Organisation mondiale de la Santé
BUREAU RÉGIONAL DE LA Méditerranée orientale

World Health Organization
REGIONAL OFFICE FOR THE Eastern Mediterranean

منظمة الصحة العالمية
المكتب الإقليمي لشرق المتوسط

REGIONAL COMMITTEE FOR THE EASTERN MEDITERRANEAN
Sixty-fifth Session
Khartoum, Sudan, 15-18 October 2018

October 2018

SIDE EVENT

STRENGTHENING PHARMACOVIGILANCE IN THE EASTERN MEDITERRANEAN REGION

Objectives of the event

The objectives of this event are to:

- advocate for the importance of countries establishing effective pharmacovigilance systems;
- encourage reporting of adverse drug reaction reactions/adverse events following immunization, medical errors, lack of efficacy and interaction of medicines, vaccines, biologicals, and medical devices;
- identify major challenges and priorities for countries and highlight areas of progress;
- increase awareness of available guidance on establishing and/or strengthening national pharmacovigilance programmes and the importance of participating in global reporting mechanisms;
- advocate for the use of common standards and terminology for pharmacovigilance systems and the establishment of networks.

Background

Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse drug reactions, medical errors and other medical product-related problems. A national pharmacovigilance programme aims to ensure safety in relation to the use of medicines, vaccines and biologicals, and to support public health programmes by providing reliable, accurate information on assessments of risk–benefit profiles of medicines, vaccines, biologicals and medical devices. Pharmacovigilance is considered one of the core functions of national regulatory systems for medical products. National regulatory authorities are established to safeguard the quality, safety and efficacy of medical products circulating in local markets and are encouraged to establish national programmes.

WHO established its International Drug Monitoring Programme in response to the thalidomide tragedy in 1961. The programme works with WHO collaborating centres on pharmacovigilance in Morocco, Ghana, the Netherlands, and with the Uppsala Monitoring Centre, a WHO collaborating centre for international drug monitoring, to promote the reporting of adverse drug reactions, medical errors, lack of efficacy (substandard, falsified medicines), and interaction of medicines reported by national pharmacovigilance systems.

The main sources of data are individual case safety reports from health care providers, patients and pharmaceutical companies. To become a member of the WHO International Drug Monitoring Programme, countries should have a basic functioning reporting system in place with a set of criteria for effective reporting. In the Region, 10 countries are members of the Programme and six are associate members.

Although vaccines are among the safest of pharmaceuticals, the occasional severe adverse event or cluster of adverse events associated with their use may rapidly become a serious threat to public health. Effective surveillance systems for the collection of adverse event data are needed which take into consideration the specificities of vaccines, their distribution and delivery channels to public health care facilities. Moreover, pharmacovigilance of vaccines does not only require collaboration at national level but also at regional and international levels from data collection to risk assessment to problem-solving.

Regional challenges

There are wide disparities in pharmacovigilance systems in the Region with some countries completely lacking an effective pharmacovigilance programme. This is further compounded by a lack of adequate human and financial resources to support national pharmacovigilance systems. Greater political will is needed to establish and/or strengthen national programmes and to develop an integrated common approach to pharmacovigilance which could be achieved through an exchange of experience between countries to learn from the successful experiences of countries with an effective system in place. Political unrest and challenges faced by countries affected by emergencies have in some instances hampered countries' efforts to make progress in the area of pharmacovigilance. Misunderstanding of the importance of detecting and reporting of adverse events and ways to mitigate vaccine hesitancy and refusal and to ensure sustainability of confidence in vaccines remain issues yet to be adequately addressed in some countries.

Expected outcomes

- Increased awareness of progress of national pharmacovigilance programmes in the Region to rally much needed political commitment.
- Increased understanding of the monitoring of quality, safety and efficacy of medicines and vaccines, especially surveillance and reporting of adverse drug reactions.
- Identification of the initial steps required implementing or establishing effective drug and vaccine safety programmes in the Region.
- Identification of common and specific challenges facing Member States in strengthening their pharmacovigilance programmes and ways to address them.