4th ISLAMIC CONFERENCE OF HEALTH MINISTERS

REPORT
TECHNICAL COMMITTEE OF DEVELOPMENT AND HARMONIZATION OF STANDARDS ON PHARMACEUTICALS AND VACCINES AMONG OIC MEMBER STATES

A. BACKGROUND

1. The First Islamic Conference of Health Ministers (1st ICHM) (12 - 15 June 2007, in Kuala Lumpur, Malaysia) adopted resolution on Self-Reliance Program on Vaccine Production (KLOICHMC-1/2007/2.1). The resolution *inter alia* called, for:

   1.1 OIC Member States to consider being self-reliant and self-sufficient in their immunization programmes by ensuring the reliable supply of good quality, safe, effective and affordable vaccines by strengthening National Regulatory Authorities

   1.2 OIC Member States to ensure vaccine producers from OIC Member States invest in advanced bio-technology to develop good quality and effective vaccines, and strive to achieve WHO prequalification status for their products by 2010

2. The 2nd ICHM (1 – 4 March 2009, Tehran, Islamic Republic of Iran) adopted a resolution encouraging the OIC Member States, with the cooperation of the relevant OIC institutions, to work towards harmonizing the relevant standards and regulations to facilitate registration, manufacturing and marketing of drugs, vaccines and radiopharmaceutical among the OIC Member States.

3. The 3rd ICHM (29 September – 1 October 2011, Astana, Republic of Kazakhstan) adopted Resolution No. 3/3-ICHM on Self-Reliance in Production of Medicines and Vaccines and welcomed Malaysia's initiative to host the 1st Technical Meeting of the Development and Harmonization of Standards on Pharmaceuticals and Vaccines (DHSPV). The OIC-DHSPV will facilitate OIC Member States to achieve the goal of self-reliance in pharmaceuticals and vaccines.

B. TECHNICAL COMMITTEE OF THE DEVELOPMENT AND HARMONIZATION OF STANDARDS ON PHARMACEUTICALS AND VACCINES (DHSPV)

4. The 1st Technical Meeting was held on 1-2 October 2012 in Kuala Lumpur, Malaysia. The meeting was attended by representatives from OIC Member States i.e. Brunei Darussalam, Gambia, Indonesia, Malaysia and Saudi Arabia, as well as from international bodies, i.e. World Health Organisation, Statistical, Economic and Social Research and Training Centre for Islamic Countries (SESRIC) and Islamic Development Bank (IDB, Kuala Lumpur Regional Office).

5. The 1st Technical Meeting deliberated on the Terms of Reference (ToR) and Structure of the Technical Committee of the Development and Harmonization of Standards on Pharmaceuticals and Vaccines (OIC-DHSPV). The Meeting decided to establish an interim Pro Tem Committee comprising nine Member States representing the African, Arab and Asian region to finalize the Terms of Reference of the Technical Committee. Each Member State will be represented by three members, i.e. National Drugs Regulatory Authority (NDRA), Standard body and pharmaceutical industry. The Meeting also agreed for Malaysia to be the interim Secretariat to the Pro Tem committee.

6. The OIC General Secretariat invited OIC Member States and international organizations to nominate representatives for the Pro Tem Committee with the view of holding a meeting of the Pro Tem Committee by end of December 2012 at Purtrajaya, Malaysia. The proposed meeting was cancelled due to underwhelming responses. A draft Terms of Reference of Technical Committee was instead circulated to all OIC Member States for endorsement through circulation.

7. Several OIC Member States provided their comments to the draft Terms of Reference and these comments have been incorporated. The revised Terms of Reference (**Annex A**) is submitted for consideration by the 6th Meeting of Steering Committee on Health.

8. The 1st Technical Meeting also recommended for the Islamic Development Bank (IDB) to consider supporting initiative of the OIC Member States towards production and self reliance of pharmaceuticals and vaccines.

9. Malaysia will be hosting the 2nd Technical Meeting of OIC-DHSPV on 25-26 November 2013 in Kuala Lumpur, Malaysia. Malaysia wishes to encourage active participation from OIC Member States in this 2nd Technical Meeting towards realizing the agenda of development and harmonization of Standards on Pharmaceutical and Vaccines and supporting the self-reliance of pharmaceutical and vaccine initiatives.

10. Prior to this meeting, Malaysia is organizing a one week training programme on 18 – 22 November 2013 in the field of pharmaceutical regulatory system for national drug regulatory officers. The purpose of this training programme is to provide better understanding and updated information regarding Malaysia's regulatory system. This is anticipated to facilitate the harmonization and development of standards among OIC members. This is in line with one of the Key Performance Indicators in the Strategic Health Programme of Action (SHPA).

C. ACTION PLAN OF OIC-DHSPV

11. Malaysia drafted a 2-Year Action Plan for the Technical Committee OIC-DHSPV for period of 2014-2015, as per **Annex B**. The Action Plan describes on the action to be taken under the OIC-DHSPV, including the formation of Working Groups as well as coordination on capacity building and Post Marketing Alert System (PMAS). This Action Plan will contribute to implementation of proposed initiatives outlined in the OIC Strategic Health Programme of Action (OIC-SHPA). The action plan has been tabled and subsequently endorsed by the 6th Steering Committee on Health.

D. PROPOSAL FOR THE CONSIDERATION OF THE 4th ISLAMIC CONFERENCE OF HEALTH MINISTERS

12. Malaysia as the Convener of the 1st Technical Meeting of OIC-DHSPV would like to recommend the following for the consideration:

12.1 Approval on the Terms of Reference (ToR) of the Technical Committee for the Development and Harmonisation of Standards on Pharmaceuticals and Vaccines (OIC-DHSPV)

12.2 Approval on 2-Year Action Plan of OIC-DHSPV