Expert Group Meeting on Strengthening Regional Cooperation in Healthcare Biotechnology and Biomedical Sector

ESCAP-APCTT

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Director
Malaysia Genome and Vaccine Institute
22 MAC 2022
CAPACITY BUILDING FOR THE PRODUCTION OF LOCAL HUMAN VACCINE – LESSONS FROM COVID-19 PANDEMIC

01 National Vaccine Development Roadmap

- National Science Council Bil.2/2020, 14 July 2020
  - Commissioned a study for the National Vaccine Development Roadmap

02 National Vaccine Institute

- The Prime Minister in a statement gave the mandate to MOSTI to focus on the development of a local human vaccine

PM: MOH handles vaccinations, health strategies; Mosti to focus on R&D

Bernama
Published: Aug 26, 2021 4:16 PM · Updated: 6:16 PM

All vaccination-related programmes and health strategies related to Covid-19 will from now on only be handled by the Health Ministry through its newly appointed minister Khairy Jamaluddin, said Prime Minister Ismail Sabri Yaakob.

He said the Science, Technology and Innovation Ministry (Mosti), now helmed by former health minister Dr Adham Baba, will focus on research and development (R&D) to produce Covid-19 vaccines.
Launching of the National Vaccine Development Roadmap (NVDR) and transformation of Malaysia Genome and Vaccine Institute (MGVI) on 1st November 2021

“Through the implementation of PPVN and establishment of MGVI, highly skilled human capital in various fields of research especially those related to healthcare and vaccines can be produced.”

Datuk Seri Ismail Sabri Yaakob
Prime Minister
NATIONAL VACCINE DEVELOPMENT ROADMAP BACKGROUND & OBJECTIVES

- National Science Council Meeting in 2020
- Proposal to develop a roadmap on vaccine development
- MOSTI and MOH co-chair the committee to monitor development of roadmap
- Development of the National Vaccine Development Roadmap

**ASPIRATION**
Malaysia to become self-sufficient in vaccine manufacturing and R&D within 10 years

**ROADMAP OBJECTIVES**
To develop a national roadmap that will enable stakeholders and government to understand the as-is scenario and the gaps within the vaccine industry
To formulate a strategic plan from a short term, mid-term and long term perspective to develop Malaysia’s capability towards becoming a vaccine producing country
PROPOSED STRATEGY FRAMEWORK

Proposed strategy framework will focus on each Critical Pathways to formulate specific strategies that will enable local vaccine development.
Research and Development

Pilot Scale GMP Facility

MGVI
Malaysia Genome and Vaccine Institute

ICR
MINISTRY OF HEALTH MALAYSIA
(Research that matters to patients)

CRM
CLINICAL RESEARCH MALAYSIA
Your Global Solutions in One Nation

SOLBIO™

MVP
MALAYSIAN VACCINES AND PHARMACEUTICALS
( Co. No. 82361-X )

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MANUFACTURING INFRASTRUCTURE STRATEGY – ACTION PLAN (1/2)

The action plan includes using the PPP model to develop vaccine manufacturing capabilities, collaboration with global network for ease of market entry and identification of vaccine in demand, as well as developing halal certification capabilities.

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<tr>
<th>Parameters</th>
<th>Activities</th>
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<tr>
<td>R&amp;D Support</td>
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<td>Raw Materials</td>
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<td>Manufacturing Facility</td>
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- **Access potential local manufacturers to build up PPP**
- **Develop fill and finish**
- **Initiate partnership with public and private entities**
- **R&D Support**
- **Initiate collaborations with raw materials producers**

The table below outlines the activities and timeframes for the action plan:

- **Short Term (1 to 3 years)**
- **Medium Term (3 to 6 years)**
- **Long Term (6 to 10 years)**

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<th>Parameter</th>
<th>Activities</th>
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<tr>
<td>R&amp;D Support</td>
<td>Initiate collaboration between research centers with manufacturers (local/global)</td>
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<td>Acquire GLP certification for research labs</td>
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<td>Create specific funding programs for early-stage new vaccine researches</td>
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<td>Highlight the R&amp;D done currently on vaccines by research centers to assess stability to move to commercialization</td>
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<td>Enhance the capability of existing private labs owned by small players to be able to conduct preclinical studies or early stage of vaccine R&amp;D</td>
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<td>Conduct R&amp;D in various aspects aside from the biologics such as adjuvants, additives, new chain technologies, animal models, process development</td>
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<td>Create specific funding programs for early-stage new vaccine researches</td>
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<th>Manufacturing Facility</th>
<th>Assess potential local manufacturers in order to build PPP for vaccine ecosystem building based on their capacity</th>
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<th>Y2</th>
<th>Y3</th>
<th>Y4</th>
<th>Y5</th>
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<td>Develop fill and finish infrastructure with GMP and other relevant certification</td>
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<td>Develop bulk manufacturing infrastructure with GMP and other relevant certification</td>
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<td>Develop expertise and capabilities on cold chain for human vaccine storage and distribution</td>
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<td>Ensure participation of existing players in packaging manufacturing (syrings, vials) to manufacture packaging for human vaccines</td>
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<td>Initiate partnerships with public or private entities (such as academic organizations, universities, and financing institutes) to acquire know how and/or technology</td>
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<td>Support local vaccine manufacturers to secure supply contract to international organizations like GAVI, UNICEF, and PAHO. Existence of market is critical for local manufacturers to proceed with development and manufacturers.</td>
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<td>Participate in local and global manufacturers’ networks or associations to do advocacy, exchange experiences, training etc. (e.g. Developing Countries Vaccine Manufacturers Network (DCVMN))</td>
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<td>Ensure there is a system between the manufacturer and government to monitor adverse events after product commercialization</td>
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| Raw Materials | Initiate collaboration with raw materials producers to prepare for bulk manufacturing of vaccines | | | | | | | | | |
Vaccine manufacturing

Talent development

Diagnostic

Supply chain

Clinical trial hub

Raw material

Open-sharing facility

Affordable vaccine