Annex A

Terms of Reference (ToR)

The Organization of Islamic Cooperation (OIC)

Technical Committee for the Development and Harmonization of Standards on Pharmaceuticals and Vaccines (OIC-DHSPV)

Background

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

- 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
- 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

Subsequently, during the 2nd ICHM in Iran held on 1 – 4 March 2009, a resolution was adopted, which encouraged 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.

The 3rd ICHM in Kazakhstan held on 29 September – 1 October 2011 requested Malaysia to host the 1st Technical Meeting on the Development and Harmonization of Standards on Pharmaceuticals and Vaccines (DHSPV) as it is reflected in its Resolution No. 3. The OIC-DHSPV will facilitate OIC Member States to achieve the goal of self-reliance in pharmaceuticals and vaccines.

Article 1: Objective

1.1 To achieve harmonization, alignment of technical requirements, approaches and greater regulatory cooperation (gradual adoption of internationally recognized technical guidance documents, standards and best practices) towards improving access to pharmaceuticals and vaccines deemed suitable for OIC Member States.

Article 2: Scope

2. The scope of the OIC-DHSPV shall include the following:

2.1 Exchange of views on harmonization of relevant standards and regulations concerning the registration, manufacturing and production of pharmaceuticals and vaccines.

2.2 Examination of issues related to the supply, procurement and distribution of pharmaceuticals and vaccines that conform to standards which are acceptable to OIC Member States.

2.3 Discussion on ways and means to share technical expertise and technology in the pharmaceutical field.

2.4 Identification of areas for regulatory and inter-agency cooperation.

2.5 Consideration of establishment of various technical working groups in relevant technical areas to assist the OIC-DHSPV. The working groups will meet as required.

Article 3: The Membership of OIC-DHSPV

3.1 All OIC Member States

3.2 OIC General Secretariat and relevant OIC institutions

3.3 Intergovernmental organizations and other institutions

- The World Health Organization (WHO);
- The United Nations Children's Fund (UNICEF)

3.4 Pharmaceutical and Vaccine Manufacturers

3.5 Invitees – any other members deemed necessary

Article 4: Structure

The OIC-DHSPV functions under the authority of and guided by Islamic Conference of the Ministers of Health as in **Annex 1.**

4.1 The OIC-DHSPV shall comprise of:

4.1.1. Chair and two (2) Vice Chairs, who shall not be from the same OIC Member State or Region;

4.1.2. Representative(s) from the OIC General Secretariat and relevant OIC Institutions:

- The Islamic Development Bank (IDB);
- The OIC Standing Committee on Scientific and Technological Cooperation (COMSTECH);
- The Islamic Educational, Scientific and Cultural Organization (ISESCO);
- The Statistical, Economic and Social Research and Training Centre for Islamic Countries (SESRIC);
- The Islamic Chamber of Commerce and Industry (ICCI)

4.1.3. Delegations from OIC Member States shall comprise three (3) delegates representing the National Drug Regulatory Authorities (NDRA), Standard Body and pharmaceutical and vaccine manufacturer;

4.1.4. International agencies/bodies;

4.1.5. Experts;

4.1.6. Others.

4.2 Technical Working Groups may be established to assist the OIC-DHSPV.

Article 5: Duties, Responsibilities and Procedures

5.1 The meetings of the OIC-DHSPV should normally be chaired by the Chairman who shall ensure compliance with the Rules of Procedures of the OIC (see para 5.6).

5.2 The Vice Chairs shall assist the Chair in all Meetings. In the absence of the Chair, one of the Vice Chairs by acclamation shall assume the duties and responsibilities of the Chair.

5.3 The Chair/Vice Chairs shall report on the proceedings and the decisions made by the OIC-DHSPV for consideration by the ICHM.

5.4 The …… (name of Member State) shall perform secretarial duties for the OIC-DHSPV. This will include:

i. Coordination of convening of the OIC-DHSPV meetings
ii. Necessary documentation for the meeting
iii. Submitting decisions of the meetings for approval of the ICHM

5.5. The lead country for capacity building will coordinate the training needs of OIC Member States and present a report to OIC-DHSPV.

5.6. The meetings will be governed by the Rules of Procedure of the OIC Conferences and Meetings as in **Annex II**.

Article 6: Meetings and Reports

6.1 All expenses for attending the meeting shall be borne by the participants.

6.2 The meeting reports shall be submitted to the Steering Committee on Health and subsequently the ICHM.

Vice-Chair of OIC-DHSPV

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Vice-Chair of OIC-DHSPV

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Chair of OIC-DHSPV

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