

**The Fourth Islamic Conference of Health Ministers
Jakarta, Republic of Indonesia, 22 – 24 October 2013**

Concept Paper

Seventh Working Session: Panel Discussion V on Self Reliance on supply and production of pharmaceuticals including vaccines

Overwhelming evidence demonstrates the benefits of immunization as one of the most successful and cost-effective health interventions known. Over the past several decades, the benefits of immunization have been demonstrated through achievements such as the eradication of smallpox, an accomplishment that has been called one of humanity's greatest triumphs. Vaccines have saved countless lives, lowered the global incidence of polio by 99 percent and reduced illness, disability and death from diphtheria, tetanus, whooping cough, measles, *Haemophilus influenzae* type b disease, and epidemic meningococcal A meningitis.

The WHO's Global Vaccine Action Plan 2011–2020 indicated that there is important progress in the last decade - *"In the last 10 years, great advances have been made in developing and introducing new vaccines and expanding the reach of immunization programmes. More people than ever before are being vaccinated and access and use of vaccines by age groups other than infants is expanding. As a result of immunization combined with other health care and development interventions—including improved access to clean water and sanitation, better hygiene and education—the annual number of deaths among children under five years of age fell from an estimated 9.6 million in 2000 to 7.6 million in 2010, despite an increase in the number of children born each year."*

The OIC Member States made commitment to expand national immunization services to reach all unvaccinated children with life-saving vaccines of assured quality that will significantly contribute towards MDG4 and consider being self reliant and self sufficient in their immunization programmes by ensuring reliable supply of good quality, safe, effective and affordable vaccines by strengthening National Regulatory Authorities and improving capacity for vaccine production and distribution in the OIC Member States.

The OIC General Secretariat and relevant OIC institutions in collaboration with Member States are promoting self-reliance in vaccines and drugs. This includes collaboration between WHO and IDB in IDB training programme on pre-qualification, validation and certification procedures for OIC vaccine producers. More recently, the OIC has endeavoured to expand the scope of its efforts for promoting self-reliance by following a two track approaches:

- i. Collaboration between the national regulatory bodies and standards organizations for development and harmonization of standards on pharmaceuticals and vaccines; and
- ii. Cooperation between medicine and vaccine manufacturers in the OIC Member States.

Within the first track, a Technical Committee for the Development and Harmonization of Standards on Pharmaceuticals and Vaccines (OIC-DHSPV) was established. The technical committee in its first meeting (Kuala Lumpur, 1-2 October 2012) reviewed the regulatory control of pharmaceuticals and vaccines in the OIC Member States discussed challenges to produce pharmaceuticals and vaccines in the OIC region; and deliberated on the structure of the Technical Committee. The meeting identified two spheres areas of collaboration: the first sphere

is national regulatory bodies and department of standards; and the second sphere is cooperation with private sector involved in production of vaccine and drug in the OIC Member States.

A first meeting of medicine and vaccines manufacturers held in Dubai on 27 – 28 February 2013 discussed the current status of medicines and vaccines production in the OIC region and major challenges to achieving self reliance in production of medicines and vaccines. The meeting reviewed status of medicine and vaccines production in the OIC countries, discussed major challenges to self-reliance, identified possible avenues for collaboration and the OIC role in facilitating cooperation and joint action. The participants agreed to work together for promoting self-reliance and emphasized that the objective could be achieved through joint action in a phased manner.

The meeting recommended several short, medium and long term measures towards self reliance of vaccines production that includes: strengthening industry-academia linkages, harmonization of standards, creation of pooled procurement facility for vaccines and related supplies through public-private partnership, establishment of a strategic stock of medicines and vaccines for emergency, and securing WHO pre-qualified status.

A second meeting of the Medicine and Vaccines Manufacturers held in Bandung on 16 June 2013 agreed on elements for the short, medium and long term plan towards achieving self reliance in Vaccine Production and Availability through down-stream and up-stream approaches.

A draft plan document elaborating Short Term Actions (2014-2016), Medium Term Actions (2017-2019), and Long Term Actions (2020 and beyond) is presented as background document for the panel discussion. The document inter alia recommends establishment of Vaccine Manufacturers Group with the task to coordinate collaboration in vaccine manufacturing between each other (toll manufacturing, under license and supply agreement, etc); Development of Quality Management System (QMS); Collaboration and Transfer of Technology to develop the Fill and Finish Production Capabilities; provide intermediate material and support expertise by manufacturer which has been recognized by WHO; Pooling Mechanism within the OIC for procurement. Increase capacity for vaccine production; Provision of incentives from the Governments for investment in vaccine manufacturing in OIC countries; Establishment of OIC Research Center for new products development to anticipate new diseases by using potential resources among OIC member states which have been recognized by WHO; Cooperation in joint development and joint production of raw materials (bulk antigens); and Further expansion of OIC indigenous manufacturing capacity.

Draft Terms of Reference of Manufacturers Group and Concept Paper on Pooling Procurement Mechanisms are also presented.

Member States are requested to take into account the outcomes and recommendations emanating from the two tracks being followed by the OIC so far and provide their inputs for the future course of action:

Date: 23 October, 2013	Time: 14:00 hours	Room:
Moderator: Ministry of Health, Malaysia		
Rapporteur: Malaysia		
Session Programme and Speakers:		
No.	Name	Organization
1.	Dr Iskandar, President Director	BioFarma (Vaccines manufacturer from Indonesia)
2.	Dr André SPIEGEL, MD, MPH Professeur agrégé du Val-de-Grâce Administrateur Général	Pasteur Institute (Vaccines manufacturer from Senegal)
3.	Dr Majed Saeed Bahatheq, Chief Executive Officer	Arabio (Vaccines manufacturer from Kingdom of Saudi Arabia)
4.	Hind Khatib-Othman, Managing Director – Country Programmes	GAVI
5.	Dr David Hipgrave, Senior Health Advisor	UNICEF

Key Questions to be addressed by Panel Members

1. BioFarma

- Present the status of vaccines production
- Do we have the right strategy and the right tools needed to reach self reliance in production and supply of drugs and vaccines?
- How can the manufacturers group cooperates in the efforts to be self reliance in production and supply of drugs and vaccines?

2. Pastuer Institute, Dakar, Senegal

- What are the biggest challenges facing to achieve self reliance in productions and supply of drugs and vaccines in Africa?
- What are the implications if do not achieve self reliance in productions and supply?

3. Arabio

- Why is self reliance in production and supply of drugs and vaccines a top priority for the Arab Region?
- What are the biggest challenges in realizing the vision?
- What are some innovative ways used to mobilize participation of Member States?
- What are the achievements from the launching of the initiative?

4. GAVI

- How does GAVI support countries who wish to use locally-produced vaccine?
- Is self-reliance in the production of vaccines a good investment?
- How does GAVI assist OIC member states who are GAVI-eligible?

5. UNICEF

- What are some of the specific actions taken to meet the need for supply of drugs and vaccines?
- How can UNICEF cooperate with the OIC and its members to implement Pooling Mechanism?