34th Annual Meeting of Representatives of National Pharmacovigilance Centres participating in the WHO Programme for International Drug Monitoring
Dubrovnik, Croatia
30th October- 2nd November 2011

The thirty-fourth annual meeting of representatives of national pharmacovigilance centres participating in the WHO Programme for International Drug Monitoring was held in Dubrovnik, Croatia. The meeting included eight working groups that discussed various issues in pharmacovigilance. The summaries of discussions and / or recommendations from each working group are presented here.

WG1. Optimizing communications between national PV centres (e.g., through VigiMed)

National PV centres communicate with each other to effectively share and discuss safety data on particular medicines, and on regulatory decisions. Many national centres use VigiMed (the information exchange forum managed by the Uppsala Monitoring Centre, the UMC), along with other forms of communication.

National centres share PV information also through formal agreements and contracts, through informal interaction, e.g. through links from training programs, and through their websites. VigiMed appears to be the most commonly used and preferred form of informal communication among the participants. Problems and challenges in regard to the new version of VigiMed include: the time taken to familiarize with the current (new) version, the need to login with a password, the lack of criteria, e.g. priority of posts, repetition of issues over time.

The group recommended an easier access to the official VigiMed website; information on unregistered and withdrawn drugs; establishing a search-friendly index of issues or topics with links to other documents; and using medical translator for documents. The UMC was requested to provide quick tips on the use of VigiMed and to include the function to "flag" topics of high priority, provide a linked access to PV bulletins and reports, continue monitoring experiences with VigiMed (data on use and users).

WG2. Assessing the preventability of medicines-related problems

The 'P method' was developed in the context of the Monitoring Medicines (MM) project (www.monitoringmedicines.org), to identify preventable adverse drug reactions (ADRs) in pharmacovigilance (PV) databases and to assist health care providers in taking necessary measures to minimize medication errors (ME). The method consists of 20 criteria, which are specific questions that help classify whether an ADR is a "preventable", "non preventable" or a "not assessable" case.

Within this working group, discussions were held on the use of the P method in assessing the preventability of ADRs. Discussions centred on the applicability and efficacy of the P method in preventing MEs, and recommendations for using the method more effectively, including the harmonization of various terms and the development of a guideline on the use of the method.

WG3. Involving traditional medicine (TM) practitioners in pharmacovigilance

In many countries across the world, particularly in Asia, Americas and Africa, a significant portion of the population has relied on traditional medicines to meet their health needs, especially in the context of primary health care. Traditional medicines, such as herbal medicines, are highly lucrative in the international marketplace, but are subject to adulteration and counterfeiting, posing serious threat to patient safety. There is a strong need to expand the scope of PV, to include traditional medicines, while strengthening effective national regulatory and quality assurance measures, so that health risks due to such medicines can be prevented.

This working group discussed various issues surrounding traditional medicines, identified the major challenges, proposed solutions, and recommended an approach to incorporate these medicines into PV practices, including the creation of a task force for traditional medicines in national pharmacovigilance centres, necessary education and training for TM practitioners, enhanced communication between physicians and TM practitioners, such as herbalists, and training TM practitioners to report ADRs and other information

WG4. How to demonstrate impact of pharmacovigilance activities

Pharmacovigilance systems collect reports, ensure quality of reports, detect and evaluate signals and implement measures based on findings from analyses (e.g. label changes). Measuring the impact of PV systems on public health is necessary for increasing awareness of drug safety and stakeholder's involvement, and making critical decisions on resource use and allocation.

This working group held discussions on how the impact of PV activities on health can be measured. Discussions centred on potential indicators, their relevance and ease of use. The group identified possible indicators (from the least relevant / easiest to measure, to the most relevant / difficult to measure) as: number of ADR reports of adverse drug reactions, quality of reports, number and percentage of signals that lead to action, assessment of knowledge, change in prescription volume, change in prescription patterns and actual patient outcome.

WG5. Improving safety information to patients and their carers (parents, partners, etc.)

Effective communication of drug safety information to patients and their care takers is crucial for making informed decisions about medicines and managing risks involved with use of medicines. This working group discussed the tools and options that are available, and ways to improve the use of these to improve communication between health care practitioners and patients. The group recommended that education related to drug safety should start at an early age, e.g. in schools; relevant information should be provided to the public through radio programme, short films etc; there needs to be face to face communication, between health care practitioners and patients on medicines safety; information sheets, pictograms and various visual tools that target different sub-populations of the public should be developed; and such materials should be adjusted to country, culture, life-style, accessibility to media and specific patient characteristics.

WG6. Experiences in using documentation grading statistics to improve data quality

Documentation grading is a system, developed at UMC over the last year, for measuring the amount of information provided on Individual Case Safety Reports (ICSRs) as they appear in VigiBase (the WHO ICSR database). Secondary, the more information a report contains, the more useful it usually is for e.g. signal analysis. Documentation grading is also used to identify any problems in the data of the reports received at UMC.

This working group held discussions on the effective use of documentation grading statistics in enhancing the quality of reports, enhancing feedback from UMC to NCs on the quality and improving drug safety. When a report is received, the data will be assessed for "completeness" A ‘completeness score’ from 0 to 1 is generated for each report using an algorithm of the following criteria: age and gender, time of onset, age at onset, primary source and drug start date. A 'completeness' score is a quantitative measure and is calculated as a mean of the scores for each drug-ADR combination. "Relevance," a new parameter that is still under development by the UMC, is a qualitative measure that aims to identify information that may strengthen causal associations between a drug and an ADR in ICSRs.

The following suggestions were made in regard to improving documentation grading statistics: include more criteria in reports, such as information on the reporter and sender, causality, medical history, action taken, concomitant drugs, medical confirmation, follow up and senders' comments; establish different criteria for vaccines and include information on batch number, dose number; implement a policy so that results are received twice a year; incorporate documentation grading statistics into VigiLyze.

The group recommended that, in order to enhance ICSR quality, it was important to decide what information is unnecessary, make appropriate improvements to reporting forms; identify technical problems in extraction of data; improve educational materials and define target groups for training; assess impact of activities by comparing grading results from different periods and by evaluating the impact of the quality of reports in producing signals

WG7. Future role of Periodic Safety Update Reports (PSURs): requirements for generic manufactures

This working group discussed the European (EU) and other legislations on PSURs and their consequences, PSUR obligations in low- and middle-income countries, who is responsible for PSURs, and problems and challenges concerning PSURs for generic medicines. Of the 23 countries represented in the group, 14 have established requirements for PSURs for generic products, with the majority harmonized with EU legislations; three countries are in the process of developing requirements; and no requirements exist in four countries. In two countries, older requirements for other types of periodic reports that are not PSURs exist. The quality of generic pharmaceutical manufacturing and the regulatory and inspection resources vary widely among countries, some countries need generic PSURs as a "safety net"; but reviewing PSURs is time consuming and the volume of work can be a real challenge when agencies do not have enough staff and other resources.

With regard to work load, the group considered the European model of collective (reciprocal) reviews and work-sharing; reviewing the entire PSUR for new products but only the executive summary and table of contents for generic products. But in general the group agreed that generics manufacturers should not be exempt from submitting PSURs

WG8. Integrating national pharmacovigilance and public health programmes

Efforts have been made, especially in resource-limited countries, to integrate national PV and public health programmes (PHPs). Closing the gap between PV and PHPs can yield benefits for both sides and the country. PV capacity may be improved and a monitoring system may be established through PHPs, if this is lacking in the country. PHPs can benefit by regularly receiving information on ADRs of drugs used in the programmes, which can lead to improvements in patient safety. National PV centres and PHPs, thus, need each other.

The members of the working group discussed how to integrate pharmacovigilance and public health programmes. They shared their experience and proposed a model for integration. It was stressed that each country has specific needs, so one model wouldn't fit all. It is important to establish a legal framework and clarify the roles and responsibilities of the various stakeholders, across PV centres and PHPs, for information sharing, training and capacity building, technical support and communication and feedback.