

36th Annual Meeting of Representatives of National Pharmacovigilance Centres participating in the WHO Programme for International Drug Monitoring Rome, Italy 26-28 November 2013



The Annual meeting of Representatives of National Pharmacovigilance Centres participating in the WHO Programme for International Drug Monitoring was held in Rome, Italy, 26-28 September 2013. At the meeting eight working groups discussed various issues in pharmacovigilance (PV). A summary of these discussions is provided.

WG1. Ensure government commitment to Pharmacovigilance (PV)

All countries agreed that there needs to be more support from the government to PV. The importance of support to, and recognition for PV from the highest relevant authority was discussed. The barriers to gain support were identified and the strategies to overcome such barriers were considered. The following recommendations were made:

National PV centres to:

1. Initiate policies, fundraising dialogue and advocate
2. Develop good qualitative and quantitative metrics
3. Involve patients to educate and promote PV (via media, parliament or other means)
4. Build networks of interested parties
5. Develop media and public communication strategies

WHO Collaborating Centres to:

1. Adopt a proactive approach
2. Provide a better assistance by sharing, updating, adapting and translating technical documents

WHO to:

1. Provide comprehensive and relevant recommendations
2. Liaise with governments and collaborate with partner programmes (HIV, TB, Vaccines)
3. Promote PV as an essential part of public health programmes

It was suggested that studies which measure the performance of PV be published to demonstrate the successes in and economic impact of preventing adverse drug reactions (ADRs).

WG2. National Pharmacovigilance Centre (NPVC) experiences with different systems for ICSR data management

The number of reports submitted is rapidly increasing in all countries; these reports are often related to patient reporting and an increased number of PV activities. Objectives of this working group were to: discuss and review the different systems countries are using for managing data from individual case safety reports (ICSRs); to review NPVCs' experience with WHO ICSR data management system VigiFlow; and to discuss funding for the development of such a system. The following recommendations and conclusions were made:

1. Systems should be adapted to the country's PV specificities (report numbers, report types, available resources, internet and software capability, centralised vs decentralised PV systems)
2. Electronic reporting should be encouraged as it is needed to reduce work of NCs
3. The choice of the software is related to the number of reports
4. WHO should make a revision of the 1996 booklet 'Safety Monitoring of Medicinal Products: how to set up a pharmacovigilance centre'.

WG3. Pharmacovigilance of herbal medicines

The objectives were to review the 2008 Herbal Working Group Recommendations and to discuss key issues on the PV of herbal medicines (regulation, legislative loopholes, guidelines for safety monitoring, constraints with reporting herbal ADRs and training courses). The following recommendations were made:

National Pharmacovigilance Centres (NPVCs) to:

1. Collect data about herbal medicine practice
2. Organize training for herbal medicines practitioners and providers
3. Collect reports of ADRs with herbal medicines and send them to the Uppsala Monitoring Centre (UMC)

WHO Collaborating Centres to:

1. Communicate to NPVCs to engage in and develop PV of herbal medicines
2. Provide training and financial support for PV of herbal medicines
3. Assist WHO in developing and promoting this area of work

WHO to:

1. Promote and build capacity in NPVCs
2. Provide a platform for the exchange of experiences
3. Create an international committee of experts
4. Provide grants for local initiatives
5. Develop recommendations for data collection

It was suggested that PV of herbal medicines be increased by inviting people with most impact to the NPVC meetings, and to also increase collaboration with herbal practices. Additional considerations are to establish regional centres for herbal medicines which can liaise with NPVCs; encourage practitioners to report; and ensure all new herbal medications are entered in the WHO Herbs Dictionary.

WG4. Promote safety monitoring of medicines in children

Despite all the general agreement on the subject, monitoring of medicines in children remains inadequate worldwide. The working group reviewed the methodologies and ongoing efforts on safety monitoring of medicines in children. The following recommendations were made:

Member states and NPVCs to:

1. Enable and stimulate reporting of ADRs in children
2. Enable and promote reporting of off-label use and information sharing by protecting reporters' identity
3. Collect and use data from poison control centres and drug information centres
4. Provide more information to prescribers and patients on ADR monitoring in children

WHO Collaborating Centres and WHO to:

1. Provide PV training for paediatricians and family doctors
2. Gather and share information on off-label use with NPVCs
3. Collect and provide information on outcome with off-label drug use for policy decisions.

WG5. PV Centres to support the work of product quality surveillance systems

The objectives were to understand, define and evaluate the national strategies and role of NPVCs in detecting poor quality products. The following recommendations were made:

NPVCs to:

1. Proactively investigate and manage quality-related adverse events
2. Cooperate with Regulatory authorities to avoid duplication of efforts
3. Accept reports on quality defects even if no ADR has occurred
4. Maintain traceability of product batches in ADR reporting systems
5. Adopt relevant tools and technology for the detection of quality related ADRs on site
6. Refer to global ADR resources (VigiBase, VigiMed) when investigating local cases

Healthcare Professionals to:

1. Report the absence of therapeutic efficacy
2. Report absence of expected ADRs since this may also indicate lack of active pharmaceutical ingredient in the product
3. Report suspected quality defects and contribute to the prevention of ADRs
4. Learn how to respond to and collaborate in the investigation of reports of quality-related ADRs.

WHO to:

1. Collate and share the related experiences from countries in this area of work
2. Draft a guideline on how to deal with reports related to quality defects at NPVCs.

Recommendations for the Patient to report on reactions (especially on OTCs); and for the Pharmaceutical manufacturers to maintain tight control of their customer service, PV and quality control units were also mentioned.

WG6. How can we use mass media to promote PV

Most NPVCs are aware of the importance and influence of media and have a public relations office. It was discussed that the media should be used more to introduce PV to the public and highlight patient safety. The importance of linking media, advocacy and government was mentioned. To establish a positive relationship with media a direct, regular and good communication between the press and PV should be established. The following recommendations were made:

National Centres to:

1. Make PV activities and PV data more transparent
2. Provide in-house training on how to communicate with the media
3. Establish regular workshops, conferences and updates for journalists
4. Adopt a proactive approach (PV campaigns)

WHO Collaborating Centres (CCs) to:

1. Promote the use of platforms such as VigiMed for sharing experiences between NPVCs.
2. Establish a toolkit to promote adequate communication with media (e.g. materials for in-house training)

WHO to:

1. Establish an “International PV day” as part of the better communication principles
2. Develop guidance for better media communication for NPVC

WG7. How can sentinel sites and their networks support PV

The objectives of the working group were: to debate the use and value of sentinel sites for PV; identify situations when it could be useful; provide examples of sentinel sites around the world; and discuss whether disease-specific sentinel sites could be used for PV.

The following recommendations were made to WHO:

1. Create an inventory of sentinel sites in collaboration with each country, and document their experiences
2. Develop or review guidelines on the use of sentinel sites for PV
3. Identify priorities for setting up or contracting sentinel sites
4. Foster international collaboration for establishment and interaction between sentinel sites in different countries
5. Set up protocols based on previous examples to enable collaboration and data integration
6. Examine how these sentinel sites would be set up and sustained.

WG8. Integrating PV in curricula

The objective of this working group was to:

- Highlight the importance of PV in curricula
- Discuss the broad content of PV
- Discuss ways to integrate it in curricula
- Highlight the ongoing activities.

It was discussed that PV should be integrated into the curriculum to: educate healthcare providers who will in turn provide quality PV reports; PV knowledge can reduce cost to society by avoiding preventable side effects; it will enhance patient safety; and it will support recruitment of well-trained PV workers.

The level and content of PV education should be adapted to the situation, the country, and different professional groups. The 3 most important target groups identified were: medical, pharmacy and nursing students. PV education should be introduced early, and integrated into clinical diagnosis training or as part of existing subjects such as pharmacology. There should be practical sessions where students would be trained to fill in ADR forms. The NPVC staff, regulators and industry representatives should be invited as lecturers, and WHO PV toolkits or online courses could help as teaching aids.