Minimum Requirements for a functional Pharmacovigilance System

Introduction

Pharmacovigilance (PV) is defined as the "science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems"[1]. It is a very important medical discipline to prevent drug-related adverse effects in humans, ensure patient safety and promote the rational use of drugs.

PV is well established in most industrialized countries but its practice in low and middle income countries is variable with some countries having absolutely no systems at all whilst a few have systems comparable to the best in industrialized countries. In view of the importance of pharmacovigilance to all countries, the World Health Organisation, upon request from the Global Fund against AIDS, TB and Malaria (Global Fund) and key multilateral and technical agencies, has embarked upon an extensive and wide ranging consultative process to produce a Pharmacovigilance Strategy for use by all countries that are seeking to advance PV systems, through the Global Fund and similar health initiatives. The process includes the identification of (and the specifications for) the minimum requirements for PV.

Minimum Requirements for Pharmacovigilance

The current document describes the *minimum requirements* for any national PV system and sets out what needs to be done as a minimum to ensure that a national PV system exists and is able to provide some measure of assurance for and security of medicines safety. Such a system is expected to be sustainable with guaranteed funding and with a key focus on patient safety.

The minimum requirements were developed through a thorough and interactive process involving:

a) face to face meeting of pharmacovigilance practitioners, disease control managers, technical agencies and donors in Geneva on 14th -15th January 2010[2];
b) discussion of the proposed minimum requirements document by the World Health Organization's Advisory Committee on the Safety of Medicinal Products (ACSoMP) at its meeting on 26th – 28th April 2010;
c) further email and telephone consultations between WHO, Global Fund and ACSoMP members;
d) consolidation of all views and comments and production of the Draft Minimum Requirements Document for wider stakeholder consultation.

[1] WHO: Pharmacovigilance: ensuring the safe use of medicines. Geneva, WHO, October 2004.
[2] World Health Organization and Global Fund Meeting to Determine Minimum Requirements for Pharmacovigilance, Geneva, Switzerland, 14-15 January 2010 . Copy of the meeting report available from Dr Shanthi Pal, WHO (pals@who.int)

The Minimum Requirements Document is preceded by a section agreed upon by various experts as constituting the main functions of any national pharmacovigilance system.

Functions of a National Pharmacovigilance System

The functions of a national pharmacovigilance system include the following:

1. To promote PV in the country, notably, to collect and manage adverse drug reaction (ADR) reports, reports of medication errors and suspected counterfeit/substandard drugs;
    - to collaborate and harmonize with existing ADR collection activities within the country (e.g. national disease control programmes, Ministry of Health etc.) as well as international cohorts monitoring ADRs in defined patients or populations.
2. To identify signals of medicine safety i.e. unknown or poorly characterized adverse events in relation to a medicine or a combination of medicines and/or its use.
3. To undertake assessment of risk and options for risk management.
4. To identify if there are quality problems in medicines resulting in ADRs; and more generally, support the identification of medicine quality issues.
5. To provide effective communication on aspects related to medicine safety, including dispelling unfounded rumors of toxicity attributed to medicines and/or vaccines.
6. To apply resulting information from pharmacovigilance for the benefit of public health programmes, individual patients and national medicines policies and treatment guidelines.
7. To develop and maintain drug utilization information.
8. To identify issues associated with unregulated prescribing and dispensing of medicines.

Minimum Requirements for a Functional National Pharmacovigilance System

The following are the ***minimum*** requirements that the WHO and partners agree should be present in any national pharmacovigilance system.

1. A ***national pharmacovigilance centre*** with designated staff (at least one full time), stable basic funding, clear mandates, well defined structures and roles and collaborating with the WHO Programme for International Drug Monitoring.

2. The existence of a ***national spontaneous reporting system*** with a national individual case safety report (ICSR) form i.e. an ADR reporting form.

3. A ***national database*** or system for collating and managing ADR reports.

4. A national ADR or pharmacovigilance ***advisory committee*** able to provide technical assistance on causality assessment, risk assessment, risk management, case investigation and, where necessary, crisis management including crisis communication.

5. A clear ***communication strategy*** for routine communication and crises communication.

(see powerpoint presentation: 'Minimum requirements for pharmacovigilance in countries', http://www.who.int/medicines/areas/quality_safety/safety_efficacy/PV_Minimum_Requirements_presentation.ppt).