DIA Learning

Pharmacovigilance Workshop

(Middle East & Africa Region)

14-15 October 2019
Royal Maxim Palace Kempinski, New Cairo, Egypt

Keeping up-to-date with the pharmacovigilance landscape in MEA region.

OVERVIEW

In a rapid changing environment, pharmacovigilance plays a key role in maintaining the focus on patient safety. Middle-East & Africa Regions are gaining more space in the pharmaceutical landscape with the innovation and development of new medicines.

This workshop's aim is to bring together key stakeholders from different regions to share good practices and requirements into getting the actual guidelines into practice.

The conference format is designed to stimulate dialogue and generate solutions through a series of interactive sessions and workshops conducted in an informal setting allowing for in-depth discussion in smaller groups.

LEARNING OBJECTIVES

- Seek direct answers to the business challenges you are facing every day
- Understand how other organisations are managing through the shift of sharing all information to sharing relevant information
- Ensure that your pharmacovigilance work matches up with inspector expectations, and delivers the efficient outcomes for patients.

KEY TOPICS

- Overview of the Pharmacovigilance landscape in MENA Region
- PV developments and Impact in MENA Region
- Signalling and emerging safety issues
- Inspections and Audits
- Risk Management Plan
- PSMF: general developments

WHO WILL ATTEND

Established professionals who are seeking to increase their network of like-minded colleagues; share their thoughts and practices with others; learn the most current regulatory views and gain practical knowledge in key areas in pharmacovigilance, including:

- Signal management
- Risk Management Planning
- PSMF maintenance
- Clinical Trials

Professionals involved in:

- Drug Safety/Pharmacovigilance
- Risk Management, including Risk Evaluation and Mitigation Strategies (REMS)
- Benefit-risk assessment and communication
- Medical Product Safety Assessment
- Regulatory Affairs
- Clinical Trials
- Pharmaceuticals, biologics, combination products, devices
- Clinical Research and Clinical Research Organizations
- Health Outcomes
- Academic Research Centers
- Regulatory Agencies

PROGRAMME ADVISORS

Reem El Essa
Senior Pharmacy Specialist and Inspector Pharmacist at Drug Inspection Administration, Pharmacovigilance Focal Point in Kuwait Drug and Food Control, Kuwait

Mohammed I. Fouda
Head of Signal Detection Department, Saudi Food and Drug Authority (SFDA), Saudi Arabia

Sultana Essa Bin Haider
Pharmacovigilance Officer, Drug department, Ministry of Health & Prevention, UAE

Nadjat Loumi
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Manal Mohammed Younus
Head of Iraqi Pharmacovigilance Centre, Directorate of Technical Affairs, Ministry of Health, Iraq

Shanthi Pal
Group Lead, Medicines Safety, Safety & Vigilance, World Health Organization, WHO, Switzerland

Hadir Rostom
Head of the Egyptian Pharmaceutical Vigilance Center (EPVC)- Central Administration of. Pharmaceutical Affairs- Ministry of Health, Egypt

PROGRAMME COMMITTEE

Shahinaz Badr
Regional Pharmacovigilance Manager, NewBridge Pharmaceuticals, Africa, Middle East, and Turkey

Sean Burke
EEMEA Regional Lead, Pharmacovigilance, MSD, UK

Dana Isleem
Pharmacovigilance Manager-Middle East & Africa at Bristol-Myers Squibb, UAE

Raghda Mohamed
Drug Safety Lead - South Europe, Middle East and Africa Cluster, Shire Export Service GMBH, UAE

DAY ONE | MONDAY, 14 OCTOBER 2019

08:30 OPENING CEREMONY (EXCELSIOR 1)

Thomas Bols, Senior Vice President and Managing Director, DIA Europe, Middle East and Africa
Inas Chehimi, MERN Chair and Head DRA Middle East & North Africa, Novartis Pharma Services AG, United Arab Emirates
Peter Pitts, MERC 2019 Chair & President, Center for Medicine in the Public Interest, US
Rasha Ziada, Head of Central Administration of Pharmaceutical Affairs (CAPA), Ministry of Health, Egypt
Representative of the Ministry of Health of Egypt

09:15 SHORT BREAK

Transition to Workshop Room

09:30 SESSION 1 (ORLOV)

SETTING UP THE SCENE: WHERE ARE WE AT IN DIFFERENT COUNTRIES?

Session Chair:
Marianne M Mounir, Pharmacovigilance Lead-Egypt, Libya, Sudan,Yemen and Central African Sub-region, MSD, Egypt

This session aims to give an overview of the current activities in MENA region and highlight the latest developments and challenges by industry.

National QPPV Role
Sean Burke, EEMEA Regional Lead, Pharmacovigilance, MSD, UK

EFPIA Activities in the MENA Region
Hugo Mourik, PV EMEA Area Head for Developed & Emerging Markets, Affiliate Support EMEA, Pharmacovigilance, Astellas Pharma Europe B.V., The Netherland

Panel discussion with Q&A

10:30 COFFEE BREAK

11:00 SESSION 2 (ORLOV)

ARAB LEAGUE GVP INSPECTION

Session Chair:
Dana Isleem, Pharmacovigilance Manager-Middle East & Africa at Bristol-Myers Squibb, UAE

Achieving a successful outcome in an audit or inspection is a formal objective for many leaders. But what does 'success' look like?
The Pharmacovigilance inspections are designed to determine compliance with regulatory pharmacovigilance obligations and in this session
We will share some practises on the planning and conduct of the pharmacovigilance Inspection of the different parties involved to focus on some particular areas of concern and bring some thought-provoking ideas to the table for discussion.

SFDA Inspections – Regulators' Perspective
Amal M. Arafah, Pharmacovigilance systems inspector, National Pharmacovigilance Center, SFDA, Saudi Arabia

Arab League GVP Inspection - Pharma Perspective
Marouane Ek Kabaili, Cluster Safety Lead North Africa & Middle East, Pfizer, Morocco
Dana Isleem, Pharmacovigilance Manager-Middle East & Africa at Bristol-Myers Squibb, UAE

Panel discussion with Q&A

12:00 LUNCH

13:15 SESSION 3 (ORLOV)

PSMF - GENERAL DEVELOPMENTS

Session Chair:
Marianne M Mounir, Pharmacovigilance Lead-Egypt, Libya, Sudan,Yemen and Central African Sub-region, MSD, Egypt

The purpose of this session s to share knowledge and come up with some best practices between participants so that delegates leave the session better equipped and with an informal network of colleagues to tap into for working on the PSMF outside the EU.

Different types of PSMF / Examples across the region (PSSF)
Sean Burke, EEMEA Regional Lead, Pharmacovigilance, MSD, UK

Panel discussion with Q&A

14:15 COFFEE BREAK

14:45 SESSION 4 (ORLOV)

SIGNALLING

Session Chair:
Shanthi Pal, Group Lead, Medicines Safety, Safety & Vigilance, World Health Organization, WHO, Switzerland

This session will explore the latest developments in signal detection activities and how the tools provided by different regulatory authorities and other data sources are used to support drug safety monitoring. The focus will be on sharing methods and tools to capture ADRs as well as challenges in the region to process and receive the data.

ICSR and Other Data Sources
Mohamed Abdel Hady, Pharmacovigilance and Epidemiology Manager at Gilead Sciences, UAE

Qualitative and Quantitative Improvements to Data Collection
Phil Tregunno, Group Manager, Vigilance, Intelligence and Research Group Medicines and Healthcare products Regulatory Agency (MHRA), UK

VigiBase and Signal detection and Analysis Support for the WHO PIDM
Monica Plöen, Head of Pharmacovigilance Collaborations, Uppsala Monitoring Centre, WHO Collaborating Centre for International Drug Monitoring, Sweden

Panel discussion with Q&A
Additional Panellist:
Mohammed I. Fouda, Head of Signal Detection Department, Saudi Food and Drug Authority (SFDA), Saudi Arabia

16:30 COFFEE BREAK

17:00 OPTIONAL - SESSION 4* (EXCELSIOR 1)

HIGHLIGHTS OF THE DAY AND WRAP-UP

Session chair:
Inas Chehimi, MERN Chair, Head RA Middle East & North Africa, Novartis Pharma Services AG, UAE

"Parking lot" style session and discussion with all speakers of the day.

17:30 NETWORKING RECEPTION

18:30 END OF DAY 1

DAY TWO | TUESDAY, 15 OCTOBER 2019

09:00 SESSION 5 (ORLOV)

RISK MINIMISATION MEASURES

Session Chair:
Raghda Mohamed, Drug Safety Lead - South Europe, Middle East and Africa Cluster, Shire Export Service GMBH, UAE

The primary goal of a Risk Minimization Plan (RMiP) is to develop activities that help patients and health care providers understand an important known or potential risk associated with a drug and to lessen the chance that a serious side effect might occur. This session will share good practices across MENA region and present examples from EU-RMP creation.

Risk Minimisation Plan in EU
Mohamed Abdillahi, Risk Management Product Lead, Pfizer, UK

Challenges and good practices from other regions
Hadir Rostom, Head of Egyptian Pharmaceutical Vigilance Center, Egypt

Risk Minimization Activities
Raghda Mohamed, Drug Safety Lead - South Europe, Middle East and Africa Cluster, Shire Export Service GMBH, UAE

Panel discussion with Q&A

10:30 COFFEE BREAK

11:00 SESSION 6 (ORLOV)

HARMONISATION & SIMPLIFICATION OF PV GUIDELINES IN THE REGION

Session Chair:
Shahinaz Badr, Regional Pharmacovigilance Manager, NewBridge Pharmaceuticals, Africa, Middle East, and Turkey
This session will tackle the impact of communication between industry and regulators in overcoming some of the challenges faced. Sharing the learnings from recent experiences of UAE, Algeria and Iraq where the collaboration and dialogue led to harmonization, and simplification of the national GVP guidelines.

Harmonisation, Simplification and the Impact of Communication
Sultana Essa Bin Haider, Pharmacovigilance Officer, Drug department, Ministry of Health & Prevention, UAE

GVP Implementation in Kuwait
Reem El Essa, Coordination & Development Superintendent Pharmaceutical Services Administration, Ministry of Health, Kuwait

Walking the Harmonisation Pathway
Manal Mohammed Younus, Head of Iraqi Pharmacovigilance Centre, Directorate of Technical Affairs, Ministry of Health, Iraq

Algerian Pharmacovigilance Guideline
Nadjat Loumi, Directrice générale Centre National de Pharmacovigilance & Matériovigilance, CNPM, Algeria

Panel discussion with Q&A
Additional Panellist:
Laila Kazim, Head of Pharmacovigilance, Ministry of Health & Prevention, UAE **- remote presentation**

13:30 SESSION 7 (HOPE)

MERC PHARMACOVIGILANCE SESSION

Session Chairs:
Hadeer Rostoom, Head of Egyptian Pharmaceutical Vigilance Center, Egypt
Reem El Essa, Senior Pharmacy Specialist and Inspector Pharmacist at Drug Inspection Administration, Pharmacovigilance Focal Point in Kuwait Drug and Food Control, Kuwait

Smart Safety Surveillance for Priority Medical Products
Shanthi Pal, Group Lead, Medicines Safety, Safety & Vigilance, WHO, Switzerland

SFDA's experience – moving to the investigation phase
Mohammed I. Fouda, Head of Signal Detection Department, Saudi Food and Drug Authority (SFDA), Saudi Arabia

Kuwait's Roadmap on Pharmacovigilance
Reem El Essa, Senior Pharmacy Specialist and Inspector Pharmacist at Drug Inspection Administration, Pharmacovigilance Focal Point in Kuwait Drug and Food Control, Kuwait

Q&A and Panel Discussion
Additional Panellists:
Phil Tregunno, Group Manager, Vigilance, Intelligence and Research Group Medicines and Healthcare products Regulatory Agency (MHRA), UK
Sean Burke, EEMEA Regional Lead, Pharmacovigilance, MSD, UK

Conference Venue

Royal Maxim Palace Kempinski Cairo
First Settlement,
11477 Cairo
Egypt
Tel: +20 2 224 95300
Hotel Location

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