

**SIXTH MEETING OF STEERING COMMITTEE ON HEALTH  
REPORT  
TECHNICAL COMMITTEE OF DEVELOPMENT AND  
HARMONISATION OF STANDARDS ON PHARMACEUTICALS AND  
VACCINES  
AMONG OIC MEMBER STATES**

**A. BACKGROUND**

1. The First Islamic Conference of Health Ministers (1<sup>st</sup> 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 2<sup>nd</sup> ICHM (1 – 4 March 2009, Tehran, Islamic Republic of Iran) adopted a resolution encouraging the OIC Member States to strive, 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 3<sup>rd</sup> 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 1<sup>st</sup> 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 1<sup>st</sup> 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 (WHO), Statistical, Economic and Social Research and Training Centre for Islamic Countries (SESRIC) and Islamic Development Bank (IDB, Kuala Lumpur Regional Office).
5. The 1<sup>st</sup> 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 Putrajaya, 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 6<sup>th</sup> Meeting of Steering Committee on Health.
8. The 1<sup>st</sup> 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 is planning to host the 2<sup>nd</sup> Technical Meeting of OIC-DHSPV, tentatively scheduled on 24-27 November 2013 in Kuala Lumpur, Malaysia, subject to approval by the Government of Malaysia. Malaysia wishes to encourage active participation from OIC Member States in this 2<sup>nd</sup> 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. Malaysia will borne the accommodation and local hospitality of the 2 participants from each OIC Member States attending this meeting.

#### **C. ACTION PLAN OF OIC-DHSPV**

10. 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).

#### **D. PROPOSAL FOR THE CONSIDERATION OF THE 6<sup>TH</sup> STEERING COMMITTEE ON HEALTH**

11. Malaysia as the Convener of the 1<sup>st</sup> Technical Meeting of OIC-DHSPV would like to recommend the following for the consideration of the 6<sup>th</sup> Steering Committee on Health:
  - 11.1 Approval on the Terms of Reference (ToR) of the Technical Committee for the Development and Harmonisation of Standards on Pharmaceuticals and Vaccines (OIC-DHSPV)
  - 11.2 Approval on 2-Year Action Plan of OIC-DHSPV