Adverse Drug Reaction Reporting System in Pharmacovigilance

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Abstract: Pharmacovigilance is the process of the collection, detection, analysis, monitoring and prevention of various ADRs (adverse drug reactions) or AEs (adverse events) and any drug-related issues and problems. After the thalidomide tragedy (1961) health professionals, doctors, nurses, clinicians, dentists, pharmacists, WHO (World Health Organization) started International Drug Monitoring Program (1968) with the collaboration of WHO (World Health Organization) to protect public health and safe use of the medicinal products and improving public health to decrease ADRs (adverse drug reactions) occurs from the interventions or pharmaceutical products. Pharmacovigilance aim is to care and safety of patient in relation to the medicinal use. The purpose of pharmacovigilance is to secure early detection. In 2010, there are 134 countries were the members of the WHO (World Health Organization) for International Drug Monitoring program. WHO establish various pharmacovigilance centers for the reporting of ADRs. The hospitals and pharmaceutical industries can report ADRs (adverse drug reactions) to regional pharmacovigilance center or directly to the drug regulatory authority like USFDA (United States Food and Drug Administration) in America, EMA (European Medicine Agency) in Europe, MHLW (Ministry of Health and Labour Welfare) in Japan, CDSCO (Central Drugs Standard Control Organization) in India. The suspected unexpected serious adverse reactions can be reported within 7 calendar days and ADRs can be reported in 15-30 calendar days. The adverse drug reaction can also reported online.

Keywords: Pharmacovigilance, ADRs, WHO, USFDA

1. Introduction

Pharmacovigilance is the process of the collection, detection, monitoring, analysis of ADRs/AEs that occurs from the medicines. The WHO started pharmacovigilance program in each country for the prevention of ADRs, safe use of medicines, decrease number of ADRs, promote public health, protection of public health. WHO (World Health organization) started International Drug Monitoring Program (1968) with the collaboration of WHO collaborating centre UMC (Uppsala Monitoring centre) to protect public health and safe use of the medicinal products and improving public health to decrease ADRs (adverse drug reactions) occurs from the interventions or pharmaceutical products. Pharmacovigilance aim is to care and safety of patient in relation to the medicinal use. The purpose of pharmacovigilance is to secure early detection. In 2010, there are 134 countries were the members of the WHO (World Health Organization) for International Drug Monitoring program. WHO establish various pharmacovigilance centers for the reporting of ADRs. The hospitals and pharmaceutical industries can report ADRs (adverse drug reactions) to regional pharmacovigilance center or directly to the drug regulatory authority like USFDA (United States Food and Drug Administration) in America, EMA (European Medicine Agency) in Europe, MHLW (Ministry of Health and Labour Welfare) in Japan, CDSCO (Central Drugs Standard Control Organization) in India. The suspected unexpected serious adverse reactions can be reported within 7 calendar days and ADRs can be reported in 15-30 calendar days. The adverse drug reaction can also reported online.

2. Aims of Pharmacovigilance

1. To improve patient safety and care.
2. To improve public health.
4. To promote education and clinical training.
5. To promote rational and safe use of medicines.

Origin of Pharmacovigilance

In 1937, diethyleneglycol (DEG) mistakenly used to solubalize Sulphanilamide which causes death of 107 peoples. In 1956 thalidomide launched in market. Thalidomide causes foetal abnormalities (sealed limbs) 20,000 cases are reported maximum in Germany.

Regulatory Authorities

INDIA-CDSCO (Central Drug Standard Control Organization)
US- USFDA (United States Food and Drug Administration)
UK-MHRA (Medicinal healthcare Products Regulatory Authority)
JAPAN-MHLW (Ministry of Health and Labor Welfare)
EUROPE-EMA (European Medicine Agency)

History of Pharmacovigilance

In 1962 USA revised law requiring to prove safety and efficacy before issuing marketing authorization. In 1963 British committee on safety of drug monitoring. In 1964 UK starts yellow card system. In 1964-1965 national ADRs reporting system in UK Australia newzealand Canada westgermany, Sweden. In 1978 WHO centre moved from Geneva to uppala. In January 2005 national pharmacovigilance centre established with the advisory of CDSCO (Central drug standard control organization), King Edward Medical College Mumbai, AIIMS (All India institute of medical sciences). In 2010 establishment of Pharmacovigilance Program in India (Ghaziabad).

Spontaneous Reporting System

India – ‘SADR’ Form:
In India Reporting of ADR done by
1. Healthcare Professional
2. Consumer Reporting
focus on the impact and consequences of decisions and non-decisions.

References