

REPORT OF THE FIRST MEETING OF MEDICINE AND VACCINES MANUFACTURERS FROM THE OIC MEMBER STATES

DUBAI, 27-28 FEBRUARY 2013

- 1. The General Secretariat of the Organization of Islamic Cooperation (OIC) in cooperation with the Science, Technology and Innovation Organization (STIO), organized the first meeting of medicine and vaccines manufacturers from OIC Member States hosted by the National Research Foundation (NRF), Ministry of Higher Education and Science Research, United Arab Emirates at Dubai on 27-28 February 2013.
- 2. The meeting was attended by the representatives of a select group of medicine and vaccines manufactures from OIC Member States, OIC General Secretariat, COMSTECH, STIO, IDB and SESRIC (list of participants is attached at Annex-I).
- 3. Dr Husam Sultan Al Ulama, Director of NRF welcomed the delegates and wished them success in their deliberations. Prof. Dr Sehamuddin Galadari, Vice Provost for Research and Graduates, United Arab Emirates University underscored the importance of the promotion of self reliance in medicine and vaccines production for the development of a healthy society. He offered services and expertise of the Department of Health Sciences and Research in this endeavour.
- 4. Ambassador Abdul Moiz Bokhari, Assistant Secretary General for Science and Technology, in his remarks stated that meeting was part of the efforts of the OIC General Secretariat and its institutions to promote self-reliance in medicine and vaccines production in the OIC Member States.
- 5. The Assistant Secretary General informed the participants that initially the meeting had been restricted to a select group of companies/bodies with a view to focusing on the existing and emerging epidemics and communicable diseases in the OIC Member States i.e. Polio, Malaria, HIV/AIDS, Tuberculosis, Meningitis, Influenza, Hepatitis Type B and C. The assessment and conclusions of the first meeting would shape the agenda and participation of the subsequent meetings to be planned under the initiative.
- 6. The meeting was chaired by Amb Abdul Moiz Bokhari. The Agenda and Programme of Work of the meeting are at Annex II & III.

Reports of the General Secretariat and OIC institutions on Promoting Self-Reliance in the Production of Medicine and Vaccines.

7. Dr Razley Nordin briefed the meeting about the decisions of the OIC including Islamic

Summit Conferences, Islamic Conferences of Health Ministers and Council of Foreign Ministers, which emphasize the need for self reliance and self sufficiency in vaccines and medicines through production, reliable supply of good quality, safe, effective and affordable vaccines, investment in advanced bio-technologies and strengthening public-private partnerships in this regard.

- 8. Elaborating on the role of the IDB, Dr Bashier Sallam detailed the efforts of the Bank pursuant to its Self-Reliance in Vaccine Production (SRVP) programme. The SRVP was approved in December 1997 with a budget of US\$5.6 million and the implementation of the approved projects is being followed up by the concerned IDB Departments. The IDB has been supporting pre-qualification of OIC vaccine producers in collaboration with the WHO. The programme provided a collaborative platform for the IDB to work closely with the concerned producers to develop a comprehensive training programme on pre-qualification, validation and certification procedures.
- 9. Dr Umut UNAL (SESRIC) gave a presentation on the status of production, consumption and trade in medicines and vaccines in the OIC Member States. The presentation underscored the need for improving manufacturing capacities in the pharmaceutical industry in the OIC Member States where local industry covered a small portion of domestic pharmaceutical demand leading to heavy reliance on imports from foreign sources.

Recommendations of the meeting

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10. The meeting recognized the importance of promoting self reliance in production of medicine and vaccines and expressed its commitments to work together for the achievement of this goal. The meeting further recognized that the objective could be achieved through joint action in phased manner by various stakeholders in the spirit of Islamic Solidarity and fraternity. In this regard the meeting made the following recommendations:

Requirement for data and information

- 1. SESRIC may undertake study/collate data on the following aspects:
 - a. Estimated requirements of expanded programme of immunization (EPI) or other selected vaccines based on disease burden for OIC countries for the next 10 years;
 - b. Status of bulk and finished product capacity installed and planned;
 - c. Supply and demand gap assessment and the resource requirements.
- 2. OIC to obtain guidelines for the WHO pre-qualification for circulation among the OIC vaccine and medicine manufacturers (including time line, cost and other needs)

Major Challenges to Achieving Self Sufficiency

1. Formulation, filling and packaging (FFP) capability exists but may not be sufficient to meet all the demand of OIC countries. Investment is required to increase capacity.

- 2. Active Pharmaceutical Ingredients (APIs) for vaccines are manufactured within OIC countries (Iran and Indonesia) but API manufacturing capacity is not sufficient. Therefore investment is necessary to increase the API manufacturing capacity.
- 3. Functional National Regulatory Authorities (NRAs) in each OIC member country to ensure basic product quality (CGMP) and facilitate intra-OIC trade.
- 4. Harmonization of standards of NRAs of OIC member countries is also critical to achieving self-sufficiency.
- 5. Industry-academia linkages needs to be strengthened. Centers of Excellence be established to promote clinical development of new vaccines, improving manufacturing process efficiency and developing halaal ingredient substitutes, etc.

Prospects of Cooperation and Joint Action

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- 1. Establishing partnerships and collaborations in R&D, manufacturing including contract manufacturing, marketing and distribution between the participants of the meeting.
 - The meeting welcomed the offer by Razi Institute (Iran), defined as Razi Grant to fund R&D for human and veterinary vaccines for OIC countries.
- 2. Training courses/workshops on Quality Management System (QMS) (CGMP, Validation, Clinical Trials, etc) may be instituted. In this regard, the meeting welcomed the offers of training by Pasteur and Razi Institutes (Iran) and Macter Int'l Ltd (Pakistan).
- 3. Utilizing the website of COMSTECH as a platform for online discussion, more effective knowledge sharing and learning initially between participants and later could be enlarged to include others.
- 4. OIC should strengthen cooperation with relevant international organizations including WHO, UNICEF and GAVI.
- 5. Possibility of establishing strategic stock for emergency may be explored.
- 6. Mutual recognition of registration and harmonization of regulatory requirements by OIC member states.

Innovative ways for Public-Private partnership

- 1. Creation of pooled procurement facility for vaccines and related supplies through public-private partnership under the OIC to facilitate access of the needy countries to quality essential vaccines.
- Procurement of vaccines at reasonable cost to be effected with preference from OIC Member Countries.
- 3. Promote private-public partnership through renting governmental facilities to private sector to increase production capacity e.g. technology park.

Role of OIC to facilitate regional cooperation

1. The General Secretariat to report to the Ministers of Health, Council Foreign Ministers and the Islamic Summits on the status of medicine and vaccines

- manufacturing in the OIC Member States and seek their guidance and support for promoting self reliance.
- 2. The General Secretariat agreed to facilitate participation of the delegates attending to the First Meeting of Vaccine and Medicine Manufactures (27 28 February 2013) in the upcoming Vaccine Summit in Abu Dhabi on 24 25th April 2013 and the Fourth Islamic Conference of Health Ministers in Indonesia.

Strategy and road map

- 1. Self reliance in medicine and vaccines production is a strategic imperative for the growth of a healthy society and social economic development of the Muslim Ummah. It calls for concerted efforts by all parties to define modalities for its realization.
- 2. The participants agreed to meet again once the need assessment studies are completed in order to detail the short term (downstream process), medium term (joint development of APIs) and long term (research and development) action plans. These action plans will also contribute to the development of Implementation Plan of the OIC Strategic Health Program Action, 2013 -2022.
- 3. The participants agreed to remain in close contact with each other and the OIC General Secretariat to exchange information on matters pertaining to promotion of self reliance of production of medicine and vaccines in the OIC countries.
- 11. The participants expressed gratitude to the National Research Foundation and Zayed University for making excellent arrangements for the success of the meeting. They also thanked the Ministry of Higher Education and Scientific Research for hosting under its auspices the First Meeting of the Medicine and Vaccines Manufacturers from the OIC Member States.