39th Annual Meeting of Representatives of National Pharmacovigilance Centres participating in the WHO Programme for International Drug Monitoring
Muscat, Oman
14 - 17 November 2016

The thirty-ninth annual meeting of representatives of National Pharmacovigilance Centres participating in the WHO Programme for International Drug Monitoring was held from 14 to 17 November 2016, at Muscat, Oman. The meeting included eight working groups that discussed various issues in Pharmacovigilance.

WG1. Defining the pharmacovigilance research question for countries: how do we go about it

For WHO and WHO CCs:

- WHO and/or WHO CCs should develop a portal/repository (research database) for sharing information on concluded and ongoing research and the methodologies used in undertaking these researches.

For National Pharmacovigilance Centres:

- Research is key in PV, especially when trying to communicate benefit and risks. It is important that such communication is backed by sound research.
- National Centres should define their research focus based on their priorities and available resources (human, financial, etc.).
- National Centres should periodically assess their PV systems and undertake impact studies that may be relevant to assessing the system.
    - Baseline burden of ADR morbidity and mortality in countries where such data are not available: This will help Centres measure the impact of subsequent PV interventions. It will also strengthen the case for PV when advocating to policy makers on the need to support PV activities.
    - Drug utilization studies: To help make sense of signals generated through the spontaneous reporting system. In addition, countries should make efforts to obtain information on the background incidence of ADRs of interest as this will further strengthen any signal generated by the system.

WG2. Pharmacovigilance communication campaigns: how to measure impact

For WHO, WHO CCs and National Pharmacovigilance Centres:

- Develop communication impact evaluation methods and framework.
- Draw on existing health communication evaluation guidelines and involve professional public health evaluators from WHO expert pool.
- Share experiences of evaluating impact of communication, e.g. in WHO Pharmaceuticals Newsletter, a database/repository of communication materials/list of URLs, or a Facebook group.

For WHO and WHO CCs:

- Integration of evaluating communication interventions in the overall set of pharmacovigilance indicators for impact assessment.
- Follow-up at the national centres meeting in 2017 and at regional events.

WG3. What people want from pharmacovigilance: what is your big question

For WHO and WHO CCs:

Recommendations on improving reporting

- Evaluation of current incentive and mandatory reporting schemes and effectiveness of increasing reporting to assist national centred in instituting evidence-based schemes to increase reporting.
- Investigate effectiveness of a National Policy/Plan and mechanisms for this to be instituted as a health system performance measure.

Recommendations on information generated from ADR reports

- Investigate how to collect and make available 'safety knowledge', rather than just ADR data for use by pharmacovigilance centres.

Recommendations on sharing information effectively

- Stock-take of countries with information or work-sharing in place, identify barriers and enablers.
- Review use of Vigimed and how usage could be improved.

Recommendations on providing effective information to the public

- What is the evidence-base that better-informed patients result in better and safer use of medicines? How could this be used by countries to enhance their pharmacovigilance efforts?
- Collect examples of effective engagement with the public in different situations as resource for pharmacovigilance centres.

For National Pharmacovigilance Centres:

Recommendations on improving reporting

- Trialling new educational methods with health-care professionals.
- Work with other areas e.g. Health-care facility accreditation.
- Consider hotlines and apps to support public reporting.

Recommendations on information generated from ADR reports

- Increase use of Vigimed.

- Consider use of VigiBase® for generating database sufficient for statistical analysis where a countries is not sufficient demographics and combined international data may not be as relevant – such as combining counties with similar population.

Recommendations on sharing information effectively

- Consider whether sharing of information is possible – legal or other barriers.
- Identify information sharing opportunities with other NPCs.

Recommendations on providing effective information to the public

- Identify methods being used and what could be added.

WG4. Solutions to improve approaches, and enhance consumer reporting

For WHO and WHO CCs:

- To facilitate the rebranding of pharmacovigilance for the public.
- To offer technical guidance to national pharmacovigilance centres to simplify ADR reporting tools and help make these tools accessible and easy to complete.

For National Pharmacovigilance Centres:

- To decentralize pharmacovigilance awareness and education campaigns by using regional and district offices, if available, to help facilitate the creation of awareness of consumer reporting.
- To collaborate with other key organizations to facilitate education and creation of awareness of ADRs, how to recognize and report them when they occur.
- To utilize Information, Communication, and Education (ICE) materials as a means to widely disseminate ADR educational literature to the general public.
- To research consumer reporting medium preference and to target reporting tools and pharmacovigilance messaging based on the reporter preference.

WG5. What to teach pharmacovigilance beginners? Topics suggested to be included in PV courses for beginners:

1. ***What is and why do we need pharmacovigilance?***
   - Subject and scope of PV
   - History of PV: important ADRs, methods and organizational developments
   - ADRs and public health
   - Limited risk prediction from molecular analogy, pre-clinical studies and pre-marketing clinical trials
2. ***Fundamental Clinical Aspects of ADRs***
   - Types and mechanisms of ADRs; Non-genetic risk factors for ADRs and complex interactions
3. ***Important ADRs and 'Risk Driving' ADRs of Important Medicines***
4. ***Individual Case Safety Reports***
   - Concerns about ADRs: medical, psychological and regulatory background and reasons for reporting
   - Contents, structure and validity of reports and reporting procedures
   - Case assessment

5. Counterfeiting, demarcation against manufacturing-related quality defects

- Counterfeiting, demarcation against manufacturing-related quality defects
- Medication error: definition, impact, detection

6. Spontaneous ICSR Reporting Systems

- Definition, settings, potential and limitations of systems
- Data transmission and entry
- Data retrieval

7. Signal Detection and Management

- Definition of a signal
- Sources, potential, detection by non-statistical medical means

8. Benefit-Risk Assessment - 'Benefit-risk': definitions

9. Pharmacovigilance and Risk Management Systems: definition, stakeholders and operation

- Pharmacovigilance systems: definition, stakeholders and operation

10. Industry and Regulatory Authorities, Mandatory Procedures from Legislation

11. PV Organisation and Public Health

- Detection, documentation and reporting of ADRs at the local level
- Public Health and stake holders, e.g. other PV projects, international organizations and industry associations

12. Communication

- Context and guidance
- Communication with patients and health-care professionals: tools, channels and processes
- Communication with patients and health-care professionals: contents and presentation

13. Sources of Information

- Primary data: figures, facts, terms, cases
- Secondary information: assessments, judgements, decisions (hardcopy or electronic version)
- Electronic/Internet methods for searching and managing information
- Materials and training courses, where appropriate, specific for regions or settings
- 'Hands-on' practical training is essential.

WG6. Why and when do we undertake cohort event monitoring?

For WHO and WHO CCs

- Review and update WHO CEM guidelines based on the experience of implementing countries.
- Provide training on how to design a CEM study.
- Provide a better understanding of the resources required and available to countries using CEM.
- Provide guidance on how reports of AEs from a CEM study should be transferred to a national database and VigiBase®.

For National Pharmacovigilance Centres

- When considering a CEM study, consider the information needed to answer a specific question and whether CEM is the most appropriate method (CEM is expensive and time consuming – and is not always feasible).

- Take into account the resources required and resources actually available.
- When conducting CEM write a study protocol and have it assessed according to local rules and regulations.

WG7. Herbal-Drug interactions

For WHO and WHO CCs:

- To provide guidance on implementing an expert committee for herbal medicines and herbal drug interaction.
- To guide and support herbal drug interaction campaigns, workshops, trainings and e-learning.
- To support countries to improve reporting from health professionals and consumers.
- To encourage countries, particularly China (Traditional CM products) and India (AYUSH products) to report ADR and herbal drug interactions, substandard and falsified products to the WHO global database, VigiBase®.
- To harmonize terminologies of herbal medicines terms (manuals).
- To promote integration of herbal medicine interaction monitoring in public health programmes.
- To support and help the set up herbal-PV activities in PV centres.
- To update WHO herbal pharmacovigilance guidelines (last updated in 2004).
- To provide technical support to countries to detect and monitor herbal drug interaction signals, obtain sufficient information (number, information completeness, number of countries that report, Herbal specificities) and develop VigiBase® for optimal identification of signals of herbal-adverse events and herbal drug interactions.
- To share experience of safety of herbal products via a common platform (e.g. Vigimed or others).
- To share the experience of WHO-CC in Rabat in this area of work.

For National Pharmacovigilance Centres

- Consider safety monitoring of herbal drug interactions as a component of PV.
- Obtain regulatory status for herbal medicines, herbalists and traditional practitioners.
- Collaborate with institutions that conduct research and teach herbal and traditional medicines, for the integration of PV of herbal medicines and herbal drug interaction in the curriculum of health-care professionals and in public health programmes.
- Plan to establish herbal medicine monographs.
- Commit reports of suspected ADRs with herbal medicine use and herbal drug interaction to VigiBase®.

WG8. Statistical methods in pharmacovigilance

For WHO and WHO CCs:

- To evaluate whether a minimum database size and heterogeneity can be identified for given methods, for example, to identify when disproportionality analysis is relevant.

For National Pharmacovigilance Centres:

- Consider clinical review and causality assessment as the most important components of decision-making for signals.