

Summary report on the

WHO-EM/EDB/130/E

Meeting of the Steering Committee for Eastern Mediterranean Drug Regulatory Authorities

Amman, Jordan
9–10 April 2019



World Health
Organization
REGIONAL OFFICE FOR THE
Eastern Mediterranean

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1. Introduction

Effective regulation of medicines and medical products promotes and protects public health. Regulation aims to ensure the quality, safety and efficacy of medical products (medicines, vaccines, diagnostics, medical devices, and so on) through enforcement of legislation, norms and standards. National regulatory authorities (NRAs) for medical products, with adequate capacity, can efficiently play this role.

The World Health Organization (WHO) Regional Office for the Eastern Mediterranean organized the first Eastern Mediterranean Drug Regulatory Authorities Conference (EMDRAC) in 1993, to serve as a biennial event bringing together NRAs from the Region as well as regulatory leaders from regional and international organizations to exchange experience and share cutting-edge professional approaches and techniques spanning all core regulatory functions. At the 2018 Eastern Mediterranean Drug Regulatory Authorities Conference (EMDRAC 2018) held in Salalah, Oman, in July 2018, it was agreed by NRAs to establish a steering committee to meet annually for capacity-building, collaboration, harmonization and monitoring of the EMDRAC recommendations. The steering committee would be composed of selected directors of NRAs in the Region, in order to:

- enhance cooperation between regulatory authorities in the Region;
- identify and plan capacity-building activities related to the regulation of medical products;
- exchange relevant information on safety and quality of medical products;
- promote effective regulation and regulatory systems of medical products;

- review progress made in the implementation of EMDRAC and International Conference of Drug Regulatory Authorities (ICDRA) recommendations;
- promote research on the regulation of medicines, vaccines and medical products.

The WHO Regional Office for the Eastern Mediterranean organized the first meeting of the Steering Committee for Eastern Mediterranean Drug Regulatory Authorities from 9 to 10 April 2019, in Amman, Jordan. The meeting was attended by representatives from 11 Member States of the Region (Afghanistan, Bahrain, Egypt, Iraq, Jordan, Kuwait, Morocco, Oman, Palestine, Saudi Arabia and Syrian Arab Republic). The WHO Secretariat comprised staff members from headquarters, the Regional Office and country offices.

The objectives of the meeting were to:

- develop and agree on terms of reference for the Steering Committee;
- discuss regional and national challenges encountered by NRAs in the regulation of medical products;
- facilitate further collaboration between NRAs and promote regulatory harmonization initiatives.

The expected outcomes were:

- terms of reference for the Steering Committee reviewed and agreed by participants;
- progress reviewed of medical products regulation in the Region;
- progress reviewed of implementation in EMDRAC 2018 and 18th ICDRA recommendations;
- challenges identified in convergence efforts in regulation of medical products, and possible solutions;
- regional plan of action agreed for strengthening regulatory capacity and harmonization of regulation of medical products in the Region.

The opening remarks of Dr Ahmed Al-Mandhari, WHO Regional Director for the Eastern Mediterranean, highlighted the importance of regulation in all its forms to ensure the safety, efficacy and quality of medicines and medical devices. He underlined the need to address the current alarming situation of regulatory bodies in countries, and the beneficial role of EMDRAC as a regional forum in which to discuss regulatory issues of mutual interest, share and exchange knowledge, and establish regional collaboration and cooperation for strengthening the regulation of medical products. This will improve access to quality, safe and affordable medical products to meet the goals of UHC2030 and the 2030 Agenda for Sustainable Development. It was emphasized that the meeting would focus on the development of the terms of reference of the Steering Committee and agree on priority activities for the next biennium, in line with the regional road map of work and WHO's Thirteenth General Programme of Work 2019–2023.

2. Summary of discussions

Challenges in the regulation of medical products in the Region were discussed in group work sessions. The main challenges include: the lack of coordination between NRAs at regional level; absence of well-trained human resources; weak registration systems (especially for medical devices, vaccines and other biologicals); weak pharmacovigilance systems; lack of capacity for local production; poor implementation of good manufacturing practices; weak post-marketing surveillance and inspection; poor quality control laboratories; and lack of proper pricing control systems.

Regulation of medical products in emergency settings was discussed, including procedures that should be followed and actions implemented by regulators in different emergency settings including outbreaks,

natural disasters and conflict situations with damaged health systems and medical product shortages.

The terms of reference of the Steering Committee were discussed and elaborated in a group work session. It was agreed that the Committee will act as an advisory body to enhance capacity-building, collaboration, harmonization and networking among NRAs in Member States of the Region, and to prepare and monitor implementation of EMDRAC recommendations. Membership of the Committee will be voluntary for Member States, and members will be composed of designated representatives from Member States (head of the NRA or his/her alternative). The Steering Committee will be composed of nine members, serving for a period of two years and for a maximum of two terms. The chair and vice-chair will serve on a rotational basis among countries, and will be selected upon mutual agreement by members of the Steering Committee. Other Member States of the Region can attend Steering Committee meetings as observers. Guests and experts can be invited to Steering Committee meetings, as needed. The WHO Regional Office for the Eastern Mediterranean will provide secretariat support to the Steering Committee.

Criteria for selecting members of the Steering Committee will be based on the regulatory capacity and geographic location of countries. NRAs in the Region will be divided into five groups, as follows:

- group 1 includes north African countries (Egypt, Libya, Morocco, Tunisia);
- group 2 includes countries in the Intergovernmental Authority on Development (IGAD) bloc (Djibouti, Somalia, Sudan);
- group 3 includes Gulf Cooperation Council (GCC) countries (Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates, Yemen);

- group 4 includes Iraq and countries in the Levant (Iraq, Jordan, Lebanon, Palestine, Syrian Arab Republic);
- group 5 includes countries in southwest Asia (Afghanistan, Islamic Republic of Iran, Pakistan).

It was agreed that the Steering Committee will include: two members from north African countries (group 1); one member from IGAD countries (group 2); one member from southwest Asian countries (group 5); and two members from GCC countries (group 3) in its first two-year term and three members in the next term; and three members from the Levant and Iraq (group 4) in its first two-year term and two members in the next term.

3. Conclusions

Participating countries acknowledged the importance of a well-functioning NRA for medical products to safeguard their quality, safety and efficacy. It was stressed that insufficient political commitment and limited financial and human resources contribute to inefficient regulatory systems. The importance and necessity of collaboration in regulatory activities was recognized, in order to facilitate access to new medical products with high public health importance through the sharing of relevant information and assessment and/or inspection reports that may shorten the registration period. Participants reviewed progress and challenges in the regulation of medical products in their respective countries, and recommended possible solutions for the Region. Participating countries agreed on the draft terms of reference of the Steering Committee for Eastern Mediterranean Drug Regulatory Authorities, which will be submitted to the heads of NRAs in countries for endorsement (when finalized).

It was agreed that the Steering Committee for the period 2019–2020 will include the following members: Afghanistan, Egypt, Iraq, Jordan, Morocco, Oman, Saudi Arabia, Sudan and Syrian Arab Republic.

4. Recommendations

To the Steering Committee

1. Serve as a platform for information sharing, convergence and cooperation in the Region.
2. Work towards obtaining and building commitment from Member States in the area of regulatory systems strengthening.
3. Consult with NRAs on topics of interest for the EMDRAC, and subsequently approve the agenda.
4. Promote collaboration between Member States, including exchange of information and expertise on existing requirements and regulations.
5. Promote harmonization of the regulatory guidelines among Member States.
6. Facilitate the implementation of EMDRAC recommendations by NRAs.
7. Facilitate signing of memoranda of understanding between NRAs for the exchange of information and technical assistance in needed services for strengthening regulatory systems.
8. Meet face-to-face at least twice a year, and hold virtual meetings (via teleconference) every four months or as the need arises.

To WHO

9. Provide technical and administrative support to the Steering Committee.
10. Facilitate and organize face-to-face and virtual meetings of the Steering Committee.
11. Develop, manage and update advocacy and information materials.
12. Ensure reporting on activities of the Steering Committee and disseminate the information to all Member States.
13. Develop a networking tool (EZcollab or SharePoint) for the heads of NRAs in the Region to share all information related to the regulation of medical products.

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