ASEAN Capacity for Vaccine Research and Development and Production

Malaysia Country Case Study
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Executive Summary

Malaysia, with a population of 32.7 million (2021) and a growth rate of 0.2 percent, is relatively small among ASEAN nations, ranking fifth in population size. Malaysia’s National Immunization Program (NIP) is fully financed by the Government and provides free vaccines to all children, regardless of income. The NIP includes vaccines to prevent and control 13 diseases, many of which have achieved greater than 95 percent coverage. Malaysia began vaccinating its adult population against COVID-19 in February 2021 following the initiation of the National COVID-19 Immunization Program (PICK); eligibility was later expanded to include teens (beginning in September 2021) and children ages 5-12 (in February 2022).

Malaysia has no domestic human vaccine manufacturing capacity and imports all vaccines for the NIP as well as for COVID-19. Procurement of NIP vaccines is accomplished through government central tender contracts, under MOH oversight, and managed by Pharmaniaga Bhd, a government-linked organization; vaccines are distributed to facilities nationwide by a Pharmaniaga subsidiary. Procurement of COVID-19 vaccines, however, was overseen by a Special Committee comprised of representatives from the Ministries of Health (MOH) and Finance (MOF) and the Ministry of Science, Technology and Innovation (MOSTI) due to complex market conditions driven by the limited number of manufacturers and resource-rich vaccine-producing countries. MOH and local health departments oversee distribution, storage, and delivery of NIP and COVID-19 vaccines, including among hard-to-reach populations living in remote areas.

In November 2021, recognizing the security threat posed by relying on other countries for its vaccine supply, the Malaysian Prime Minister launched the National Vaccine Development Roadmap (NVDR), which envisions Malaysia achieving self-sufficiency in vaccine manufacturing and R&D within 10 years. Under the NVDR, Malaysia has allocated nearly US$8 million to establish a National Vaccine Research Center, which will focus on vaccine R&D, pre-clinical and clinical study of new vaccines.

Domestic manufacturers have already made investments and are keen to further expand their capacity if a wider regional market were available.

The Malaysia Genome Institute will also be expanded and renamed the Malaysia Genome and Vaccine Institute (MGVI), with a charge of boosting coordination among various groups currently engaged in isolated R&D efforts.

In addition to its emerging R&D capacity, Malaysia has established human vaccine fill-and-finish capacity within three domestic pharmaceutical companies, two of which have plans to increase production capacity; it also has domestic capacity for animal vaccine manufacturing. What Malaysia lacks is the capacity for full-spectrum vaccine manufacturing, from R&D to large-scale production. To bring the country to this level, stakeholders interviewed as part of this study reported the following challenges:

1. Need for more upfront investment by the Government to move projects from R&D to human clinical trials and beyond;
2. Need for increased focus and investment to bring the National Regulatory Authority to WHO Maturity Level 3;
3. Inadequate access to raw materials needed for upstream production;
4. Need for established relationships with foreign manufacturers for technology transfer;
5. Need for new vaccine bioprocessing platforms and technology in R&D and manufacturing;
6. Shortage of trained human resources with skills, experience and knowledge of full vaccine development and manufacturing processes;
The Malaysian government has put incentives in place to attract investment in pharmaceutical manufacturing, including a preferential tax rate and relocation incentive. But manufacturers report that Malaysia’s small population size makes it hard to justify the substantial investment required for vaccine manufacture, especially without an established regional market to access.

In sum, Malaysia has political will and broad stakeholder support for building a vaccine security ecosystem and has already begun taking steps towards this goal. It has a well-established vaccine delivery system which was further strengthened during COVID-19, and which could serve as a model for other countries in the region that struggle to achieve high vaccination coverage and reach vulnerable groups. It has some domestic experience in vaccine R&D and growing expertise in clinical trial conduct and oversight, and is poised to support the regional vaccine ecosystem from this early stage of vaccine development. It has substantial experience in fill-and-finish production and an established base for veterinary vaccines which are exported to several countries. In addition, the mature rubber industry in the country can contribute to the global vaccine manufacturing supply chain. Domestic manufacturers have already made investments and are keen to further expand their capacity if a wider regional market were available, for example by introducing common vaccination schedules and packaging, or harmonizing regulatory approvals across ASEAN nations. Malaysia would benefit from regional efforts to capacitate staff with skills in vaccine R&D and modern manufacturing technologies while addressing export restrictions and other trade barriers.
**Introduction**

COVID-19 has devastated the ASEAN region, threatening two decades of human and economic development gains. With a population of more than 600 million, the region has reported more than 13 million COVID-19 cases as of October 2021, with Indonesia, the Philippines, Malaysia, and Thailand leading in number of confirmed cases. In the absence of effective treatment options, vaccination and preventative behaviors remain cornerstones for ASEAN governments to stop COVID-19’s spread, save lives, and revive economies. Despite rapid innovation and development of mRNA, viral vector, and protein subunit vaccine technology platforms, low and middle-income countries (LMICs) continue to struggle to access vaccines. ASEAN countries have remained net importers of essential vaccines, notwithstanding strong potential for local research and manufacture. Consequently, COVID-19 vaccination coverage varies widely, ranging from 10 percent in Myanmar to 80 percent in Singapore. These disparities render the region vulnerable to new variants, surges, and vaccine escape. To contain COVID-19 and respond to future pandemics, ASEAN must build strong regional capacity to develop, test, and scale up manufacture of vaccines—building on country-level strengths and avoiding duplication. Galvanizing ASEAN vaccine development and manufacturing efforts aligns with the November 2019 declaration of ASEAN leaders on regional vaccine security and self-reliance.

**Proposed Research and Value Addition of the Project**

While some evidence on regional vaccine manufacturing capacity for ASEAN exists, there has been limited research on the technical, operational, financing and strategic partnership opportunities that exist in the region and might be leveraged to advance regional vaccine security. To address this knowledge gap, the United Kingdom Foreign, Commonwealth and Development Office (UK FCDO) and the World Bank initiated the ASEAN Vaccine Development and Manufacturing Research Project. This project complements the ASEAN Vaccine Security and Self-Reliance (AVSSR) Initiative and the Coalition for Epidemic Preparedness Innovations (CEPI) 2021 plan, and supports the November 2019 declaration of ASEAN leaders on regional vaccine security and self-reliance.

The proposed research will assist senior policy makers to identify options to accelerate regional vaccine manufacture and to overcome barriers, including through identification of foreign direct investment opportunities. The research will involve a combination of desk reviews and stakeholder interviews to prepare a regional-level scoping of ASEAN’s vaccine landscape, including gaps and opportunities across the value chain from R&D to last mile distribution. In addition, five ASEAN countries—Indonesia, Malaysia, Philippines, Thailand and Vietnam—were selected to conduct detailed analyses of their country’s current vaccine system, including current processes related to procurement and distribution, manufacturing capabilities (current or potential), and regulatory systems related to domestic vaccine registration and production. The outputs of this research initiative will include a report summarizing policy and financing options...
for vaccine manufacturing in the region, country case studies, and knowledge exchange sessions with policy leaders and other relevant stakeholders.

The country case study for Malaysia will include: i) information on COVID-19 vaccine research and development, trials, and manufacturing, gained through a literature review of relevant information, conversations with key informants and stakeholders, and information from other formal or informal sources; and ii) a deep-dive case study on value proposition for vaccine manufacturing in Malaysia covering both public and private sectors (including for COVID-19), with a focus on a) the demand for various vaccines within the country; b) current production and/or scope for future production of key components of the vaccine value chain (i.e. active ingredients, fill and finish, manufacturing and packaging, logistics, and last mile support and underlying technology); c) existing partnerships and potential hubs for vaccine manufacture in the country; d) local availability of human resources for different components of the vaccine value chain; e) regulatory framework and incentives for domestic vaccine manufacture; and f) trends in import and export of vaccines and sources before and during COVID-19 pandemic.

Malaysia Country Context

Malaysia has the fifth largest population among ASEAN member states with an estimated population in 2021 of 32.7 million and an annual population growth rate of 0.2 percent. The decline in the population growth rate was due to the lower number of non-citizens residing in Malaysia, from 3.0 million in 2020 to 2.7 million in 2021. This was in line with the closure of national borders and the return of foreigners to their respective countries during the Movement Control Order (MCO) following the spread of the COVID-19 pandemic worldwide. The growth rate of citizens remained stable at 1.0 percent with the population increasing from 29.7 million in 2020 to 30.0 million in 2021. In 2021, the male population outnumbered the female population by almost 1 million (16.8 million males versus 15.9 million females).

Nearly one quarter (23 percent) of the Malaysian population was under 14 years of age in 2021, while the percentage of the population aged 15-64 was nearly 70 percent. The median age increased from 29.3 years in 2020 to 29.6 years in 2021. The population of Malaysia in 2021 was 70 percent Bumiputera (Malay), 22 percent Chinese, and nearly 7 percent Indian; this distribution is consistent with 2020 data. The three states with the highest population composition in 2021 were Selangor (20 percent) Sabah and Johor (just under 12 percent). Population density varies greatly across Malaysia. On average, the country has a population density of 99 persons per square kilometer, though urban centers like W.P. Kuala Lumpur have much higher population densities (7,188 persons per square kilometer in Kuala Lumpur).¹

Burden of Disease

¹ The Current Population Estimates, Malaysia, 2021; Released By: Dato' Sri Dr. Mohd Uzir Mahidin, Chief Statistician Malaysia, Department of Statistics, Malaysia 15th July 2021
The latest National Health and Morbidity Survey 2019 shows that the prevalence of non-communicable diseases (NCD) in Malaysia continues to rise. A new report from the Ministry of Health (MOH) Malaysia and the World Health Organization (WHO) reveals that noncommunicable diseases (NCDs), particularly cardiovascular diseases, diabetes and cancer, cost the Malaysian economy upwards of RM 8.91 billion, equivalent to about 0.65 percent of the country’s gross domestic product (GDP). Tobacco use, unhealthy diet, harmful use of alcohol and physical inactivity are modifiable behavioral risk factors that increase the risk of NCDs. In the report, unhealthy diet contributed to over two-thirds (69 percent) of the cost of lost productivity due to premature deaths from cardiovascular diseases (CVDs), while tobacco use contributed to more than one-third (37 percent) of losses.

Risk factors associated with COVID-19 mortality in Malaysia include advanced age and the presence of comorbidities like hypertension and diabetes mellitus, suggesting that effective prevention strategies, such as encouraging acceptance of the COVID-19 vaccination and adhering to social distancing and community quarantine measures could help reduce infection and mortality rates among high-risk populations. Despite the pandemic, efforts to prevent and control the spread of infectious diseases in Malaysia are still ongoing. The government has updated ‘The Prevention and Control of Infectious Diseases’ Regulations to better coordinate measures to control the COVID-19 pandemic and the transmission of other infectious diseases in Malaysia.

Table 1. Incidence and mortality rate of communicable diseases, 2020 (per 100,000 population)

<table>
<thead>
<tr>
<th>Communicable Diseases</th>
<th>Incidence Rate</th>
<th>Mortality Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Food and Water Born Diseases</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cholera</td>
<td>0.35</td>
<td>0.00</td>
</tr>
<tr>
<td>Dysentry</td>
<td>0.48</td>
<td>0</td>
</tr>
<tr>
<td>Food Poisoning</td>
<td>28.93</td>
<td>0.02</td>
</tr>
<tr>
<td>Hepatitis A</td>
<td>0.14</td>
<td>0</td>
</tr>
<tr>
<td>Typhoid and Paratyph</td>
<td>0.20</td>
<td>0</td>
</tr>
<tr>
<td><strong>Vaccine Preventable Disease</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diphtheria</td>
<td>0.04</td>
<td>0.02</td>
</tr>
<tr>
<td>Acute Poliomyelitis</td>
<td>0.00</td>
<td>0.01</td>
</tr>
<tr>
<td>Others Tetanus</td>
<td>0.06</td>
<td>0.01</td>
</tr>
<tr>
<td>Neonatal Tetanus</td>
<td>0.03</td>
<td>0.01</td>
</tr>
<tr>
<td>Pertusis</td>
<td>0.42</td>
<td>0.02</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>12.64</td>
<td>0.26</td>
</tr>
<tr>
<td>Other Specified Viral Hepatitis</td>
<td>0.02</td>
<td>0</td>
</tr>
<tr>
<td>Measles</td>
<td>1.46</td>
<td>0.00</td>
</tr>
<tr>
<td><strong>Vector Borne Diseases</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chikungunya</td>
<td>7.98</td>
<td>0</td>
</tr>
<tr>
<td>Dengue Fever</td>
<td>276.11</td>
<td>0</td>
</tr>
<tr>
<td>Dengue Haemorrhagic</td>
<td>1.04</td>
<td>0.45</td>
</tr>
<tr>
<td>Japanese Encephalitis</td>
<td>0.09</td>
<td>0.01</td>
</tr>
<tr>
<td>Malaria</td>
<td>8.71</td>
<td>0.02</td>
</tr>
<tr>
<td>Plague</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Relapsing Fever</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Typhus</td>
<td>0.03</td>
<td>0</td>
</tr>
<tr>
<td>Yellow Fever</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Zika Virus Infections</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Filariasis</td>
<td>0.71</td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Communicable Diseases</th>
<th>Incidence Rate</th>
<th>Mortality Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tuberculosis/Leprosy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>72.57</td>
<td>7.12</td>
</tr>
<tr>
<td>Leprosy</td>
<td>0.60</td>
<td>0.02</td>
</tr>
<tr>
<td><strong>Sexually Transmitted Infections</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AIDS</td>
<td>3.19</td>
<td>1.50</td>
</tr>
<tr>
<td>HIV</td>
<td>9.66</td>
<td>0.41</td>
</tr>
<tr>
<td>Chancroid</td>
<td>0.01</td>
<td>0</td>
</tr>
<tr>
<td>Gonorrhea</td>
<td>7.18</td>
<td>0</td>
</tr>
<tr>
<td>Syphilis</td>
<td>10.63</td>
<td>0.05</td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>10.13</td>
<td>0.25</td>
</tr>
<tr>
<td><strong>Zoonosis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Avian Influenza</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Ebola</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Hand, Foot and Mouth Diseases</td>
<td>52.90</td>
<td>0</td>
</tr>
<tr>
<td>Leptospirosis</td>
<td>8.94</td>
<td>0.12</td>
</tr>
<tr>
<td>Rabies</td>
<td>0.03</td>
<td>0.02</td>
</tr>
<tr>
<td>Viral Encephalitis</td>
<td>0.09</td>
<td>0.01</td>
</tr>
<tr>
<td>Nipah</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Others Viral Encephalitis</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Surveillance</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mers-Cov</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>COVID-19</td>
<td>360.25</td>
<td>1.48</td>
</tr>
</tbody>
</table>

Sources: Ministry of Health Malaysia, 2020; Ministry of Health Malaysia, 2021; Ismail SN, 2022.
The Impact of COVID-19 on Service Delivery

The first case of COVID-19 was detected in Malaysia on January 25, 2020. In response to a quickly evolving pandemic situation, the government enacted community quarantine measures beginning in March 2020. Before a vaccine was available, quarantine restrictions were determined by the number of cases and available hospital capacity. Malaysia established the National COVID-19 Immunization Program (PICK) in early 2021 to be administered by the Special Committee for Ensuring Access to COVID-19 Vaccine Supply (JKJAV); it is the largest immunization program in the history of the country. PICK was implemented in phases beginning in end-February 2021; the first groups vaccinated included healthcare workers and frontliners followed by additional target groups as summarized in Table 2. On February 3, 2022, the Government launched the National COVID-19 Immunization Program for Children (PICKids), which expanded vaccine eligibility to children age 5-12.

Table 2. COVID-19 vaccination campaign (PICK) implementation strategy

<table>
<thead>
<tr>
<th>Flow</th>
<th>Target group</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 1</td>
<td>Healthcare workers and frontliners comprising essential services, defense and security personnel</td>
<td>26 February 2021 – April 2021</td>
</tr>
<tr>
<td>Phase 2</td>
<td>High-risk groups; including disabilities, senior citizens and elderly people with comorbidities</td>
<td>April – August 2021</td>
</tr>
<tr>
<td>Phase 3</td>
<td>Adults aged 18 and above consisting of citizens and non-citizens.</td>
<td>May 2021 – February 2022</td>
</tr>
<tr>
<td>Phase 4</td>
<td>Workers in critical industries: food, manufacturing, construction, retail, plantation, and hospitality</td>
<td>14 June 2021 onwards</td>
</tr>
<tr>
<td>Phase 5</td>
<td>Adolescents aged from 12 to 17 with underlying medical conditions</td>
<td>8 September 2021 onwards</td>
</tr>
<tr>
<td></td>
<td>Adolescents aged from 12 to 17 with no medical issues based on age de-escalation</td>
<td>20 September 2021 – present</td>
</tr>
</tbody>
</table>

Source: JKJAV, 2021

Beginning in April 2022, Malaysia entered into a COVID-19 endemic phase. As of November 2022, Malaysia had recorded over 4.9 million cases of COVID-19 and over 36,548 deaths. At the same time, over 72 million doses of vaccine have been administered, with 27 million persons—84 percent of the population—fully vaccinated with two doses; over 16 million people have received a booster dose.³

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² The original table, depicted in the document ‘National COVID-19 Immunization Program,’ prepared by JKJAV, contained just three phases; the final two phases were added after the document’s publication date.
³ [https://data.moh.gov.my/covid-vaccination](https://data.moh.gov.my/covid-vaccination) Date: 12th December 2022
Immunization Program and Vaccine Procurement

Brief Summary of National Immunization Program

The Malaysian National Immunization Program (NIP) was introduced in the 1950s to curb the spread of infectious disease; it is based on the Expanded Immunization Program designed by the World Health Organization (WHO). The NIP provides free vaccination services to all children in Malaysia, regardless of income, to prevent and control thirteen (13) diseases: tuberculosis, Hepatitis B, diphtheria, tetanus, whooping cough (pertussis), polio, *Haemophilus influenzae* type B (HiB), measles, mumps, rubella, Japanese encephalitis (JE), pneumococcal disease (beginning January 2020), and cancer caused by the human papilloma virus (HPV). The 2021 national immunization schedule is shown in Table 3. In November 2020, MOH introduced the 6-in-1 vaccine (diphtheria, tetanus, pertussis, polio, HiB and Hepatitis B) in line with advancements in other developed countries. Coverage data show greater than 95 percent coverage for a number of vaccines (Table 4).

Table 3. National Immunization Schedule, 2021

![Table 3](https://example.com/table3.png)

Source: Immunise4Life, Ministry of Health Malaysia

---

4 Ministry of Health Malaysia; Immunise4Life programme by Ministry of Health Malaysia, Malaysian Paediatric Association and Malaysian Society of Infectious Diseases & Chemotherapy, supported by the Vaccination is Protection for Kids initiative. From CodeBlue 19 November 2020, [https://codeblue.galencentre.org](https://codeblue.galencentre.org)
Table 4. Childhood immunization coverage, 2020

<table>
<thead>
<tr>
<th>Vaccination</th>
<th>Coverage Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>B.C.G. Immunisation of Infants&lt;sup&gt;1&lt;/sup&gt;</td>
<td>98.80%</td>
</tr>
<tr>
<td>DPT - HIB Immunisation Coverage of Infants (3rd Dose)&lt;sup&gt;2&lt;/sup&gt;</td>
<td>97.68%</td>
</tr>
<tr>
<td>Polio Immunisation Coverage of Infants (3rd Dose)&lt;sup&gt;3&lt;/sup&gt;</td>
<td>97.68%</td>
</tr>
<tr>
<td>MMR Immunisation Coverage of Children Aged 1 to &lt; 2 years</td>
<td>97.42%</td>
</tr>
<tr>
<td>Hepatitis B Immunisation Coverage of Infants (3rd Dose)&lt;sup&gt;4&lt;/sup&gt;</td>
<td>101.23%</td>
</tr>
<tr>
<td>HPV Immunisation Coverage of Girls 13 years (2nd Dose)&lt;sup&gt;5&lt;/sup&gt;</td>
<td>95.73%</td>
</tr>
</tbody>
</table>

<sup>1</sup>Denominator: Live births from TBI (Births Information System)
<sup>2</sup>Denominator: Live births (2019) from Department of Statistics, Malaysia
<sup>3</sup>Denominator: Female population aged 15 years
<sup>4</sup>Preliminary

Source: Ministry of Health Malaysia, 2021
Quantity, Sources and Budget of Procured Vaccines

Table 5. Financial allocation, 2021

![Financial Allocation, 2021](image)

*Source: Ministry of Health Malaysia, 2021*

Table 6. National Health Accounts 2018-2020

![National Health Accounts](image)

*Source: Ministry of Health Malaysia, Malaysia National Health Accounts Database, 1997-2019*

In 2019-20, the budget for vaccines in Malaysia was approximately US$85 million, of which US$63 million was allocated for child vaccines. Among vaccines for children, US$19 million was allocated for pneumococcal vaccine, US$21 million for hexavalent (6-in-1) vaccine, and US$1 million for HPV vaccine. There are no specific adult vaccines included in the NIP; the most common adult vaccines are: Hepatitis B (for healthcare workers), influenza, typhoid (for food handlers), meningococcal (for Hajj pilgrims), yellow fever and cholera vaccines (in select regions).
In 2021, the vaccine budget increased dramatically due to the availability of COVID-19 vaccines; US$1.06 billion was allocated for the vaccination program that year, which included COVID-19 vaccines, consumables, and logistics costs. Of that amount, US$746 million was allocated for COVID-19 vaccination program alone. The budget allocation for the NIP in 2022 includes an
additional increase of US$242.5 million from the previous year, bringing the total budget to US$1.298 billion; out of this amount, US$422 million was allocated for the COVID-19 vaccination program while the remaining US$869 million went towards vaccine procurement (for booster vaccine and updated vaccines), post-immunization surveillance, outsourcing of private medical practitioners, and contingencies for other medical and health expenses for 2022.  

Vaccine Procurement

Pharmaniaga Bhd, a government-linked organization, has a long-standing concession agreement with MOH for the provision of medicines and medical supplies to MOH facilities. Pharmaniaga, which has warehousing and logistics facilities, is the biggest Bumiputera tender agent in the country, with exclusive concession to supply 700 items in the Approved Product Purchase List (APPL)—comprised of medicines and other medical items determined by MOH—to government hospitals, institutions, and clinics; this makes up over one-third of the government’s drug supply. Pharmaniaga also separately provides logistics and distribution of all products in the APPL for MOH, beyond the 700 items it procures.

The current concession agreement between MOH and Pharmaniaga Bhd has been extended through the end of December 2022. The extension was granted to its wholly-owned subsidiary, Pharmaniaga Logistics Sdn Bhd (PLSB), through which 400 items are supplied from Pharmaniaga to MOH and another 300 items are from open tender. The extension also allows PLSB to provide logistics and distribution services to MOH for five years through the end of December 2024. The new logistics and distribution concession agreement will be completed by the end of 2022, which is expected to include the same scope of services as the previous agreement.

MOH complies with an eProcurement system in which there is no direct negotiation on tender or contract value. Any tender value or supply worth more than RM1 million (approximately US$227,000) must be submitted and procured via eProcurement managed by the Ministry of Finance (MOF). On the other hand, any tender value or supply worth less than RM1 million can be initiated directly by an individual MOH clinic or hospital. Further information on the government procurement process is presented in detail on the Ministry of Finance website under Government eProcurement, as well as on the Ministry/Government Agency website under the tender/quotation category. For any international competitive bidding, limited international bidding, procurement through UN agencies, or bilateral contracts with companies related to vaccine supply, the process must proceed through the appropriate procedure set by the MOF. Any special vaccine supply arrangement should also be reviewed by MOH.

NIP vaccines and injection supplies are included in the MOH operational budget. Vaccines are procured through government central tender contracts and delivered to all government health facilities throughout the country. This management mechanism ensures timely vaccine delivery.

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5 Ministry of Health Malaysia; Malaysian National Budget Speech 2021 and 2022; IQVIA and NVDR 2021
6 Pharmaniaga press release.
good cold chain maintenance and efficient vaccine supply with minimal disruptions. MOH Malaysia rarely experiences a stock out of vaccine supply.

For COVID-19 vaccines under the NIP (from 2020 onwards), a specific procurement process was initiated through the Ministry of Science, Technology and Innovation (MOSTI), MOH and MOF, leading to the establishment of the Special Committee for Ensuring Access to COVID-19 Vaccine Supply (JKJAV) in October 2020. All COVID-19 procurement was required to be vetted and approved by the JKJAV committee. Of the 88.1 million doses of COVID-19 vaccine that were delivered to Malaysia, more than half were Pfizer vaccine (51.4 million doses), followed by Sinovac vaccine (20.4 million doses), AstraZeneca vaccine provided via COVAX facility (6.4 million doses) or procured by Malaysia (6.4 million doses), and Cansino vaccine (3.5 million doses).

Vaccine Management System

MIMOS, Malaysia’s national applied research and development center under MOSTI, developed the Vaccine Management System (VMS) to ensure strong vaccine management practices within the COVID-19 National Immunization Program (Program Imunisasi Covid-19 Kebangsaan, or PICK). VMS is a comprehensive IT platform that integrates a number of activities related to vaccine supply, logistics, tracking and delivery to the targeted population; specifically, it tracks vaccine movement through the supply chain; allows for traceability based on vaccine serial number; provides vaccination status to authorities in the form of Digital Health Certificates; prevents counterfeit vaccines; provides vaccination status checks and monitors for eligibility for subsequent vaccine doses; and allows patients to provide feedback on vaccine symptoms. The VMS project was developed with the support of MOH, who now has full ownership of the program. It can be accessed by the public via http://www.pharmacy.gov.my/vms/ and downloaded by doctors and the authorized body of the COVID-19 vaccination program.

Vaccine Delivery and Distribution

The logistics surrounding vaccine distribution can be broken into three components: (1) logistics and resources to deliver the vaccine; (2) storage facilities and capacity; and (3) temperature control across the supply chain. The government of Malaysia has extensive experience with vaccine distribution including to rural villages and urban areas throughout the country. These distribution plans involve health departments (under MOH oversight) that are capable of administering vaccines among hard-to-reach populations, including those that must be reached by mobile units deployed to particularly remote areas. For NIP vaccines, Pharmaniaga Bhd, which distributes a significant portion of MOH facilities’ medicine supply, has logistics and distribution experience covering minus 20°C and 2-8°C temperature requirements. Through MOH, the government of Malaysia has diligently supported vaccine distribution and its logistics partners with knowledge and supply chain facilities that are capable of handling, storing and delivering vaccines to Malaysians.

7 The Malaysian government is bound by non-disclosure agreements (NDA) with vaccine manufacturers, which prevent the details of each agreement from being disclosed, including the price of the vaccine.
There are guidelines in Malaysia to ensure that high standards of quality assurance and integrity are maintained in vaccine distribution processes. All involved parties, including manufacturers, importers and wholesalers of any type of vaccine, are required to comply with proper distribution and storage procedures to ensure product quality, efficacy and safety. These procedures should include the management of personnel, premises, facilities, transportation and adequate documentary procedures. The relevant guidelines relating to vaccine delivery are as follows:


The biggest challenge related to COVID-19 vaccine storage and distribution involves the handling of ultra-cold vaccines (i.e. Pfizer-BioNTech COVID-19 vaccine), since the equipment needed for these vaccines is not standard in vaccination centers throughout Malaysia. However, MOH worked with a vaccine supplier to conduct trainings and initiate a special vaccine logistics process. Deep freezers (-70°C) were then sent to specific vaccination centers throughout the country before the Pfizer-BioNTech vaccine was delivered to the sites. See Figure 3 for pictorial representation of the Pfizer-BioNTech vaccine delivery process.
Projected Needs of Vaccines: The National Vaccine Development Roadmap

The National Vaccine Development Roadmap (NVDR) was launched in November 2021 by the Prime Minister of Malaysia and is divided into three phases over a 10-year period (2021-2030). The NVDR envisions Malaysia achieving self-sufficiency in vaccine manufacturing and R&D within 10 years in order to safeguard its national biosecurity, while at the same time developing a self-sustaining vaccine ecosystem; in this way it will also contribute to the economy. The main objectives of the roadmap are: i) to enable stakeholders and the government to understand the current scenario and gaps within the domestic, regional and global vaccine industry; and ii) to formulate short-, medium- and long-term strategic plans to enable Malaysia to become a vaccine-producing country. The NVDR does not focus solely on COVID-19 but includes the development of vaccines for other diseases as well. Under the NVDR framework, the Malaysia Vaccine Sectoral Working Group, comprised of representatives from various ministries and agencies, and the Malaysian Vaccine Project Office (MVPO) were created to plan, implement and monitor the National Vaccine Development Project.

Under the NVDR, the government has allocated RM35 million (US$7.9 million) to establish a National Vaccine Research Center (NVRC), which will focus on vaccine R&D, pre-clinical and clinical study for new vaccines. It has also proposed to fund the establishment of a Production
Vaccine Development Center for RM5-10 million (US$1-2 million), which includes civil construction, equipment and consulting costs.

In line with these objectives, the Malaysia Genome Institute has been upgraded to the Malaysia Genome & Vaccine Institute (MGVI). The MGVI is entrusted with conducting research and development of vaccines for the country and establishing a Consortium of Vaccine Expert Council for Vaccine Research and Development, which is divided into four main areas: (1) vaccine discovery; (2) pre-clinical study; (3) clinical trials; and (4) process development and ecosystem.

The establishment of the MGVI will support vaccine research for new infectious diseases, boost collaboration, and expand access to research facilities to conduct vaccine research, which are in line with the National Policy on Science, Technology and Innovation (NPSTI) 2021-2030. The governance of the MGVI will be centralized under the National Institute of Biotechnology Malaysia (NIBM), while the activities will be disbursed throughout a number of facilities to better leverage existing capabilities. These facilities include:

1. Institute for Medical Research (IMR), to conduct vaccine discovery research (e.g., BSL-3 labs)
2. MGVI, to conduct vaccine discovery research and supporting R&D (e.g., genome sequencing)
3. Institute for Clinical Research, Clinical Research Malaysia, and hospitals for their experience and expertise in conducting clinical trials
4. IPharm, Institute for Medical Research, SIRIM and Veterinary Research Institute for their capabilities around conducting preclinical studies on animals
5. University Research Centers for their expertise in conducting vaccine R&D
6. Manufacturers for their contribution to process development

These existing facilities can be grouped into several Centers of Excellence based on critical functions of vaccine development. The Malaysia Investment Development Authority (MIDA) and the Technology Depository Agency (TDA) may assist in developing these Centers in the National Vaccine Research Center through the Industrial Collaboration Program, by attracting and engaging with foreign manufacturers to develop R&D capabilities, production facilities and processes, and human resources.

New Vaccines Under Development and Vaccine Platforms

Malaysia has existing healthcare infrastructure for conducting clinical trials, with a growing pool of qualified and well-trained investigators and support staff, robust ethical reviews by an Ethics Committee, and regulatory oversight by the NPRA. To date there have been 220 study sites in Malaysia where sponsored research has been conducted, with 66 percent of them at public hospitals and government clinics within the Ministry of Health. Malaysia has established human

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8 Clinical Research Malaysia Annual Report, 2021
clinical trial facilities for Phase II, Phase III and Phase IV; it also has two Phase I or ‘First in human’ trial facilities.\(^9\)

There are several small vaccine development projects currently underway in various government agencies, research institutes and private sector organizations in Malaysia. Specifically, IMR/National Institute of Health Malaysia is developing a leptospirosis vaccine using killed/inactivated vaccine platform technology; also in process is influenza vaccine development using three platforms – activated, mRNA, and vector platform technology. Malaysia’s National Influenza Center and IMR have received influenza samples from the public and private sector; IMR is also gathering data under the WHO Global Influenza Virological Surveillance and Response System.

In addition, prior to the initiation of the NVDR, a number of vaccine development projects had already been funded by MOH and MOSTI; they will be brought under the auspices of the NVDR.

**Project 1:** Two COVID-19 vaccines based on inactivated and mRNA technology will be developed by the Institute for Medical Research (IMR). This vaccine development will focus on Variant of Concern (VOC) COVID-19 which has been identified in Malaysia. The research fund for this project, which totals RM3.5 million (US$794,000) has been allocated by the Ministry of Health (under the ‘research project’ budget line item) and SUKUK Prihatin (through the ‘COVID-19 research allocation special aid’ fund).

**Project 2:** This project, titled “Development of Mucosal/Oral/Subunit Vaccines Against Cholera, Tuberculosis and COVID-19,” is a cholera vaccine study developed in collaboration with Universiti Sains Malaysia (USM) and Asian Institute of Medicine, Science and Technology (AIMST) with the Ministry of Science, Technology and Innovation (MOSTI) also providing funding in the amount of RM10.5 million, using the Strategic Research Fund (SRF8).

**Project 3:** A pre-clinical evaluation of “A Therapeutic Cancer Vaccine for The Treatment of Head and Neck Cancer” by Clinical Research Malaysia (CRM) at a cost of RM3 million is being financed by MOSTI.

Finally, the Malaysia Government has a Bilateral Investors Agreement with the Coalition for Epidemic Preparedness Innovation (CEPI) to enable Malaysia to gain access to vaccine R&D, technology transfer and new expertise for local researchers. Based on information from NVDR, MOSTI has provided RM3 million in funding to CEPI to support its work and advance vaccine development for emerging epidemic threats. Malaysia is also the first country outside of China to conduct Phase III Clinical Trials for an inactivated COVID-19 vaccine made by the Institute of Medicinal Biology Chinese Academy of Medical Sciences, China (IMBCAMS), which involves 3,000 volunteers.

\(^9\) National Vaccine Development Roadmap Strategy Framework, 2021
These R&D efforts, consolidated under the NVDR framework and combined with the fill and finish capacity within several vaccine manufacturers (see below) and the established rubber industry in Malaysia, an essential input in the global vaccine manufacturing supply chain, may together serve as a springboard to advance Malaysia’s efforts towards vaccine security and help achieve the regional goal of building a strong vaccine ecosystem in ASEAN.

Adverse Events Following Immunization (AEFI) and Pharmacovigilance Systems

Malaysia initiated its national pharmacovigilance system in 1987 with the establishment of the Malaysian Adverse Drug Reactions Advisory Committee (MADRAC). MADRAC acts as an advisory body to the Drug Control Authority (DCA) on local and international drug safety issues. The National Adverse Drug Reaction Monitoring Center, located within the National Pharmaceutical Regulatory Agency (NPRA), serves as the secretariat to MADRAC, and has been a member of the WHO Program for International Drug Safety Monitoring since 1990. One of the requirements for pharmaceutical companies is the establishment of a pharmacovigilance system within their organizations that can effectively identify and address deficiencies that may impact patient safety. This guideline, which is intended for product registration holders (PRHs), outlines the requirements and procedures of Good Pharmacovigilance Practices (GVP) including but not limited to the submission of adverse drug reaction (ADR) and adverse event following immunization (AEFI) reports, and the submission of information regarding product safety to the DCA.10

Robustness of Regulatory Systems

In response to the COVID-19 pandemic, the National Pharmaceutical Regulatory Agency (NPRA) introduced new ‘Guidance and Requirements on Conditional Registration for Pharmaceutical Products During Disaster’. These guidelines are broader than COVID-19 and cover any new pharmaceutical product including vaccines for use during a disaster. NPRA identified the need for this guidance as most pharmaceutical products (including vaccines) had yet to complete their Phase III clinical studies and so could not be fully registered in Malaysia due to lack of data. The main objective of the new guidelines is to provide expedited access to pharmaceutical products for treatment or prevention during disasters without compromising quality, safety and efficacy, using a risk-based approach. The guidelines state: i) the product should be at least in an on-going Phase III clinical study with preliminary data on safety and efficacy; and ii) the product must have been given authorization for use (via emergency use approval or any pathway equivalent to it) or obtained marketing authorization from national regulatory authorities of the country of origin or any Drug Control Authority (DCA) reference agency or the World Health Organization (WHO).

Upon submission of the required documentation and fulfillment of the above conditions, the guidelines state that NPRA will conduct a priority review within 70 working days from the date the complete application is received. If granted, a conditional registration is valid for one year;
thereafter, the conditional registration may be renewed twice, with the possibility of two extensions of one year each.

**Vaccine Registration Process**

In general, a complete quality program will be expected at the point of submission for the registration of new vaccines. The application must be submitted with detailed information on chemical manufacturing and controls; site(s) where the product, if registered, is or would be manufactured and the current status of that site with respect to current Good Manufacturing Practice (cGMP) requirements; and relevant information regarding the product supply chain. Such information assists NPRA in evaluating the availability of the product to the recipients and whether the anticipated storage conditions and distribution plan is likely to affect the safety and efficacy of the product. Any quality documents that are not available should be justified and are subject to the review of NPRA. During the COVID-19 pandemic, NPRA did not accept any documentation related to GMP certification from non-PIC/S countries.

**Applicability of Regional Harmonization Policy**

The ASEAN Common Technical Dossier (ACTD) is the main reference on the format of a registration application for drug products and pharmaceuticals for human use among ASEAN countries. This format is appropriate for NCE (New Chemical Entity), Biologics (Biotechnological Products and Vaccines), MaV (Major Variations), MiV (Minor Variations) and G (Generics). The ACTR Quality only provides the requirements for new product registration (NCE, Biologics, and Generics). For the requirements for variation of biotechnological products and vaccines, reference should be made to the WHO Guidelines on Procedures and Data Requirements for Changes to Approved Biotherapeutic Products (2017) and WHO Guidelines on Procedures and Data Requirements for Changes to Approved Vaccines (WHO TRS 993, Annex 4), respectively.

Evaluation processes for vaccine registration in ASEAN countries require documentation in three main areas: (i) GMP onsite inspection of the facilities, (ii) vaccine information based on Dossier Structure (CMC), and (iii) vaccine samples\(^{11}\) from a declared source of manufacturing. However, not all countries have the same registration standards. For example, some countries require that the vaccine be registered as a WHO pre-qualified vaccine, and some will accept the pre-qualification without further requirements for registration. Furthermore, each vaccine application must originate from the same source of manufacturing facilities as for finished products, though many vaccines are manufactured through fill and finish arrangements in which bulk vaccine preparations are used to produce vaccines at a site different from the origination point.

It is also noted that there is not yet ‘approval harmonization’ among ASEAN nations, meaning that an approval granted for vaccine registration in one ASEAN country is mutually accepted by

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\(^{11}\) Testing of vaccine samples refers to the final vaccine product from commercial batch. There is no testing required as far as registration process is concerned.
other countries. Instead, each application for vaccine registration in an ASEAN country must be prepared as a new submission according to ACTD format. The existing divergence between regulatory requirements and registration procedures among ASEAN countries means that regulatory groups of manufacturing companies must prepare tailor-made CTDs for each country where they apply for registration, which involves reworking the same information to meet different or additional information with little to no added value. Overall this leads to redundant efforts, lengthy regulatory processes, and delayed access to much-needed vaccines for the target population, especially during pandemics.

**Specific Gaps to Address for Enhanced Oversight for Vaccine Manufacture**

There are five main challenges related to the creation of a vaccine manufacturing ecosystem in Malaysia, which were highlighted and discussed during key stakeholder interviews.

**Challenge 1: Financial.** Currently there is a lack of sufficient funds to move to the next stage of vaccine development, for example from R&D to first-in-human clinical trials. Moreover, there is limited collaboration among academia, research institutions and pharmaceutical companies when it comes to R&D; instead, the groups are siloed and developing vaccines individually. Finally, local pharmaceutical companies have not been fully involved in the process of identifying the most suitable potential vaccine candidates and vaccine technology platforms for the country.

**Challenge 2: Raw materials.** Domestically there is inadequate access to raw materials for vaccines which includes the initial vaccine strain, host cells, antibodies, peptide and required materials for vaccine production, and vaccine technology platform. Furthermore, there is limited initial collaboration with foreign manufacturers for vaccine raw materials or a shared strategy to bring in relevant vaccine technology requirements.

**Challenge 3: Manufacturing facilities and R&D.** Malaysia fully imports all of its NIP vaccines. The gap between R&D continuation from the early stages of vaccine development to industry/manufacturing is one of the factors that contributes to the country’s inability to meet local or global demand. In addition, Malaysia currently lacks human vaccine manufacturing capabilities (from drug substances/product stages) within both government-linked companies (GLC) and private companies. However, the NVDR outlines a strategy framework to address the gaps in Malaysia's vaccine development, which includes acquiring and developing vaccine related technologies from established vaccine manufacturers via partnerships, technology in-licensing, or adoption schemes.

**Challenge 4: Human Resources.** Existing human resources need to acquire specific skills, experience and knowledge of full-spectrum vaccine development and manufacturing and meeting stringent GMP requirements related to vaccines. A talent pool in research and manufacturing must be established that includes scientists with experience in pre-clinical studies, molecular biologists, bioprocess engineers, lab technicians that can work on specific vaccine technology platforms, and trained regulatory experts with experience based on WHO requirements. Local training schemes for scientists and researchers around vaccine
bioprocessing and manufacturing are limited due to the lack of local vaccine development in Malaysia.

Challenge 5: Halal vaccine. In 2012, Malaysia—a member of the Pharmaceutical Inspection Co-operation Scheme (PIC/S)—became the first country in the world to develop a national standard on halal pharmaceutical products; to date, this is the main reference for pharmaceutical industries in this area. However, Malaysia is currently lacking in halal vaccine development guidelines, vaccine production, and standard certification. The Malaysian Department of Islamic Development (JAKIM) has initiated a series of discussions among experts and scholars to come up with a new standard for vaccine development, though a lack of trained scientists in halal vaccine development may limit these efforts.

Domestic Manufacturing and Distribution Capacity

Current Domestic Manufacturers

In Malaysia, there are three main pharmaceutical/manufacturing companies that are partially involved in human vaccine production—Duopharma Biotech Berhad (DBB), Solution Biologics Sdn Berhad (SOLBIO) and Pharmaniaga Berhad (PB). Additionally, one company—Malaysia Vaccines and Pharmaceutical—is engaged in animal vaccine manufacturing.

Duopharma Biotech Group began with the establishment of Duopharma (M) Sendirian Berhad in 1978. Duopharma Biotech was incorporated in 2000 and is today one of Malaysia’s leading pharmaceutical companies listed on the Main Market of Bursa Malaysia Berhad. DBB has core competencies in the pharmaceutical industry around manufacturing, R&D, and commercialization and marketing of over 300 generic drugs as well as consumer healthcare products, which are well-recognized and accepted by consumers in Malaysia, regionally and globally. DBB has also diversified into the biosimilars space with technology and commercialization collaborations with credible and strong international partners. Headquartered in Kuala Lumpur, Duopharma Biotech owns and operates three manufacturing plants in Klang, Bangi and Glenmarie, Selangor; it also has subsidiary companies in the Philippines and Singapore, and a representative office in Jakarta, Indonesia.

DBB has the current capacity to do fill and finish production of 12-15 million doses each year. The company has developed a meningitis vaccine in partnership with a US company; a Halal certificate has been obtained for this vaccine. In addition, it is developing a dengue vaccine in partnership with a Taiwanese company, which is in early stages of development. Finally, it is currently working to develop a vaccine for foot and mouth diseases, which is currently in early clinical trial stage.

DBB has invested approximately US$2 million for cold-room facilities (-40°C) that can store 900,000 doses of finished vaccine in vial forms. At the moment, DBB has no dedicated facility for vaccine development/manufacturing; however, under DBB’s manufacturing facilities expansion plan, the company is developing biologic facilities/lines for insulin and erythropoietin (EPO on
CHO cell) that can be retrofitted for other types of vaccine platforms, which will help control capital costs. These facilities will be ready in late 2022 and the first marketing batch is planned for Quarter 1 2025.

Solution Biologics Sdn Bhd (SOLBIO) is a local company and a wholly-owned subsidiary of Solution Group Bhd. In 2021, SOLBIO entered into a market authorization, manufacturing and commercialization agreement with CanSino Biologics Inc., based in Tianjin, China. It is also planning to enter into the life sciences business and develop pediatric and adult vaccines that are part of the NIPs of other countries in the region.

In February 2022, SOLBIO received GMP approval from the NPRA to commence local formulation and fill and finish of CanSinoBIO’s single-dose COVID-19 vaccine, Convidecia. With this approval, Malaysia became the regional fill-and-finish center and manufacturing partner for CanSinoBIO with responsibility for marketing Convidecia to other ASEAN member states. The SANBIO facility is located in Bukit Jalil and is capable of producing up to three million vaccine vials per month or 36 million vials per year. This GMP certification will enable the company to increase production of the Convidecia vaccine for private sale from mid-November 2021, while increasing supply of the vaccine to meet demand in Malaysia and the region. This certification is important because it allows SANBIO to formulate the vaccine and fill it on-site, unlike in the past when the group only received finished doses and active pharmaceutical ingredients (API) from CanSinoBIO in bulk. SOLBIO now has the ability to process the API for filling into vials that can be stored in its own cold room. SOLBIO and CanSinoBIO are also collaborating to produce an inhaled version of the Convidecia vaccine.

Pharmaniaga Berhad (PB) is the largest integrated pharmaceutical group in Malaysia and is listed on the Main Board of Bursa Malaysia Securities Berhad. PB has an established reputation as a provider of quality products and services within the healthcare industry; the group has also expanded into the community pharmacy segment in Malaysia. Pharmaniaga Life Science (PLS), a subsidiary of Pharmaniaga Berhad, has its own EU-certified manufacturing plant located in Puchong, Selangor, which completed fill and finish manufacturing of nearly 1.9 million doses of Sinovac COVID-19 vaccine in May 2021. Based on its current capacity, PLS is positioned to increase production from 2 million to 4 million doses of Sinovac per month. Pharmaniaga Research Center (PRC), another PB subsidiary, is also planning to increase the capacity of its original small volume injectable facilities, which will reach peak utilization in 2024. The new pre-filled syringe line for multi-dose form will be ready in 2025 with a capacity of 20 millions doses per year.

Malaysian Vaccines and Pharmaceutical (MVP) was incorporated in 1982 and was originally known as Remee Holding Sdn Bhd (Remee). MVP has become a market leader for animal vaccines in ASEAN, with new markets opening outside the region as well. MVP has diversified its initial range of products and now offers sixteen (16) vaccine formulations covering a variety of animal diseases. In terms of vaccine technology, MVP has strong quality control/quality assurance capacities to ensure vaccines meet required specifications before they are approved
and released for sale. MVP’s live virus vaccines are supplied in a stable freeze-dried form with a packaging system that maintains shelf life and efficacy.

Constraints faced by Domestic Vaccine Manufacturers

During interviews, representatives from manufacturing companies expressed a number of shared challenges and concerns. First, domestic consumption for vaccines represents approximately US$100 million annually, which mainly comes from government tenders/supply for NIP and other use in the private sector. This amount is insufficient to sustain the substantial upfront investment needed for a full manufacturing facility. Second, vaccine development that is carried out by government agencies, private research entities, and public and private universities is not fully compliant with WHO standards. Two reasons for this are that R&D facilities lack advanced lab equipment for vaccine research, and research budgets are insufficient during the vaccine development stage. Third, offtake business agreements are essential if local manufacturers would like to develop or supply vaccines to the government, due to the fact that substantial investments are subject to sustainable ROI over a certain period of their investment. Fourth, trained technical personnel and scientists in vaccine R&D are currently lacking in Malaysia, requiring substantial R&D and manufacturing exposure and training. Finally, companies express that it would be preferable to have universal (neutral) packaging that is acceptable to other ASEAN countries, as this would save costs and expedite the vaccine registration process.

Additional constraints highlighted during key stakeholder interviews include:

- Substantial capital requirements (land, infrastructure and equipment)
- Liquidity for operations, since there are other lines required to produce non-vaccine products
- Long-term or advance market commitments to purchase domestically made vaccines by governments/donors in the region
- Limited domestic capacity to develop and test vaccines using new platforms
- Limited competent human resources for manufacture that meets GMP requirements at R&D stage
- Limited domestic market since value is based on population size
- Export restrictions (within the region and outside)
- High tariffs for exports within the region
- Non-tariff barriers within the region

Incentives for Domestic Manufacture of Vaccines

The Malaysian Government announced a number of incentives and business-friendly policies under its annual budget 2021 to attract further investment in the manufacturing of pharmaceutical products in Malaysia. These incentives include an offtake agreement and a preferential tax rate of 0-10 percent for a maximum of 20 years. Additionally, as part of the National Economic Recovery Plan (PENJANA) initiative, Malaysia is offering a special Relocation Incentive until December 2022 for new investments in the manufacturing sector, including the
pharmaceutical industry, that provides zero percent special tax rate for 10 years for new investments with capital investment between RM300 million to RM500 million, or zero percent special tax rate for 15 years for new investments with capital investment above RM500 million. These incentives expand upon existing incentives offered by MIDA, which include grants for R&D, training expenses, machinery modernization and automation.\textsuperscript{12}

Patents

The specific technology used for vaccine development and other outcomes of the vaccine development process are potentially patentable and subject to the patent requirement. In Malaysia, there are two sets of law that govern patents: Patents Act 1983 and Patents Regulations 1986. The ‘Act’ covers the criteria for patentability, rights attached to patents and duration of patents, while the ‘Regulations’ relate to patent application procedures. In order to obtain a patent in Malaysia, the inventor must make an application to the Intellectual Property Corporation of Malaysia known as MyIPO. The patent specification must: include a description of the invention and the inventor’s claims (including novelty), identify the inventive step, and describe the industrial application. Generally, patents should be filed as soon as possible since most countries including Malaysia award patents to applicants on a first-to-file basis. In terms of duration of patent validity, once granted, Malaysia patent law states that the duration of a patent is 20 years from the filing date of the application, subject to the timely payment of proscribed annual fees, except for patents filed before August 2001, for which patents have a duration of 20 years from the date of filing or 15 years from the date of grant, whichever is longer.

SWOT Analysis: Malaysia’s Potential Contribution to ASEAN Vaccine Value Chain

<table>
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<th>STRENGTHS</th>
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<tr>
<td>• Strong Government support through launching of National Vaccine Development Roadmap (NVDR)</td>
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<tr>
<td>• Established Malaysia Genome &amp; Vaccine Institute (MGVI)</td>
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<tr>
<td>• Established Consortium of Vaccine R&amp;D Experts, which includes representatives from public and private sectors</td>
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<td>• Established Clinical Research Malaysia (CRM) to</td>
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<tr>
<th>WEAKNESSES</th>
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<tr>
<td>• Small market size for vaccines</td>
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<tr>
<td>• Inadequate access to raw materials needed for vaccine R&amp;D and manufacturing, and limited collaboration with foreign companies around technology transfer.</td>
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<tr>
<td>• There is a shortage of skills, experience and knowledge among existing human resources in human vaccine development and manufacturing</td>
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<td>• Existing R&amp;D facilities have inadequate</td>
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\textsuperscript{12} For more information on the incentives provided for vaccine manufacturers, please visit MIDA’s website at www.mida.gov.my
conduct end-to-end clinical research
- Ready fill & finish capacity for human vaccines within three pharmaceutical companies.
- Upstream industrial support (rubber industry)
- Well-developed logistics infrastructure
- Online and fast-track vaccine registration system

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<tr>
<th>OPPORTUNITIES</th>
<th>THREATS</th>
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<tr>
<td>● Preliminary strategy on NVDR has just launched</td>
<td>● Non-comprehensive strategic policy for international collaboration for vaccine development</td>
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<tr>
<td>● Two domestic pharmaceutical manufacturers have made investments and shown readiness to increase manufacturing capacity (Duopharma and Pharmaniaga).</td>
<td>● Advancement of neighboring countries with an established vaccine R&amp;D/manufacturing infrastructure</td>
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<tr>
<td>● Solution Biologic (SOLBIO) is ASEAN hub for CanSino COVID-19 vaccine</td>
<td>● Longer ‘Return of Investment’ term for facilities investment due to small domestic market size</td>
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<tr>
<td>● Government’s initiative in developing Halal vaccine ecosystem</td>
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<tr>
<td>● Enhance government incentives to attract investment in manufacturing of pharmaceutical products, including vaccines.</td>
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Strengths

1. The Government has launched the National Vaccine Development Road Map (NVDR) for a period of 10 years, with all strategies identified and laid out in the framework.

2. Establishment of the Malaysian Vaccine Sectoral Working Group (MVSWG) at the policy level and the Malaysian Vaccine Project Office (MVPO) at the operational level to coordinate national vaccine development. Under the MVSWG, a Vaccine Collaboration Network (VCN) was formed to ensure closer working relationships with stakeholders from government, industry and academia.

3. A development/special grant of RM350 million was approved for the next four years, which includes R&D funding and the upgrading of Malaysian Genome & Vaccine Institute (MGVI) under the Ministry of Science and Technology (MOSTI). This is in line with the National Policy on Science, Technology and Innovation (NPSTI) 2021-2030.
4. Establishment of Consortium of Vaccine Expert Council for Vaccine R&D at the national level with inter-agency/ministerial/public-private sector representatives to strategize and work hand-in-hand for future vaccine development.

5. Clinical Research Malaysia was established by MOH in 2012 to conduct and provide various services related to end-to-end clinical research for local and international clients.

6. Three local pharmaceutical companies—Duopharma Biotech Berhad, Pharmaniaga Berhad and Solution Biologics Sdn Bhd—have established fill and finish facilities related to human vaccine development and manufacturing.

7. Pharmaniaga LifeScience Sdn Bhd (PLS), a wholly-owned subsidiary of Pharmaniaga Berhad (Pharmaniaga), is progressing steadily towards establishing the world’s first Halal vaccine and insulin plants. The Halal biopharmaceutical plant is targeted for commercialization in 2024 for vaccine and 2025 for insulin; construction progress currently stands at 90 percent and 70 percent completion, respectively.

8. SOLBIO has established a collaboration with of CanSino Biologics Inc. of China (CanSinoBIO) to be the hub and ASEAN manufacturing partner in vaccine production.

9. Available upstream industrial support in Malaysia includes rubber industry, which is necessary for the production of low dead-volume syringes, gloves, rubber stoppers, vial stoppers, and syringe caps.

10. There is a ‘Halal ecosystem’ to support vaccine development.

11. Malaysia has a well-developed logistics and vaccine distribution system.

12. Malaysia has a full online and fast-track submission process for vaccine registration (expedited process for document assessment and approval). Average time taken for vaccine approval under fast-track procedure is 70 days. In comparison with other countries’ national regulatory authorities, NPRA has the fastest approval timeline for both accelerated review and normal approval.

**Weaknesses**

1. Inadequate upfront investment for R&D and manufacturing facilities, which is the main weakness faced by most of the local pharmaceutical manufacturers. Maintenance costs for the facilities are also significant over time.

2. Vaccine allocation budget is comparatively small in terms of market value.

3. Limited human resources with specific skills, experience and knowledge of vaccine development and manufacturing, and a lack of human capital in the regulatory body in advanced clinical trials and vaccine approvals.

4. Limited capabilities in international standard of certified GMP/R&D facilities and upstream infrastructure.

5. Lack of essential capabilities in certain parts of vaccine development, such as large-scale animal breeding.
Opportunities

1. The National Vaccine Development Road Map (NVDR) has just launched (in Nov 2021), which required assistance from all related parties in vaccine R&D, pre-clinical, clinical stages and broader ecosystem.
2. The two government-linked companies, Duopharma Biotech Berhad and Pharmaniaga Berhad, are at the forefront and ready to increase vaccine manufacturing capacity in Malaysia. Their experience managing domestic vaccine supply both in bulk vaccine and finished product during the COVID-19 pandemic are testimony to their importance in full vaccine manufacturing.
3. Solution Biologics Sdn Bhd has already established a collaborative relationship with CanSino Biologics Inc. of China to be the company’s ASEAN hub for human vaccine development and manufacturing. This collaboration can be further strengthened with other countries in ASEAN region.
4. There is government support for halal vaccine development.
5. MIDA has provided some enhanced incentives under annual budget 2021 to attract further investment in the manufacturing of pharmaceutical products for Malaysia, which includes vaccines.

Threats

1. Non-comprehensive strategic policy in terms of international collaboration for vaccine development will delay the vaccine manufacturing process.
2. Neighboring countries with an established vaccine R&D/manufacturing infrastructure (such as Thailand, Vietnam and Indonesia) could threaten development of domestic industry.
3. A huge investment for vaccine manufacturing facilities would expose a longer term for return on investment (ROI) for the private companies. This may affect their financial performance if they were unable to secure a significant supply of vaccine for domestic and international markets.
4. A failure to harmonize vaccine registration across countries in ASEAN could delay or interrupt the supply of vaccines.

Conclusion

Though Malaysia currently lacks some elements of a complete vaccine manufacturing program, it does have current or emerging capacity in key areas, including R&D, clinical trial facilities and vaccine fill and finish, as well as an established rubber industry to supply items necessary for vaccine manufacture and delivery. Moreover, the country has made a recent commitment through the NVDR to consolidate its vaccine manufacturing efforts under one strategic framework, with centralized oversight, and to dedicate funds to vaccine production in a more coordinated way. These efforts benefit not only Malaysia’s national vaccine security and self-reliance, but the regional vaccine ecosystem as well.
References

Stakeholders interviewed:

1. Ministry of Health (MOH)
2. National Pharmaceutical Regulatory Agencies (NPRA)
3. Pharmaceutical Service Division
4. Institute For Medical Research (IMR)
5. Bahagian Pembangunan Kesihatan Keluarga (BPKK-MOH)
6. Bahagian Perolehan dan Penswastaan (BPK-MOH)
7. Ministry of Sciences, Technology & Innovation (MOSTI)
8. Malaysia Vaccine Project office (MVPO)
9. Malaysia Genome & Vaccine Institute (MGVI)
10. Ministry of Finance, Malaysia
11. Ministry of International Trade and Industry (MITI), Malaysia
12. Pharmaniaga Berhad
13. Duopharma Biotec Berhad
14. Solution Biologics Sdn Bhd
15. Malaysian Vaccine and Pharmaceutical
16. MIDA (Malaysia Industry Development Association)

References:

Cancer Institute and Hospital, Chinese Academy of Medical Sciences. Clinical Trial: The Efficacy, Safety and Immunogenicity Study of Inactivated SARS-CoV-2 Vaccine for Preventing Against COVID-19. Available online at https://www.clinicaltrials.gov/ct2/show/NCT04659239


Ministry of Health Malaysia. Immunise4Life program website. https://immunise4life.my/


## Annexes

### Annex 1. Potential vaccine market

<table>
<thead>
<tr>
<th>Market</th>
<th>Category of Market</th>
<th>Challenges</th>
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<tbody>
<tr>
<td>Domestic</td>
<td>NEPI (NIP)</td>
<td>All current vaccine manufacturers supplying for NIP Malaysia are from abroad (multinational companies) and none from local pharma companies. This is a potential market to be developed for vaccine production locally with 3 pharma companies that have started investing into human vaccine manufacturing facilities. The readiness of manufacturing infrastructures will take approximately in 2 to 3 years.</td>
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<tr>
<td>Adult Vaccine (non-NIP) for private market</td>
<td>The market for adult vaccines is competitive and open since no local pharma companies can support the development and manufacturing of vaccine for private use. However, due to huge capital investment required from pharma company, this is a non-prioritized project until such funding assistance is available from government agency (i.e. MIDA and MITI government agencies) or co-partner with international investors.</td>
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<tr>
<td>Regional</td>
<td>Child and Adult Vaccine for private market in ASEAN region</td>
<td>SOLBIO has entered into a market authorisation, manufacturing and commercialisation agreement with CanSino Biologics Inc. based in Tianjin, China. This agreement has allowed the company to manufacture and supply vaccine for ASEAN region. However, all vaccines developed in Malaysia are still required to be registered with individual country in ASEAN region since no ‘mutual’ registration has been agreed thus far.</td>
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Annex 2. Current vaccine development in Malaysia

<table>
<thead>
<tr>
<th>Manufacture</th>
<th>Vaccine</th>
<th>Manufacturing process (up/downstream)</th>
<th>Collaboration</th>
<th>Market</th>
<th>R&amp;D Project in pipeline and partners</th>
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</thead>
<tbody>
<tr>
<td>NA</td>
<td>COVID-19 Platform mRNA</td>
<td>NA</td>
<td>NA</td>
<td>Institute for Medical Research (IMR) Ministry of Health Malaysia is currently developing COVID-19 mRNA vaccine. This vaccine development will be focusing on Variant of Concern (VOC) COVID-19 which have been identified in Malaysia. <strong>Status</strong>: Pre-clinical Stage</td>
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<tr>
<td>NA</td>
<td>Mucosal/Ora l/Subunit Vaccines against Traveler’s Diarrhea/Cholera, Tuberculosis and COVID-19</td>
<td>NA</td>
<td>USM-AIMST University &amp; MOSTI</td>
<td>Development of Mucosal/Oral/Subunit Vaccines against Traveler’s Diarrhea/Cholera, Tuberculosis and COVID-19 is in collaboration with Universiti Sains Malaysia (USM) and Asian Institute of Medicine, Science and Technology (AIMST). <strong>Status</strong>: Preclinical Stage</td>
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<tr>
<td>NA</td>
<td>Therapeutic Cancer Vaccine</td>
<td>NA</td>
<td>NA</td>
<td>Pre-clinical Evaluation of A Therapeutic Cancer Vaccine for The Treatment of Head and Neck Cancer oleh Cancer Research Malaysia (CRM) <strong>Status</strong>: Preclinical Stage</td>
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<tr>
<td><strong>UNDER DEVELOPMENT</strong></td>
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<td><strong>CLINICAL TRIAL</strong></td>
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<tr>
<td>This vaccine is developed by Institute of Medical Biology, Chinese Academy of Medical Sciences (IMBCAMS) China</td>
<td>SARS-CoV-2 Vaccine, Inactivated (Vero Cell)</td>
<td>Clinical Trial</td>
<td>IMBCAMS China, TOPPHARMA Malaysia</td>
<td>Domestic A Randomized, Double-Blinded, Placebo Controlled Phase III Clinical Trial of SARS-CoV-2 Vaccine, Inactivated (Vero Cell) in Adults Aged 18 Years and Above. Phase III Clinical Trial in Malaysia from Jan 2021 to Jan 2022. <strong>Status</strong> - Completed Phase III in Malaysia.</td>
<td></td>
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<tr>
<td>The clinical trial is sponsored by CanSino Biologics Inc.</td>
<td>Recombinant COVID-19 vaccine (adenovirus type 5 vector) for Inhalation (Ad5-nCoV-</td>
<td>Two Clinical Trials registered for these vaccines: NCT05517642 Phase 3 Malaysia</td>
<td>Hospital Ampang, Kuala Lumpur General Hospital and Hospital Selayang</td>
<td>Immunogenicity, Efficacy and Safety of Inhaled (IH) Viral Vectored Vaccine (Convidecia, CanSino) as Second Booster Dose Against Emerging Variants of Concern (VOC) of SARS-CoV-2 to Prevent Breakthrough Infections Among Sub-optimal</td>
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<tr>
<td>Manufacture</td>
<td>Vaccine</td>
<td>Manufacturing process (up/downstream)</td>
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<td></td>
<td>IH) (Study Vaccine) and mRNA vaccine</td>
<td>Malaysia</td>
<td></td>
<td></td>
<td>Responders to First Booster Vaccination. A Randomized Observer-blind Controlled Trial. <strong>Status:</strong> Actual Study Start: Sept 22, 2022 Expected completion: July 1, 2023</td>
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<tr>
<td></td>
<td>BNT162b2 (Comparator vaccine)</td>
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<td>The clinical trial is supported by Reithera SRL, Italy</td>
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<td></td>
<td>GRAd-COV2</td>
<td>COVITA Trial EudraCT No: 2020-005915-39</td>
<td>Multi-centre trial based in Italy and 11 countries outside EEA</td>
<td></td>
<td>Multi-centre Clinical Trial COVID-19 A Phase II/III, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of GRAd- COV2 Vaccine in Adults Aged 18 Years and Older: <strong>Status:</strong> End of trial status is completed</td>
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