

40th Annual Meeting of Representatives of National Pharmacovigilance Centres participating in the WHO Programme for International Drug Monitoring Kampala, Uganda 7 - 10 November 2017



The annual meeting of National Pharmacovigilance Centres (NPCs) participating in the WHO Programme for International Drug Monitoring (PIDM) provides a platform for representatives from around the world to meet and discuss pharmacovigilance (PV) issues. Representatives of Member States have the opportunity to interact with WHO and WHO Collaborating Centres (WHO CCs) face to face, exchange information on country needs, and propose how WHO and WHO CCs can support them. One of the most important outcomes from this meeting is the formation of recommendations which shape the direction of future PV activities. Recommendations are made by delegates through group work. The fortieth annual meeting of representatives of NPCs participating in the WHO PIDM was held from 7 to 10 November 2017, in Kampala, Uganda. The meeting included eight working groups that discussed various issues in PV. The summary of discussions and the recommendations are described in this article.

Generation of Recommendations

Generation of Recommendations

The annual meetings of National Pharmacovigilance Centres usually have eight working groups that run in parallel on two days. Delegates are provided with a list of objectives and expected outcomes prior to the working groups. During these sessions, a moderated discussion is conducted and attendees formulate and agree on a list of recommendations that are specifically targeted at WHO, WHO CCs and/or the National Pharmacovigilance Centres. A rapporteur is delegated from amongst the workshop participants and recommendations are then presented to the whole delegation in a plenary session. Following this, recommendations are finalized and confirmed.

WG1: Pharmacovigilance inspection: needs, capacity and cooperation

For National Pharmacovigilance Centres

- To identify if regional inspections amongst neighbouring countries can be conducted, particularly for resource limited countries.
- To include PV in regulation and enforce legislation. The law should require that Marketing Authorisation Holders (MAH)s have risk minimization plans as part of their dossiers and that MAH licenses should be issued after a risk minimization plan is in place.
- To apply strategy-based inspections and focus on new medicinal products rather than generics.
- To leverage available resources and give feedback to Contract Research Organization (CROs) and MAH when inspections are conducted.
- To take a collaborative approach to inspections. Roles and responsibilities of stakeholders (companies, health care professionals, drug regulator) should be defined.
- To use WHO indicators to measure PV processes.

For WHO and WHO Collaborating Centres

- To support capacity strengthening in Member States for PV inspections.
- To promote the sharing and exchange of information and resource materials for PV inspections, and leverage existing regulatory networks in Member States for capacity building, at regional, national and global levels.
- To create a platform where all Member States can share communication materials, check-lists and guidelines.
- To share all pharmacovigilance guidelines and tools with all Member States (e.g. tools used for medication error).
- To support countries with PV training and to promote a network to form collaborations, specifically between the NPCs and Qualified Person for Pharmacovigilance (QPPV) in MAHs, for example organising a workshop that brings them together.

WG2: Risk Management Plans (RMPs) for teratogenic drugs

For National Pharmacovigilance Centres

- To get involved in reviewing the RMPs submitted by the Marketing Authorization Holders (MAH) during registration or licensing of a product; this involves actively supervising RMP implementation and routinely ensuring information is updated throughout the lifetime of the product.
- To have a list of teratogenic medicines in PVCs

- To promote awareness of teratogenic medicines to healthcare providers through training and patient sensitization, targeting women of child bearing age.
- To obtain a PV tool-kit on use of medicines during pregnancy.
- To be able to detect signals for medicines used in pregnancy and have a plan on how to manage these signals.
- To collaborate with existing birth-defects monitoring authorities such as the neonatology departments, or the teratology information centres which deal with monitoring abnormalities in neonates.

Introduce relevant regulations to:

- prevent pharmacists from providing certain medicines (prescription and teratogenic medicines) without a prescription;
- ensure the 'caution in use' section of package inserts and patient information leaflets for teratogenic products is highlighted and prominent (pictograms can also be used to illustrate the message to patients);
- ensure pharmacists routinely check if a medicine is teratogenic and communicate potential teratogens to prescribers;
- make sure prescribers communicate to patients the risks involved in taking teratogenic medicines; and
- to provide information to patients and prescribers about medicines and risks involved when a teratogenic medicine is taken.

For WHO and WHO Collaborating Centres

- To support NPCs to enhance competencies.
- To develop and update a guidance document highlighting key issues on known teratogenic medicines.
- To develop a pregnancy tool-kit and provide a platform for countries to share experiences and a list of teratogenic medicines. The toolkit should include: causality assessments, setting up a pregnancy registry, guidance on sources of information for teratogenic medicines, methods for collecting information (e.g. reporting forms for medicines used during pregnancy).
- To organize a signal sprint for medicines used during pregnancy and investigate tools that can identify potential safety risks in medicines that are not yet known to be teratogenic.

WG3: Scope of Pharmacovigilance

For National Pharmacovigilance Centres

- Perform a stakeholder/network mapping exercise to provide an overview of definitions, rules, guidelines, and legal frameworks in different areas relevant to pharmacovigilance.
- Encourage and emphasize work and information sharing with other relevant departments and agencies.

For WHO and WHO Collaborating Centres

- To promote the application of PV to areas other than medicines and vaccines, by collating and summarizing experiences on collection, management, sharing reports and communicate risks to healthcare professionals and patients.
- To support the formation of a policy on polypharmacy practices. Polypharmacy practised by health workers, self-medication by patients and self-prescription of opioids are an increasing concern and compromises patient safety.
- To form guidelines on quality issues. Currently this is difficult to manage as there are different guidelines and overlapping responsibilities.
- To collect information on cost of ADR.
- To develop an overview of the “practical implications” of broadening the scope of pharmacovigilance for all pharmacovigilance stakeholders. Current tools, guidelines and methodologies should be modified to support the work of NPCs to broaden PV. This includes additional data sources and activities beyond the collection of ADR reports.
- To investigate/ explore the possibility of centres sending reports of safety issues/harmful effects of products other than drugs or vaccines to VigiBase (or a patient safety database) with the purpose of collecting and sharing knowledge and tools, including signal detection tools for these reports.

For all stakeholders

- All stakeholders should apply the PV ‘principles’ and tools to collect and manage reports on safety issues/harmful effects of products beyond medicines and vaccines for overall patient safety.
- The PV Community should take the opportunity to apply PV principles and tools with available resources.

WG4: Risk Minimization: Roles, Responsibilities and Implementation

For WHO and WHO Collaborating Centres

- To provide technical support and platforms to exchange information and promote collaborative initiatives.
- To help Member States strengthen assessment of gaps and avoid duplication of assessments.
- To support training centres and twinning programs.
- To form general RMP and specific guidelines for products that are used only in specific geographic areas.

WG5: How do we measure the impact of pharmacovigilance?

For WHO and WHO Collaborating Centres

- To establish a platform for sharing experience and resources for measuring the impact of PV.
- To create a tool-kit for training in planning an intervention and impact evaluation.
- To investigate if the WHO indicators capture impact.

WG6: Role of pharmacovigilance centres in promoting quality use of medicines

For National Pharmacovigilance Centres

- To collaborate with all stakeholders (regulators, universities, organizations, consumers).
- To promote quality use of medicines
- To evaluate links between pharmacovigilance centres with medicines and therapeutic committees (rational drug unit) for the rational use of medicines within countries, build collaborations and clearly define roles.
- To encourage governments to implement PV and use this data to promote quality use of medicines.
- To have a strategy to communicate and harmonize messages on rational use of medicines in public and private sectors.

For WHO and WHO Collaborating Centres

- To develop guidelines offering holistic management of ADRs and support their implementation

WG7: Communications of pharmacovigilance actions

For WHO and WHO Collaborating Centres

- Develop standardised training, including media training, on developing PV messages..
- Develop methods on how to measure success of communication.
- Support with relevant resources (technologies) and compile stories of successful communication campaigns from Member States.
- Create standard messages on topics such as online purchases and unlicensed medicines

For all

- Provide general public health awareness messages on topics such as online purchases and unlicensed medicines
- Include key pharmacovigilance messages in campaigns to encourage reporting.

WG8: Benefit-harm assessment approaches

For WHO and WHO Collaborating Centres

- To develop technical guidance tools.
- To support member states in benefit–harm assessments.
- To share assessment reports.
- To facilitate training and mentoring activities on benefit harm assessments.
- To discuss the development of benefit harm assessments tools with Council for International Organizations of Medical Sciences (CIOMs).

For National Pharmacovigilance Centres

- To promote the concepts of benefit–harm assessments in clinical meetings and undergraduate curricula.
- Mature centres to provide methods and training on benefit-harm assessment to less mature centres.
- To encourage the introduction of benefit–harm assessments as a component of an undergraduate pharmacovigilance curriculum.