advance public health through guidance on health research including ethics, medicinal product development and safety.

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CIOMS Objectives:

- To maintain collaborative relations with United Nation and Biomedical Scientific Community
- To bring together representatives from the Biomedical Scientific Community worldwide and facilitate and promote international activities

CIOMS covers a broad range of topics with the help of Working Groups. Working Groups are made up of senior scientists from Regulatory Authorities, the pharmaceutical industry and academia in order to develop consensus guidelines.

These Working Groups devised a method for adverse drug reaction reporting by manufacturers which included standardised definitions, procedures and format. The report contains the CIOMS reporting Form I, which for the first time set the minimum standard for reporting. The CIOMS Form was later the basis for establishing many national reporting forms.

CIOMS effect on PV:

International Reporting of Periodic Drug Safety Update Summaries (CIOMS Working Group II 1992)

This reports helps the international reporting of drug safety information eventually become harmonized throughout the world.

Development and Rational Use of Standardized MedDRA Queries (SMQs): Retrieving Adverse Drug Reactions with MedDRA (CIOMS Working Group on SMQs, 2004)

This targets the Regulatory Authorities, Scientific Institutions, Pharmaceutical Companies and other Organizations for appropriate use of SMQs in safety surveillance activities.

MedDRA® is a valuable health informatics tool used to code, report, analyze and communicate regulatory information for medicinal products for human use SMQs represent a standardized approach to establishing a baseline for the identification of Individual Case Safety Reports that may represent defined medical conditions that have the potential to impact benefit-risk assessments.

Management of Safety Information from Clinical Trials (CIOMS Working Group VI, 2005)

This is to help the management of clinical trial information, starting from the earliest clinical trials and extending to the post-marketing environment.

References:

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