Summary report on the

WHO-EM/EDB/125/E

Summary report on the Regional meeting on strengthening pharmacovigilance systems

Rabat, Morocco
7–10 September 2015

World Health Organization
Regional Office for the Eastern Mediterranean

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1. Introduction

Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. WHO established its Programme for International Drug Monitoring in response to the thalidomide tragedy detected in 1961. Together with the WHO collaborating centre for international drug monitoring in Uppsala, Sweden, WHO promotes pharmacovigilance at the country level. At the end of 2010, 134 countries were part of the WHO pharmacovigilance programme. The aims of pharmacovigilance are to enhance patient care and patient safety in relation to the use of medicines; and to support public health programmes by providing reliable, balanced information for the effective assessment of the risk–benefit profile of medicines, vaccines, biologicals and medical devices.

In September 2014, the First Arab and Eastern Mediterranean meeting on pharmacovigilance was organized by the Centre Anti-Poison et de Pharmacovigilance du Maroc, a WHO collaborating centre for pharmacovigilance, in Rabat, Morocco, with support of WHO. This meeting provided awareness on pharmacovigilance programmes and recommended that countries in the WHO Eastern Mediterranean Region should: have comprehensive national pharmacovigilance programmes in place; establish integrated pharmacovigilance systems; develop roadmaps or action plans for addressing gaps in national pharmacovigilance systems; be part of a network to share information; and attend annual meetings.

A regional meeting on strengthening pharmacovigilance systems was organized by WHO and hosted by the Centre Anti-Poison et de Pharmacovigilance du Maroc in Rabat, Morocco from 7 to 10 September 2015. The meeting involved 60 participants from 15

countries of the Region. Participants included representatives from ministries of health, national pharmacovigilance centres or national regulatory authorities. Resource persons from WHO and WHO collaborating centres (Ghana and Sweden) as well as expert in vaccine safety facilitated the meeting.

The overall objective of the meeting was to promote reporting of adverse drug reactions and adverse events following immunization, medical errors, and interaction of medicines, vaccines, biologicals and medical devices to the national vigilance system in the Region. Specific objectives were to:

- present the status of pharmacovigilance programmes in Region, review progress made, identify major challenges and priorities;
- provide guidance to focal points for establishing and/or strengthening national pharmacovigilance programmes and provide updates on participation in global reporting mechanisms;
- promote use of common standards and terminology for pharmacovigilance systems and build the capacity of participants in monitoring, surveillance and reporting of adverse drug reactions;
- develop a roadmap that provides next steps to be taken by countries with technical support from WHO;
- discuss the recommendations of the First Arab Meeting on Pharmacovigilance;
- set up a regional vigilance network;
- update on the recent concept and methodologies for surveillance, monitoring and assessment of adverse events following immunization;
- provide a briefing on vaccine safety monitoring during pregnancy and on vaccine safety signals;

- discuss needs and opportunities at national and regional levels for strengthening vaccine vigilance systems in the context of country health care levels; and
- explore opportunities to promote collaboration within the Region and at global level via the global vaccine safety initiative.

2. Summary of discussions

New and revised WHO pharmacovigilance indicators are available. 19 of the 22 countries of the Region responded to a survey on national pharmacovigilance systems. The findings show that ten countries are official members and six countries are associate members of the Uppsala monitoring centre. The majority of countries (85%) have national pharmacovigilance programmes in place, run by a pharmacovigilance centre that is managed by national regulatory authorities (90%). The quality of data reporting to Uppsala monitoring centre has improved over the years.

WHO pharmacovigilance indicator studies undertaken in both the African and Eastern Mediterranean Regions showed wide-ranging levels of development of national pharmacovigilance systems across low-, middle- and high-income countries in both Regions.

Several countries shared their specific areas of expertise in vigilance activities that were identified in the pharmacovigilance survey undertaken in the Region.

- Establishing a pharmacovigilance system in Palestine, especially the initial steps taken to set up pharmacovigilance activities in Gaza and West Bank
- Establishing a federal pharmacovigilance system in Sudan, especially the decentralized approach introduced at the state level

- Establishing regional pharmacovigilance centres in Egypt, especially the network of pharmacovigilance activities at facility level and regional reporting centres
- Experience on risk management plan in Jordan, especially the signal detection evaluated by a risk management approach
- Experience in management of medication errors in the Islamic Republic of Iran, especially the reporting of medical errors and action taken
- Experience in pharmacovigilance as a clinical practice in Tunisia, especially the active follow-up of adverse events integrated into service delivery
- Experience of country collaboration in the area of pharmacovigilance in Qatar, especially in a GCC setting

The importance of integrated vigilance systems was highlighted, along with use of a stepwise approach for developing integrated vigilance systems.

Participants reviewed the recommendations of the first meeting of Eastern Mediterranean and Arab countries on pharmacovigilance, organized in September 2014, most of which are on track.

During the discussions, countries emphasized the importance of sharing experience and lessons learnt as well as exchanging information on how establish a functioning national pharmacovigilance system and how to develop the existing systems and steps to implement the integrated vigilance system. It was also highlighted that the scope of vigilance extended to “patient safety”, therefore vigilance of vaccines, medical devices and herbals were highlighted as areas of interest by the participants. It was also confirmed that is important to develop one common repository where

all the adverse drug reaction reports are sent to and the need for more guidance in this area. Countries concluded that the pace of implementation of the next phase will vary between countries due to their local contexts. Further, countries emphasized the importance of technical assistance in the development and implementation integrated vigilance system.

3. Action points

Member States

- To the extent possible, adopt a stepwise, integrated approach to medicines and vaccines vigilance.
- Where vigilance systems exist, develop collaborative platforms to support integrated approaches.
- Where there is no functional vigilance system in place, develop a functional and sustainable vigilance system towards an integrated system in the long term.
- Develop an integrated vigilance model should be developed, using the Rabat pharmacovigilance centre as a reference if necessary.
- Establish a national AEFI committee.
- Include the 22 AEFI core variables in the adverse event reporting form.
- Ensure AEFI data reporting by using both WHO/UNICEF joint reporting form and Vigiflow or any other national database.
- Monitor the AEFI reporting ratio for 100 000 surviving infants as a performance indicator.
- Harmonize the management of action to be taken in case of serious AEFI cases.

WHO

- Define the broad elements of an integrated vigilance system, including what is meant by “integration”.
- Include the 22 AEFI core variables in the harmonized adverse event reporting form for medicines and vaccines.
- Include herbal medicines in the integrated vigilance system, as the use of herbal medicines in combination with conventional medical products is considerable in the Region.

For WHO and partners

- Finalize and disseminate the findings of the survey on pharmacovigilance systems.
- Invite meeting participants and resource persons to become members of the regional vigilance platform.

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