38th Annual Meeting of Representatives of National Pharmacovigilance Centres participating in the WHO Programme for International Drug Monitoring
New Delhi, India
4 - 6 November 2015

The thirty eighth annual meeting of representatives of National Pharmacovigilance Centres participating in the WHO Programme for International Drug Monitoring was held from 4 to 6 November 2015, at New Delhi, India. The meeting included eight working groups that discussed various issues in PV.

WG1. Practicalities of establishing and running a pregnancy register to follow outcomes of drug exposure

For WHO CCs and WHO:

- Lareb (the WHO Collaborating Centre for Pharmacovigilance in Education and Patient Reporting) to provide technical support, with WHO as lead, in the development of tools (which would include specific guidelines, communication and training materials) that would be used by other countries. The developed tools should take into account the differences between countries.
- WHO to support model National Pharmacovigilance Centres in the process of developing tools.

For National Pharmacovigilance Centres:

- To support the integration of 'pregnancy PV activities' into their public health programmes.
- Countries that would like to develop registries should start on a small scale and expand

WG2. Reporting and learning systems for medication errors, the role of national centres, WHO collaborating Centres and WHO

For National Pharmacovigilance Centres:

- To increase capacity and competence of the National PV Centres to identify and analyze Medication Errors (ME).
  - Identify obstacles to reporting ME and learning
  - Document procedures
  - Investigate if funds from public health programmes may be used to support MEs Reporting and Learning Systems
  - Invest in research on ME, to find out the burden of MEs in public health programmes.
- To optimize the Individual Case Safety Reporting Forms to capture MEs.
- To focus on reporting and publishing.
- To adapt definitions of adverse drug reaction and medication errors for the local legal situation (e.g. in the EU, medication errors are included in the definition of ADR).
- To improve individual record-keeping in medical facilities.
- To pursue regional collaboration between centres for competence-sharing and training on ME analysis.
- To make ADR/ME reporting one of the criteria in the private health care sector for accreditation.
- To follow the US model of getting hands-on training for pharmacists joining the PV centre, to get 6 months training in the FDA and six months in the Institute for Safe Medication Practices (ISMP).
- To conduct a study with volunteer countries to validate the 'P method' for detecting preventable ADRs.

For WHO and WHO CCs:

- To propose a Council for International Organizations of Medical Sciences (CIOMS) working group, to clarify discrepancies in definitions between patient safety and PV networks.

WG3. Data mining/signal detection at national centres: when, how, why

For WHO and WHO CCs:

- To help with capacity building in NPCs for data-mining and signal detection.
- To facilitate training through e-training and e-fora.
- To develop standardized tools for data-mining and signal generation (incorporating VigiLyzeTM).
- To help develop a template/generic SOP for signal detection to be adopted by interested countries. • To help build data-mining and signal detection into public health programmes at the point of inception, and to advise on/provide software to assist this process.
- To continue to develop and increase awareness of software, in particular VigiLyzeTM, for data-mining and signal detection and make these freely available to the countries (downloadable on the internet) to help compare national data with that of other countries.
- To support NPCs with a strategy for raising funds for this area of work

WG4. How can PV centres work with any relevant associations that can provide data and/or insights, including patient organizations and public health programmes

National PV Centres should consider the following in their collaborations with:

1. **Public health programmes (PHPs)**
    - Collaborations should be beneficial for both parties
    - Make best use of the available resources
        - PHP infrastructure to promote reporting
        - PV centre knowledge for designing reporting form for PHPs (which might need modification from the spontaneous reporting form) and signal detection
    - Schedule regular meetings where information is exchanged, so that all information can be used both by PHP and PV centres in their decision making
    - Define roles and responsibilities clearly
    - Keep scientific independence
    - Document agreements (memorandum of understanding)
    - Consider that different PHP programmes in one country may require a different approach.

2. **Patient organizations**
    - Collaboration should be beneficial for both parties
    - Listen to what patient organizations want
    - Clarify what can and cannot be done
    - Use patient organizations as ambassadors for National Pharmacovigilance Centres
    - Also involve other organizations, for example women's associations or consumer organizations

For contacting patient organizations:

- Raise the awareness about PV centres and what is being done in media directed to the public (this will encourage patient organizations to contact or invite National Pharmacovigilance Centres to collaborate)
- Choose either an umbrella organization or the biggest/most active organizations and approach these actively.

WHO and WHO CCs are recommended to:

- Create a platform where experiences (success stories but also initiatives that failed) can be shared. The stories should be practical, so that readers can try and adopt them in their own setting
- Modify existing platforms such as VigiMed and Uppsala Reports instead of creating new ones
- Include these subjects (PHPs, patient organizations) in training, using experienced organizations as trainers.

WG5. Where is PV heading/ the future of PV

For all:

- Develop and promote education and training for health-care professionals and pharmacovigilance staff
  - Support and streamline existing curriculum initiatives (including WHO-ISoP and Lareb curricula) to meet the needs of basic medical and PV education
- Explore innovative methods for raising public awareness of pharmacovigilance.
  - Facilitate the collection of best practice examples for sharing among member countries (including the dissemination of 'Take&Tell')
- Implement the WHO pharmacovigilance indicators in member countries using a standard protocol
  - Assess impact of pharmacovigilance activities
- Explore new sources and new methods for collection of patient safety data
- Explore the benefits of engaging professionals from other disciplines such as psychologists, health economists, social scientists, implementation scientists, communications experts, eco-pharmacologists, and others

For WHO CC UMC:

- Find a technical solution for reporting adverse drug reactions in situations without internet access
- Develop Vigimed as a user-friendly collaboration portal and encourage its use
- Familiarise all member countries with the use of database tools such as VigiLyzeTM, VigiGrade, etc.

The working group recognises and commends the Sierra Leone Pharmacovigilance Centre for its courage and persistence they displayed in the Ebola epidemic in their country; the working group proposes that such vivid examples of the robust effectiveness of PV should be collected and used at the highest levels for the purposes of advocacy and fund-raising.

WG6. The need for quantitative benefit-risk assessment in PV

For WHO and WHO CCs

- Provide training (capacity building)
- Provide technical guidance
- Include benefit-risk information in newsletters

For National Pharmacovigilance Centres

- Regulators such as FDA and EMA should share how they reach benefit-risk conclusions

WG7. Revisiting the WHO Minimum PV Requirements

For WHO:

- WHO should develop the new set of minimum requirements for PV and detailed guidelines to accompany the minimum PV requirements, and submit these to the 2016 National Centres meeting for approval.

Proposed Minimum Requirements for National Pharmacovigilance Centres

- A National Pharmacovigilance Centre collaborating with the WHO Programme for International Drug Monitoring and implementing at least a spontaneous reporting system
- National spontaneous reporting system with form(s) for capturing and reporting adverse events to medical products including medicines, vaccines, medical devices etc.
- A national database or system for collating, managing and sharing PV data
- A functional national advisory body for pharmacovigilance
- A communication plan for stakeholders in pharmacovigilance (to include over-the counter, internet purchases and non-medicinal drugs)
- Legislation on pharmacovigilance
- Formal link to National Regulatory Authority
- Established procedures for measuring impact of the national pharmacovigilance system
- Designated full-time staff to fulfil the minimum requirements of national PV centre
- Dedicated financial and technical resources to fulfil the minimum requirements of national PV centre

WG8. How to capture adverse events due to over-the counter (OTC), internet purchased (IP) and non-medical drugs (NMD)

- Set up a website of agents/groups that are accredited for online sale of medicines.
- Develop a tool that can help NPCs to detect adverse events online e.g. stories shared on social media
- Make Vigimed more user-friendly