

**SHORT, MEDIUM AND LONG TERM PLAN OF ACTION TOWARDS SELF  
RELINCE OF VACCINES IN THE OIC REGION  
OIC Vaccine Manufacturers  
(2014-2022)**

## **INTRODUCTION**

OIC Member States are committed to expand national immunization services to reach all unvaccinated children with life-saving vaccines of assured quality that will significantly contribute towards Millennium Development Goals point 4 (MDG4) and consider being self reliant and self sufficient in their immunization programs by ensuring reliable supply of good quality, safe, effective and affordable vaccines by strengthening National Regulatory Authorities and improving capacity for vaccine production as well as pharmaceutical medicine in the OIC Member States.

OIC recognizes the challenges facing many of its Member countries in filling the vaccination gap & shortages of many targeted essential mandatory vaccines at low affordable price especially the new vaccines, which are mainly in the form of lack of strong competent indigenous biological vaccines industry also lack capacity of downstream process. Formulation, Filling and Packaging capability exist in some OIC member but the capacity may not be sufficient to meet all the demand of OIC countries

## **BACKGROUND**

The Final Communiqué of the Tenth Session of the Islamic Summit Conference (Putrajaya, 16-17 October 2003) called for establishment of cooperation among Member States in the field of pharmaceutical production.

Self reliance in vaccines production and its availability (SRVPA) could be achieved through joint action in a phased manner, strengthen relationship and partnership among the OIC Member States in the field of vaccine production, as well as establish strong capacities for indigenous vaccines manufacturing and hence closing the vaccination gap

Two parallel tracks approaches are taken to promote Self Reliance in Pharmaceuticals and Vaccines:

- Development and Harmonization of Standards on Pharmaceuticals and Vaccines – Establishment of a Technical Committee.
- Cooperation between medicine and vaccine manufacturers in the OIC Member States

A Technical Committee on Development and Harmonization of Standards on Pharmaceuticals and Vaccines was established with the objectives of achieving harmonized and aligned 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.

The OIC General Secretariat in coordination with Science, Technology and Innovation Organization (STIO) invited manufacturers of vaccines for a meeting. The First Meeting of Medicine and Vaccines Manufacturers from OIC countries held in Dubai on 27 – 28 February 2013 decided to prepare a short term (downstream process), medium term (joint development of APIs) and long term (research and development) plan for self reliance on vaccines. The Second Meeting of Medicine and Vaccines Manufacturers from the OIC Member States hosted by Bio Farma of Indonesia on 16 June 2013 in Bandung, Indonesia detailed elements for a short, medium and long term plan, decided to establish vaccine manufacturers group and recommended Pooling Procurement Mechanisms. The establishment of vaccine manufacturers and Pooling Procurement Mechanism are correlated with implementation of thematic area No. 4: Medicines, Vaccines and Medical Technologies of the OIC SHPA (Strategic Health Program of Action, 2014 - 2022). The thematic area 4 covers self reliance in vaccine productions on the basis of the short term, medium term and long term plan.

## **VACCINE NEED AND REQUIREMENT OF THE OIC**

OIC countries display heterogeneous structure in terms of being able to manufacture new vaccines.

Low income countries obtain vaccines mostly through GAVI, while Middle income countries have been experiencing financial and operational difficulties with the introduction of new vaccines. They have the following obstacles: Lack of sufficient funds and Prevailing high prices of vaccines.

On basis of information received from GAVI Alliance on vaccine needs in 31 Member States, SESRIC prepared an Assessment of Vaccine Needs in the OIC Member States. The information shows that vaccine coverage of DTP3 in these countries is 83% compared to 85% in other developing countries and 95% in the developed countries. MCV coverage is 81% for 31 OIC Member States, meanwhile 85% for other developing and 92% for the developed countries.

Epidemiological studies in the OIC Member Countries showed that the coverage level in immunization & vaccination mainly with the mandatory vaccines scheduled in the EPI falls short of expected in most of the members countries as compared to the WHO requirements. This is mainly due to lack of financing and shortage of supply by health authorities as well as other factors such access to populations in remote areas

## **VACCINES MANUFACTURING CAPABILITIES OF THE OIC**

Manufacturing capacities of pharmaceutical and vaccines in OIC Member Countries continue to be inadequate. Production of local industry covers a tiny fraction of domestic pharmaceutical and vaccines demand and member countries rely heavily on imports and medicinal aid.

Currently, there are several manufacturers in the OIC Member States with the capability and capacity to produce vaccines. However, only two of these vaccines manufacturers have received WHO prequalification status, Bio Farma of Indonesia and Pasteur Institute of Senegal. Bio Farma of Indonesia manufactures and supplies several vaccines including vaccine for polio. Pasteur Institute of Senegal is producing vaccine for yellow fever.

## **DEFINITIONS:**

Self Reliance in Vaccine Production and Availability (SRVPA) is the capability and the capacity to conduct research & development, manufacture, supply and procurement by the OIC Member States.

Indigenous vaccine manufacturers – companies based in the OIC countries and owned by OIC governments, nongovernmental institutions and citizens as majority shareholder.

WHO Prequalification (PQ) is a reference for quality, safety and efficacy standards for vaccine manufacturing recognized by the OIC Member State in such understanding.

## **VISION & MISSION**

Vision: achievement of SRVPA of the OIC Member States to meet vaccine needs at the intra-OIC and national levels.

Mission: to ensure that all children in the OIC countries are vaccinated by products of the OIC vaccine manufacturers.

## **GOALS**

Goal: is to develop joint capability and capacity in integrated manner toward promoting SRVPA.

## **OBJECTIVES & TIMELINE**

### **I. Short Term Actions (2014-2016):**

1. Creation and updating database on vaccine needs, potential resources such as research capability, manufacturing capability and capacity (production, testing, clinical study and distribution). It requires the cooperation from the OIC Member States.
2. 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)..
3. National Capability Building through: Training, Knowledge and Experience Sharing (involvement of OIC vaccine manufacturers, WHO and other well known institutes in Europe to arrange for training and workshops).
4. Development of Quality Management System (QMS).
5. 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.
6. Preparation of technical and economical feasibility studies.
7. Pooling Mechanism within the OIC for procurement.
8. Participation in the process of development and harmonization of standards on vaccines within the OIC in accordance with the WHO standards.
9. National Regulatory Authority has to be recognized as fully functional by WHO. Enhance understanding among OIC Member States on the importance of

- Strengthening NRA Function on SRVPA to ensure quality, safety and efficacy of medicines and vaccines
10. Good distribution practice (GDP) for vaccine to increase immunization coverage (meeting WHO standards for maintaining of cold chain).

## II. Medium Term Actions (2017-2019):

1. Increase capacity for vaccine production.
2. Collaboration and joint investment in advanced bio-technology.
3. Strengthening cooperation on capability development.
4. Provision of incentives from the Governments for investment in vaccine manufacturing in OIC countries.
5. Strengthening cooperation with international partners including WHO, UNICEF and GAVI.
6. Strengthening standards in accordance with WHO requirements.

## III. Long Term Actions (2020 and beyond):

1. 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.
2. Cooperation for joint development and joint production of raw materials (bulk antigens).
3. Further expansion of OIC indigenous manufacturing capacity.

## **MOVING FORWARD**

1. Commitment to develop joint capability and capacity in integrated manner in the field of vaccine production and availability, as well as strengthen relationship and partnership, hence establishment of Manufacturers Group of OIC Member States
2. Fill the vaccination gap within the OIC member states with Pooling Procurement Mechanism to procure vaccines.
3. Identification and Establishment of research centre (Centre of Excellence).
4. Request financing from Islamic Development Bank (IDB) or any other financing organization to assist capacity and capability building of vaccine producers, National Regulatory Authorities, National Control Laboratories from OIC Member States for achieving Self Reliance Vaccine Production and Availability (SRVPA).
5. Further discussion to describe detailed action to be taken, target setting or Key Performance Indicator, estimated timeline and partners for implementing programs.