Summary report on the

Eastern Mediterranean Drug Regulatory Authorities Conference (EMDRAC)

WHO-EM/EDB/129/E

Salalah, Oman
16–19 July 2018

World Health Organization
REGIONAL OFFICE FOR THE Eastern Mediterranean

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1. Introduction

The World Health Organization (WHO) Regional Office for the Eastern Mediterranean organized the Eastern Mediterranean Drug Regulatory Authorities Conference (EMDRAC), which took place in Salalah, Oman, from 16 to 19 July 2018. The conference comprised one day of sessions open to partners and two and a half days of closed sessions for national regulatory authorities (NRAs) only.

The overall objective of the EMDRAC is to promote effective regulation and control of medical products and the establishment of functional NRAs in the Eastern Mediterranean Region.

The specific objectives of EMDRAC 2018 were to:

- review progress made in the implementation of recommendations from the 16th and 17th International Conference of Drug Regulatory Authorities (ICDRA);
- provide NRAs with an overview of regulatory assessment and WHO recommendations for the evaluation of similar biotherapeutic products and biotherapeutics products;
- discuss regional and national challenges encountered by NRAs in the regulation of medical products, including the threats of substandard medicines;
- raise awareness of the role of regulators in promoting local production as one of the viable options to improve access to quality and safe medical products;
- showcase country experiences and achievements in implementing different regulatory functions, particularly in the safety of medical products and post-market surveillance;
- discuss the role of regulators during public health emergencies and outbreaks;

- identify ways to collaborate with WHO in regional priorities, such as combating antimicrobial resistance;
- advocate for the creation of common standards for regulatory functions and practices in the Region.

The expected outcomes of EMDRAC 2018 were to:

- propose solutions to address challenges encountered by NRAs in regulation of medical products;
- agree on a draft plan of action for strengthening regulatory capacity of medical products in the Region;
- finalize recommendations of EMDRAC 2018 to be presented at the 18th ICDRA, which will be held in Dublin, Ireland, 3–7 September 2018.

EMDRAC is the only regional forum exclusively for NRAs to share information and engage in issues of regional importance. It was recommended by NRAs in the Region that one EMDRAC be held every two years to maintain the functionality of the network and collaboration among NRAs as major stakeholders in the pharmaceutical sector of the Region. The last EMDRAC was held in Tunisia in 2016.

Of the 22 NRAs invited from countries of the Region, 17 sent representatives to participate in the meeting. The WHO Secretariat comprised staff members from the WHO Regional Office for the Eastern Mediterranean, headquarters and country offices. Qualified experts from related agencies and international and regional organizations working in the field of strengthening regulatory systems attended, including the following:

- Arab Union of the Manufacturers of Pharmaceuticals and Medical Appliances;

- International Federations of Pharmaceutical Manufacturers and Associations;
- International Generic and Biosimilars Medicines Association;
- WHO temporary advisors;
- Health Canada;
- United Kingdom National Institute for Biological Standards and Control (NIBSC);
- former Director-General of Biologicals in Health Canada and former WHO staff member;
- New Partnership for Africa's Development (NEPAD).

The conference opened with remarks from His Excellency Dr Mohamad Al Hosni, Undersecretary for Health Affairs, Ministry of Health, Oman, who noted that the reach and influence of social media had increased the expectations of the general public regarding the safety of medications. Awareness had increased, the public's demand for safe and effective medicines had intensified, and the realm of pharmaceutical manufacturing was ever changing, increasing in complexity and costs. Growing portions of health budgets were being consumed by increasingly expensive medicines.

The opening remarks of Dr Ahmed Al Mandhari, WHO Regional Director for the Eastern Mediterranean, highlighted the importance of regulation in all forms to ensure the safety, efficacy, and quality of medicines and medical devices. He highlighted the need to address the current concerning situation of national regulatory bodies in the Region and said that the role of EMDRAC as a regional forum could be beneficial in providing an opportunity to discuss regulatory issues of mutual interest, sharing and exchanging knowledge, as well as establishing regional collaboration and cooperation mechanisms to strengthen the regulation of medical products to improve access to

quality, safe and affordable medical products to meet the goals of UHC 2030 and the 2030 Agenda for Sustainable Development.

2. Summary of discussions

Biotherapeutics products and similar biotherapeutic products are topical, complex and their use will be expanded with the increasing number of similar biotherapeutic products in the market. Biotherapeutics products have been successful in treating many life-threatening chronic diseases, but they are expensive and difficult to access in developing countries. As patent and data protection expire for several originator's biotherapeutics products, similar biotherapeutic products have emerged, which can offer comparable safety and efficacy if they are shown to be similar to the reference products. Their emergence can influence the affordability, accessibility and benefits of these medicines. They do, however, present a challenge to regulators. The regulation of these products, in the absence of an appropriate regulatory framework, is problematic not only for regulators but also for developers and manufacturers. Therefore, it is imperative for NRAs to develop national guidelines on the regulatory process and requirements to ensure proper evaluation of similar biotherapeutic products and to provide guidance to manufacturers for generating appropriate quality and clinical data of these products in the interest of public health.

The session focused on quality, clinical and immunogenicity assessment and country experiences were shared. Main issues included:

- building the capacity of less experienced NRAs through exchanging experiences with well-resourced NRAs;
- pooling resources and harmonization (African's experience was cited as a model to follow);

- establishing a mentoring framework for experienced and less experienced regulators;
- sharing information while at the same time respecting confidentiality;
- resolving issues of terminology around biosimilars, biotherapeutics, similar biotherapeutics;
- evaluating laboratories (routine, post-marketing surveillance, SOPs);
- assessing affordability and pricing issues and role of regulators, if any.

Participants also discussed the forthcoming 18th ICDRA, recommendations from the 17th ICDRA, regulatory convergence, harmonization and cooperation, followed by an explanatory presentation by NEPAD on medicines regulatory harmonization with a specific focus on the African Union Model Law on Medical Products Regulation and African Medicines Agency. Progress made in the implementation of recommendations from the 16th and 17th ICDRA was reviewed.

The threats of substandard medicines and latest definitions applied to substandard and falsified products, as well as regulatory approaches to address the problem of potentially sub-standard medicines were discussed. Countries shared experiences and challenges in regard to substandard medicines, the role of national quality control laboratories, and ensuring good manufacturing practices in identifying substandard products. Pakistan shared lessons learned from a tragic incident which caused the deaths of 186 patients and affected 1000 patients as a consequence of an adverse drug reaction to the cardiac medicine ‘IsoTab 20 mg tablet’, manufactured by a local pharmaceutical company in Karachi.

Local production of essential medicines through data collected from surveys, the role of regulators, conceptual framework to promote local procurement, pharmaceutical manufacturing development, and

improving access to direct acting anti-hepatic medicines were discussed.

The session on pharmacovigilance in the Region focused on how pharmacovigilance was helping countries to promote and ensure safety of medical products and medical devices vigilance. Through the herbovigilance system countries such as Oman were ensuring safety monitoring of traditional and complementary medicines.

The session on public health emergencies and medicines regulations looked at the regulation of medical products during outbreaks and pandemics and the regulator's role in addressing antimicrobial resistance. The Syrian Arab Republic and Oman shared their experiences in regulating medicines donations and in promoting rational use of antimicrobials, respectively.

A special session was dedicated to the increased threat caused by antimicrobial resistance which has a huge impact on access to lifesaving interventions in emergency situations. Working groups were organized on how to assess and compile antimicrobial consumption data.

A panel discussion looked at regulatory collaboration, convergence, harmonization and networking as a key to improving access.

To facilitate discussions on EMDRAC recommendations participants were divided in five groups:

Group 1: Bahrain, Oman, Saudi Arabia and United Arab Emirates
Group 2: Afghanistan, Islamic Republic of Iran and Pakistan
Group 3: Egypt, Jordan, Morocco and Tunisia
Group 4: Iraq, Libya, Palestine and Syrian Arab Republic
Group 5: Somalia, Sudan and NEPAD.

Each group was requested to propose three EMDRAC 2018 recommendations (one general and two specific to issues discussed during the conference).

Recommendations suggested by participants included:

- establishing a steering committee for regulatory collaboration, harmonization and networking;
- developing emergency guidelines to fast track access to lifesaving medicines during public health emergencies;
- strengthening capacity for local production, regulation and surveillance and sharing information on substandard medicines and/or falsified medical products;
- strengthening NRA registration; and
- regulating similar biotherapeutics.

Participants were provided with up-to-date information on WHO's mandate, role and guidance in regulation of medical products, and global and regional initiatives in regulatory convergence, harmonization and cooperation. Regulatory convergence is based on streamlined procedures, agreed standards and guidelines, and collaboration. The importance of a well-functioning national regulatory authority for medical products to safeguard their quality, safety, and efficacy was acknowledged. Insufficient political commitment and limited financial and human resources contribute to inefficient regulatory systems. Collaboration in regulatory activities is important in order to facilitate access to new medical products with public health importance by sharing relevant information and assessment and/or inspection reports that may shorten the registration period. A plan of action for strengthening regulatory capacity in the Region was agreed upon and recommendations to be presented at the eighteenth ICDRA proposed.

Participants were invited to attend the ICDRA meeting in Dublin, Ireland, 3–7 September 2018.

3. Recommendations

For Member States

1. Strengthen capacities of regulators to regulate local manufacturers.
2. Strengthen regulatory capacity to deal with biosimilars.
3. Minimize the number of substandard and falsified products in the Region through pharmacovigilance and track and trace systems.
4. Share information on substandard and falsified products, pharmacovigilance, drugs adverse reactions and biologicals.
5. Explore the possibility of linking rapid alert for medical devices to already established systems of pharmacovigilance for medicines.
6. Harmonize technical requirements needed for registration and pharmacovigilance, including identification of focal points in every Member State to outline a roadmap for implementation and information-sharing.
7. Develop a legal framework for strengthening the capacity of local production of medicines.
8. Based on WHO rapid benchmarking assessment, strengthen regulatory capacity for key priority areas with a focus on market authorization.
9. Establish practical mechanism in the subregion for collaboration and information-sharing in the area of post-marketing surveillance and containment of substandard and falsified medical products.

To WHO

10. Facilitate the establishment of an Eastern Mediterranean Drug Regulatory Steering Committee for regulatory collaboration, harmonization and networking.
11. Support Member States in strengthening NRA capacity through adoption of a step-wise approach to comply with international norms, standards and guidelines by providing guidance, technical support and training.
12. Develop emergency guidelines to fast track access to lifesaving medicines in emergency situations.
13. Adopt a common legal and regulatory framework for countries in the Region taking into account the experiences and lessons learnt from African Union Model Law and other relevant reference models.
14. Support countries in building capacities in industrial pharmacy and good manufacturing practices and share tools for feasibility studies to support local industries.
15. Support Member States in establishing medical devices regulation.
16. Facilitate pharmacovigilance convergence and alignment across Member States, to allow consistent and comparable practices, optimal information exchange and learning.
17. Strengthen regulatory collaboration by mapping expertise of NRAs and creating a roster of regulatory experts in various functions.
18. Support Member States in implementing guiding principles for regulatory evaluation of biotherapeutics, including biosimilars.

World Health Organization
Regional Office for the Eastern Mediterranean
P.O. Box 7608, Nasr City 11371
Cairo, Egypt
www.emro.who.int