

# The First Eastern Mediterranean Region/Arab Countries Meeting of Pharmacovigilance

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**Abstract** With many drugs coming to market and post-marketing surveillance limited to industry, there is a need for an integrated common approach to pharmacovigilance (PV) in the Eastern Mediterranean Region (EMR)/Arab region. The first meeting of the EMR/Arab countries for PV involved ten of the 22 states and revealed how these countries are learning from and working with each other in order to achieve this common approach. The aims of the meeting included highlighting challenges that could be overcome only by working as a team and setting the foundations for future PV centre work in the EMR/Arab region. The outcomes from the meeting showed that there is a need for a collaborative effort to provide a common structure, system and framework in order to establish an integrated PV system across the EMR/Arab world.

## Introduction

The first Eastern Mediterranean Region (EMR)/Arab Countries Meeting of Pharmacovigilance (PV) took place at the Centre Anti Poison et de Pharmacovigilance du Maroc (CAPM), World Health Organization Collaborating Centre (WHO CC) for Pharmacovigilance, in Rabat Morocco, from 22 to 26 September 2014. It was organised in collaboration with the WHO and the Uppsala

Monitoring Centre (UMC). The main goal of the meeting was to implement and reinforce national PV activities in EMR/Arab countries, and to define an action plan for their development. The meeting also enabled delegates from EMR/Arab countries to meet, share information and highlight the work that they are doing with regard to PV. The importance of the meeting was shown by the attendance of the Moroccan Minister of Health, Professor Houcine El Ouardi, who provided the opening remarks and declared the meeting open.

A total of 183 delegates from 28 countries, including ten EMR/Arab countries, attended this 5-day meeting. Attendees included representatives from national PV centres, the WHO and WHO CCs, UMC, marketing authorisation holders (MAHs), the Council for International Organizations of Medical Sciences (CIOMS), pharmaceutical industry, the Arab League and various universities.

## EMR/Arab WHO and EMRO Members

Currently, there are 22 WHO EMR/Arab member countries. Of these, ten are official members of the Eastern Mediterranean Regional Office (EMRO) of the WHO and four are associate EMRO members (Fig. 1).

## Meeting of PV

### Meeting Structure

The 5-day meeting included plenary sessions that covered eight thematic areas and four working groups that focused on creating a common understanding for future efforts (Table 1).

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**Electronic supplementary material** The online version of this article (doi:10.1007/s40801-015-0015-8) contains supplementary material, which is available to authorized users.

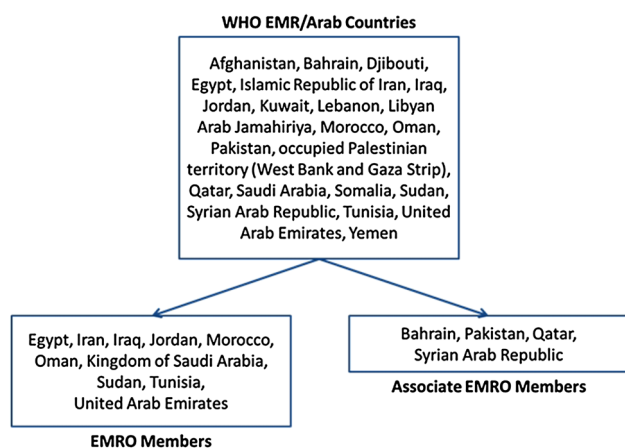
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## Meeting Premise

One of the main organisers of this meeting was Professor Rachida Soulaymani, Head of the CAPM and PV centre. Speaking about the meeting, Professor Soulaymani said:

“We organised this meeting because as a WHO CC, we have a duty to promote PV internationally, particularly in French- and Arabic-speaking countries. To this end, for more than 10 years we had a large input in the French-speaking countries; however we wanted to do the same for the Arabic-speaking countries. Pharmacovigilance in the Arabic countries is underdeveloped compared to the general development of the countries in question, and to their health and pharmaceutical expenditures. In 2014, among the 22 countries belonging to the EMR and Arab League, 40 % were official members and 20 % were associate members of the WHO [Fig. 1]. Half of the EMR/Arab countries are not yet members. Furthermore, the representation of EMR/Arab countries in VigiBase amounts to only 0.6 % of all individual case reports.



EMRO: Eastern Mediterranean Regional Office; WHO: World Health Organization

**Fig. 1** Eastern Mediterranean Region (EMR)/Arab countries organisation with the WHO

**Table 1** Meeting structure

Eight thematic areas	Four working groups
1. Role of WHO CCs and the situation of PV systems in EMR/Arab countries	1. Integrated PV system
2. Risk minimisation measures in PV	2. Harmonising terminologies and definitions
3. Databases management and signal detection	3. Risk minimisation plan
4. Integration of vigilances in a unique system (global vigilances system)	4. Strengthening national vaccine PV system
5. Strengthening of vaccine vigilance system	
6. Medication errors management	
7. PV in industry	
8. PV in clinical practice	

EMR Eastern Mediterranean Region, PV pharmacovigilance, WHO CC WHO Collaborating Centre

All countries in the region share a common language and culture, but there are no common techniques and tools, and until now, no common terminology.”

The specific aims of the meeting were to:

- Describe the situation with regard to PV systems in EMR/Arab countries.
- Discuss country-level needs and opportunities for strengthening PV systems.
- Build a consensus on Arabic PV terminology.
- Define methods for improving collaboration with the support of WHO and WHO CCs.
- Reinforce PV in specific fields such as vaccines and non-communicable diseases.
- Promote regular exchange of information on PV issues through meetings, workshops, bulletins and training.

## PV Experiences of some EMR/Arab Nations

A considerable amount of experience and knowledge exists among the EMR/Arab countries, and sharing this will allow them to move forward together. Morocco and Tunisia have built a PV system with centres that are independent from but work in coordination with their drug regulatory authorities through a national PV commission. Egypt, the Kingdom of Saudi Arabia and Jordan already have good PV regulations; those of the United Arab Emirates, Oman, Kuwait, Iraq, Sudan and Syria are improving, with all being part of their respective drug regulatory authorities. Some of these countries shared their data at the meeting.

### Morocco

The CAPM/WHO CC in Rabat is a leader for PV in the EMR/Arab region. Initiatives to develop PV centres within medical schools in Morocco first began in 1985, pioneered by Professor Mohammed Hassar, Director of the Institut

National D'Hygiene. In 1989, an opportunity arose to develop a national PV centre jointly with the CAPM, and Professor Rachida Soulaymani, a clinical pharmacologist, was made head of the new CAPM and PV centre. The CAPM became the first African and Arabic centre to join the WHO International Drug Monitoring Programme in 1992, and a WHO CC for PV in 2011. Professor Soulaymani has overseen the creation of an entire PV programme in Morocco, which encompasses training, assessments, translations, the development of PV concepts and methods, and the organisation of PV meetings and events. This has significantly contributed to the high number of reports captured since the CAPM was established (see the electronic supplementary material, online resource 1, supplement Table 1).

### Egypt

The Egyptian PV Centre (EPVC) is headed by Dr. Amr Saad, also Head of The Higher Technical Committee for Medicines. Dr. Saad has overseen many changes at the EPVC, with Egypt basing its PV system on that of the European Medicines Agency (EMA). The EPVC guidelines for healthcare professionals and marketing access holders were released in 2009. The EPVC has achieved a considerable amount with regard to capturing important safety signals and promoting improved communication for all stakeholders (see supplement Tables 2 and 3). It should also be noted that personnel training is ongoing in order to ensure the highest level of competency is achieved.

### Jordan

The Jordanian Food and Drug Agency (JFDA) was established in 2001, gained WHO membership in 2002, and had their PV guidelines approved in 2006. Under the stewardship of Dr. Nidaa Bawaresh, Head of the JFDA, there has been a concerted effort to create and maintain a reporting structure at both regional and national levels. The increase in reporting, especially of adverse drug reaction (ADR) reports, over the last 2–5 years shows that the JFDA has performed some exceptional work (see supplement Tables 4 and 5, supplement Fig. 1).

### Tunisia

The Tunisian National Centre for PV was created in 1984 and became a WHO CC for international drug monitoring in 1993. Currently led by Dr. Riadh Daghfous, Head of the Tunisian National Centre for PV, the number of reports has been increasing annually (see supplement Table 6).

### Oman

The Omani Directorate General of Pharmaceutical Affairs and Drug Control (DGPADC) was launched in 1994, and became a member of the UMC in 1995. Headed by Ahmed Alharbi, Ministry of Health, Oman has significantly increased the number of safety reports (see supplement Fig. 2) by increasing awareness, conducting workshops and providing feedback on reported ADRs. This trend is expected to continue in the future (see supplement Fig. 3).

### Kingdom of Saudi Arabia

The National Pharmacovigilance and Drug Safety Centre (NPC), created in association with the Saudi Food and Drug Agency (SFDA), was declared open in 2009 and became a member of the UMC in the same year. Led by Dr. Ghazi S. Saeed, Executive Director of Vigilance and Crisis Management Department, Saudi Arabia has organised 68 PV coordinators and 65 workshops across the country. The results have been impressive, with more than 75,000 ADRs being reported (see supplement Table 7; 75 % serious vs. 25 % non-serious), the majority of which [73,067 (95 %)] came from industry. The actions taken ranged from labelling updates to submission of risk management plans (RMPs). An advisory group consisting of the PV advisory committee, a multidisciplinary team of physicians and pharmacists has provided independent evaluation of safety concerns, and taken various actions in response to safety signals (see supplement Table 8).

## Working Groups

Four working groups were created to consider four topics that were central to the first EMR/Arab meeting. We include here recommendations from three of the working groups; working group 4 on Strengthening the National Vaccine PV System had no recommendations to share.

### Working Group 1: Integrated PV System

Integrated and vertical PV systems were discussed by working group 1. As shown in supplement Fig. 4 (see online resource 1), the consensus was that the integrated system was superior. Therefore, the goal is to make an all-in-one integrated system that can be adapted across the EMR/Arab countries, and which would unify the member states' efforts to offer the best possible PV system to their patients.

To understand the requirements for an integrated PV system, it is necessary to understand that there are different

types of vigilances, both sanitary and other types, as shown in supplement Fig. 5 (see online resource 1).

An integrated PV system for the EMR/Arab nations is vital to allow all countries to work together according to a common structure and benefit from the pooling of ideas and results. Professor Soulaymani said, “At WHO level, vigilances are segmented for vaccines, drugs, devices and cosmetics and so forth, there is a lack of coordination of vigilances which is reflected nationally. Therefore, 2 years ago the WHO in Geneva created the Department of Safety and Vigilances, headed by Clive Ondari, with view to finding a way to integrate these vigilances into a single homogenous system.”

Integration would encompass common terminologies, taxonomies, procedures, reporting forms, information systems, data management tools, training and capacity building. For an integrated system to work, a unique contact point is required. Software companies already have tools and programmes available that can be adapted to make this global EMR/Arab PV system a reality. Professor Soulaymani said, “The UMC is developing tools for this, and have done this for drugs and vaccines, also medical devices.” There is also a need to harmonise case processing procedures, to allow sharing of experiences between different countries, to develop guidelines and regulations with local authorities, and set up expert sub-committees.

Morocco provides a good example of what can be achieved in terms of building a model that is fit-for-purpose nationally, and which can also be used internationally for learning and adaption. Professor Soulaymani continued, “It is a streamlined, one-vigilance system; after receiving the cases they are cascaded to the different vigilances, all situated under one roof, where we all work together, using the common tools, methods and databases, but with individual areas of interest. The WHO wants to take this experience and show that it is possible.” The aim is to also improve communications between different departments across the Arab world to streamline systems, reduce duplication and improve outputs.

The working group offered several recommendations. If there was no vigilance system established in a given country, it advised that an integrated one should be built. If a vigilance system did exist, then it advised to harmonise whatever could not be integrated, to promote coordination between all vigilances, and to centralise reports using a national centre. It also advised establishing local regulations and harmonising guidelines across the EMR/Arab region.

#### Working Group 2: Harmonising Terminology and Definitions

There is a need for common Arabic terminologies and definitions, and the working group agreed on 20 common Arabic terms that could be used (Fig. 2).

#### Working Group 3: Risk Minimisation Plan

The aim is to create an RMP for targeted well-known risks and unknown risks of drugs in a limited resources setting and to develop an appropriate RMP. Adequate systems and structures need to be put in place to adapt the RMP to the needs of each country.

The basis of any structure is an education system in which materials are produced in the language of the country. This will enable information to flow across the Arab nations through collaborative teaching and training measures. The issue of education extends to all stakeholders in the RMP, including the public and patients. It also includes the delivery of messages, for example, via traditional and social media, to healthcare professionals via adverse events and follow-up training, the Ministry of Education, academia, industry, non-governmental organisations and the media. To prevent medication errors, the right protocols can be put in place for the right ADRs. This includes following systematic laboratory tests before prescription, providing checklists to physicians to help prescribe drugs correctly, producing leaflets with the five Rs (right drug to the right patient at the right dose via the right route at the right time), creating easily understandable warnings in Arabic, using images on those drugs, and engaging with the community through mosques and churches.

By creating an integrated system and structure for the EMR/Arab region for vigilance, it will be possible to achieve something similar for the RMP.

#### Common Arab Guidelines for PV

Under the umbrella of the Arab League, ‘The Higher Technical Committee for Medicines’ was established, with representatives from all Arab countries, to create common Arab guidelines in PV, and in bioequivalence. These Arab PV guidelines (a 523-page document comprising 16 modules) were created through administrative channels, The Arab League and health ministers, without input from any PV centres. A commission is therefore needed to scrutinise these guidelines and discuss what would be involved in implementing them.

#### Vision of the Future

The ideal scenario is to involve the rest of the Arab League member states and increase the number of EMRO members from ten. The scenario also includes creating a common PV structural framework based on the Arab Guidelines so that all Arab/EMR countries can work from this and benefit. An EMR/Arab PV model based on the EMA

**Fig. 2** Harmonised Arab pharmacovigilance terms

Terms	المصطلح المصادق عليه بالعربية
Abuse	إساءة إستعمال الدواء
Adverse drug reaction	الأثر الضار للدواء
Alert	تنبيه
Benefit/Risk	الموازنة بين فوائد الدواء و مخاطره
Birth defect monitoring	رصد عيوب الأجنة
Causality assessment	تقييم العلاقة السببية
Listed adverse drug reaction	الأثر الضار المدرج للدواء
Medication errors	أخطاء إستعمال الدواء
Misuse	إستعمال خاطئ للدواء
Pharmacovigilance centre	مركز اليقظة الدوائية
Pharmacovigilance of herbal	يقظة التداوي بالأعشاب
Pharmacovigilance system	نظام اليقظة الدوائية
Rational drug use	الاستعمال الرشيد للدواء
Reporting form/Yellow card	نموذج الإبلاغ
Serious adverse reaction	الأثر الضار الخطير للدواء
Side effect	آثار جانبية
Signal	إشارة
Spontaneous report	تقرير تلقائي
Under reporting	نقص في الإبلاغ
Vaccine safety	مامونية اللقاح

guidelines can be seen as attractive. This will enable cooperation between the EMR/Arab nations with respect to ADRs and data pooling, and help to improve the standards of national PV centres across the member states.

The “Rabat Declaration for Pharmacovigilance in the Eastern Mediterranean Region and Arab Countries” can be found under the following link: [http://www.capm.ma/Doc/Workshop/RAPV\\_2014\\_Communique\\_Final\\_Ag.pdf](http://www.capm.ma/Doc/Workshop/RAPV_2014_Communique_Final_Ag.pdf). In the declaration, various proposals have been made, including an annual or biennial PV meeting for the EMR/Arab region in order to continue building upon the success of the first meeting. Ideas for holding the meeting in different member states reflect the organisers’ view of this initiative—as all-encompassing and all-inclusive for the

good of the Arab people. The hope is to increase engagement and input from other Arab countries and create a growing pool of ideas, information and data. A unified EMR/Arab PV framework containing the experiences of its members can be greater than the sum of its parts and move forward as a single entity.

**Disclosure statement** Springer contracted the author to attend the meeting and write the report.

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