

# 35th Annual Meeting of Representatives of National Pharmacovigilance Centres participating in the WHO Programme for International Drug Monitoring Brazil 11 - 14 November 2012

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The Annual Meeting of Representatives of National Pharmacovigilance Centres participating in the WHO Programme for International Drug Monitoring was held in Brazil, 11-14 Nov 2012. At the meeting eight working groups discussed various pertinent issues in pharmacovigilance (PV). A summary of these discussions is provided.

## **WG1. Good Management Practices for national PV centres**

Pharmacovigilance is a science that needs good management practices to ensure that the aims and objectives of a country's National PV system are met in the light of limited resources.

The group discussed the principles of good management practices and how and why they should be applied to pharmacovigilance. The following recommendations were made.

### **National PV centres to:**

1. Harmonize activities on a global level (coordinated by WHO/UMC)
2. Collaborate with other national centres at the regional level
3. Support each other and share experiences.

### **WHO and its Collaborating Centres to:**

1. Provide guidance on grant applications
2. Provide a list of all available PV resources, with web links, updates and processes to access these resources

## **WG2. Wider access to data in WHO database: optimizing data utilization via Vigilize**

The objective was to discuss the optimal use of information and data extracted from the WHO Individual Case Safety Reports (ICSR) database. Four different user 'personas' were identified with distinct needs and use of the database information: the user group that needs easy-to-use interface with instant information on specific medicines issues; senior management who need evidence to provide / request funding and collaborations; the intermediate group that needs the information for decision making; and the general user group with a broad interest in the information.

The group concluded that the first version of Vigilize, the new search and statistics tool being developed by the Uppsala Monitoring Centre (UMC), needs to first address the requirement of the most immediate user from within these personas.

The following recommendations were made:

1. UMC to focus on the needs of the front- line user in the first phase of Vigilize development
2. Needs of other users should be considered in future releases
3. A user/ working group should be set up to establish user groups, confirm needs and further refine Vigilize.

## **WG3. Building capacity for safety monitoring of new vaccines**

Although, hundreds of millions of doses of vaccines are used every year in developing countries, assessments by WHO demonstrate that some countries still do not have the ability to monitor and ensure the safe use of vaccines. This working group discussed capacity building for monitoring adverse events following immunization (AEFI). The group agreed that effectiveness and safety of vaccines might vary across countries.

The following recommendations were made:

1. WHO to improve the availability of background data in low and middle income countries (LMIC) by pooling placebo data from clinical trials
2. National centres and countries to improve collaborations between medicines and vaccines PV systems; and share experiences on the introduction of new vaccines in their settings
3. Both national centres and WHO to:
  - Offer more training and build capacity in vaccine PV, especially in LMIC
  - Translate the 'online' WHO vaccine PV course into more languages
  - Develop and implement new methodologies in AEFI data collection, causality assessment and signal detection

#### **WG4. The ATC/DDD system: a tool linking drug consumption and adverse drug reaction data**

The Anatomical, Therapeutic and Chemical (ATC) classification system and the Defined Daily Dose (DDD) are recommended by WHO for measuring drug utilization in countries. The WHO Collaborating Centre for Drug Statistics Methodology in Oslo, Norway (WHO CC, Oslo), develops and maintains the ATC/DDD system.

The objective of this working group was to ascertain ways of raising awareness and promoting the use of the ATC/DDD system in PV. The following recommendations were made:

##### **WHO and national centres to:**

1. Organize capacity building and training activities for implementing ATC/DDD
2. Build links between medicine consumption and adverse drug reaction databases
3. Promote use of ATC/DDD in studying and sharing data on consumption and trends in use of specific drugs such as sibutramine; monitor the use of medicines in children in chronic diseases.

#### **WG5. The PV Toolkit and its further development**

The PV Toolkit is a collection of resources and information needed for the practice of PV. The main aim is to ensure that PV practitioners get access to information on the processes and activities involved in PV from a reliable source.

The group discussed the further development of the Toolkit and the following recommendations were made:

##### **WHO/WHO Collaborating Centre for Training and Advocacy in Pharmacovigilance, Accra, Ghana should:**

1. Facilitate the translation of the Toolkit into various WHO official languages
2. Include a URL link to all National PV centres in the Toolkit
3. Make the Toolkit more interactive and user friendly
4. Use the Toolkit as a platform for sharing experiences amongst national centres
5. Promote the Toolkit to all national centres through advocacy
6. Include Information on pharmacovigilance for special groups such as children and the elderly
7. Include standard PV training modules in the Toolkit for national centres

#### **WG6. Centralized or decentralized PV system- Pros and Cons**

This working group discussed the pros and cons of both centralized and decentralized PV systems, examples of such models in countries and challenges faced in implementing and maintaining such systems. A centralized model provides a single point of entry for information, with less financial needs; however there is decreased patient accessibility and less effective communication to health professionals. A decentralized system on the other hand is more accessible to patients and improves communication. However, decentralizing requires coordination, more funding and resources for capacity building. It was concluded that the choice of having a centralized or decentralized system will depend on the size of the country, complexity of the national health system and support from government authorities and other key stakeholders.

The group recommended that WHO should develop guidelines on setting up centralized and decentralized PV systems, highlighting the pros and cons of each system.

#### **WG7. The role of industry in national PV programmes**

The objectives of PV within the industry are essentially the same as those of regulatory agencies; that is, to protect patients from unnecessary harm by identifying previously unrecognised drug hazards, elucidating predisposing factors, and quantifying risk in relation to benefit. Although the perspectives of companies and the regulatory agencies may be different, they now work more and more closely together and share information.

The objective of the working group was to discuss the challenges and value for national pharmacovigilance programmes in collaborating with industry.

The group recommended that national centres should:

1. Provide guidance to Industry on obligations, procedures and protocols
2. Perform independent research in certain cases
3. Have the ability to monitor Marketing Authorization Holders (MAHs) risk minimization activities and obligate the MAH to carry out post-marketing studies.
4. Engage in open communication with industry.

#### **WG8. Harmonizing PV with health economics for outcome measurements- setting the research agenda**

PV is a form of intervention in the healthcare system with economic benefits, to the system, to individuals and to society. Health economics analysis (HEA) can demonstrate the cost-effectiveness of PV but only few studies have been done in this regard. The working group discussed savings to health expenditure through PV and how the cost-benefit of PV could be measured. The following recommendations were made.

##### **WHO to:**

1. Develop guidelines or protocols and standardized methods for studying the cost benefit of PV
2. Promote the concept of cost-benefit of PV and its measurement in PV training programmes

##### **National Centres to:**

1. Carry out studies to establish the cost-benefit of PV activities

