



MALAYSIA'S EXPERIENCE:

Ensuring Pharmaceutical Supply During COVID-19 Pandemic

Country Profile

The Government of Malaysia is led by a Prime Minister and a constitutional monarchy, which employs a Parliamentary system. It has three branches of government - the Executive, the Legislature and the Judiciary.



LAND AREA, POPULATION AND VITAL STATISTICS

Land Area: Malaysia - 330,155.28 sq. km

Source: Department of Survey & Mapping, Malaysia

Population and Vital Statistics	2020			2021			2022		
	Male	Female	Total	Male	Female	Total	Male	Female	Total
Total Population* ('000)	16,966.2	15,481.2	32,447.4	17,000.5	15,575.8	32,576.3	17,039.8	15,658.3	32,698.1
Total Population Density (per sq. km)	:	:	98.0	:	:	99.0	:	:	99.0
Population by Age Group: (number & percentage)									
below 15 years ('000)	4,004.0 (23.6%)	3,761.9 (24.3%)	7,766.0 (24.0%)	3,961.1 (23.3%)	3,722.6 (23.9%)	7,683.7 (23.6%)	3,902.1 (22.9%)	3,679.7 (23.5%)	7,581.8 (23.2%)
15 - 64 years ('000)	11,893.3 (70.1%)	10,589.1 (68.4%)	22,482.4 (69.3%)	11,934.4 (70.2%)	10,669.4 (68.5%)	22,603.8 (69.4%)	11,996.0 (70.4%)	10,757.3 (68.7%)	22,753.3 (69.6%)
65 years & above ('000)	1,068.9 (6.3%)	1,130.1 (7.3%)	2,199.0 (6.8%)	1,105.0 (6.5%)	1,183.8 (7.6%)	2,288.8 (7.0%)	1,141.7 (6.7%)	1,221.3 (7.8%)	2,363.0 (7.2%)
Annual Population Growth Rate (%)	1.7	1.8	1.5	0.2	0.6	0.4	0.2	0.5	0.4
Crude Birth Rate (per 1,000 population)	14.4	14.7	14.5	13.3	13.7	13.5	12.8	13.1	12.9
Crude Death Rate (per 1,000 population)	5.7	4.4	5.1	7.5	6.2	6.9	6.9	5.7	6.3
Stillbirth Rate (per 1,000 births)	5.3	4.9	5.1	5.3	4.8	5.0	5.4	4.6	5.0
Perinatal Mortality Rate (per 1,000 births)	8.5	7.5	8.0	8.7	7.6	8.2	8.9	7.4	8.2
Neonatal Mortality Rate (per 1,000 live births)	4.3	3.5	3.9	4.4	3.8	4.1	4.7	3.7	4.2
Infant Mortality Rate (per 1,000 live births)	6.4	5.4	5.9	6.4	5.8	6.1	7.4	6.1	6.8
Toddler Mortality Rate (per 1,000 population aged 1 - 4 years)	0.3	0.3	0.3	0.3	0.3	0.3	0.4	0.4	0.4
Under-5 Mortality Rate (per 1,000 live births)	7.9	6.7	7.3	7.7	7.0	7.4	9.4	7.8	8.6
Maternal Mortality Ratio (per 100,000 live births)	:	24.8	:	:	68.2	:	:	26.0	:
Life Expectancy at Birth (in years)	72.5	77.2	74.7	71.8	76.5	74.0	71.5 ^P	76.4 ^P	73.8 ^P
Distribution Live Births by Birthweight (%):									
Under 2.5 kg	10.7	12.9	11.7	11.0	13.4	12.2	11.9	14.1	12.9
2.5 kg & over	89.2	87.1	88.2	88.9	86.6	87.8	88.0	85.8	87.1
Unknown	0.1	0.1	0.1	0.1	0.0	0.0	0.1	0.1	0.1

Notes:

* The annual current population estimates are based on the Population and Housing Census Malaysia, 2020

The added total may differ due to rounding

: Not applicable

^P Preliminary

Source: Department of Statistics, Malaysia

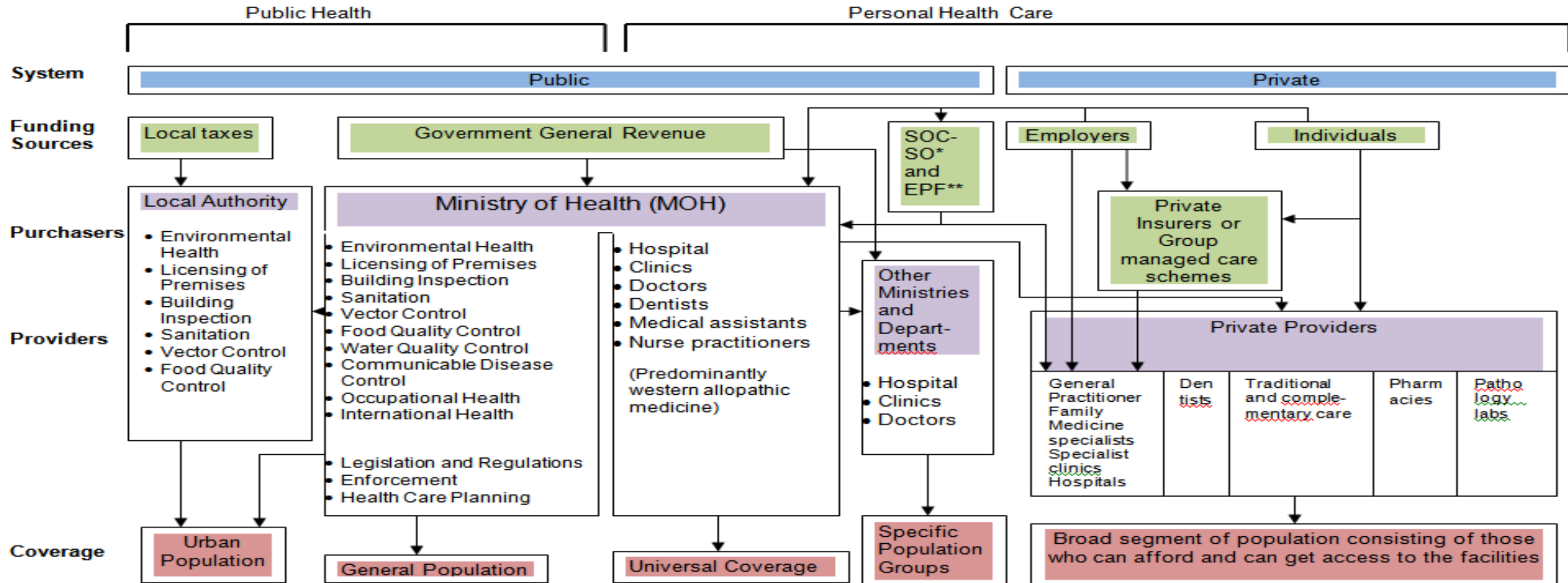
Capital	Kuala Lumpur
Geography	13 states and 3 federal territories
Land area	330,155.28 sq.km
Population	32.7 million
National language	Bahasa Malaysia
Currency	Malaysian Ringgit (MYR)
Nominal GDP (2021)	RM 1,320.85 billion
Nominal GNI (2021)	RM 1,268.80 billion
Real GDP growth rate (%)	3.1
GNI per capita (RM)	46,051

Source: Ministry of Economy, Bank Negara Malaysia, Department of Statistics Malaysia and World Bank

Malaysia is a multi-ethnic country with the predominant ethnic groups in Peninsular Malaysia being Malay, Chinese and Indian. In Sabah and Sarawak, the indigenous people represents the majority, which includes Kadazan-Dusun, Bajau and Murut in Sabah as well as Iban, Bidayuh and Melanau in Sarawak.

The Malaysian Parliament is made up of His Majesty Yang di-Pertuan Agong, the Senate (Upper House) with 70 members and the House of Representatives (Lower House) with 222 members. The general election for the 222 members of the Lower House must be held every five years.

Overview of Malaysian Healthcare System



* SOCSO: Social Security Organization

** EPF: Employee Provident Fund

Ensuring Pharmaceutical Supply During COVID-19 Pandemic



Pharmaceutical Services Programme (PSP)

Ministry of Health Malaysia

The Pharmaceutical Services Programme (PSP), Ministry of Health Malaysia (MOH) initiated its preparedness plans for COVID-19 since the announcement of the first positive case in China in December 2019.

Beginning on 18 March 2020, the Movement Control Order (MCO) was enforced nationwide and encompassed restrictions on movement, assembly and international travel to curb the spread of SARS-CoV-2.

The COVID-19 Preparedness Committee (CPC) of PSP was formed in March 2020 to facilitate, monitor and ensure effective communication regarding the access and supply of medicines, PPE and hand sanitizers, human resource needs, and the medicines supply capacity of the domestic pharmaceutical industry.

The COVID-19 Preparedness Committee (CPC) of PSP



Ensure the **availability and continuous supply of medicines** for all patients including the COVID-19 patients



Facilitating the efficient distribution and management of **hand sanitizers and personal protective equipment (PPE)** for front-line healthcare personnel



Continuous monitoring, effective communications and collaborations with other MOH divisions and the pharmaceutical industry

The COVID-19 Preparedness Committee (CPC) of PSP



The CPC conducted weekly meetings to ensure a timely effort in concordance with the current condition of COVID-19 in Malaysia. Judicious planning and strategies were carefully carried out by the CPC in coordination with the MOH Crisis Preparedness and Response Centre (CPRC).

Ensure the adequate **access to medicines** especially for COVID-19 treatment, **continuous supply of PPE** and **collaboration** with other department/ agencies/ ministries

Communication & collaboration

Owing that there was no standard treatment regime available for COVID-19, **close communication and discussions with the MOH Infectious Disease Team** were carried out to identify the list of drugs used in combatting COVID-19.

Budget

Due to the significant increase in medicines usage during the COVID-19 pandemic, an additional budget of about RM35.4 million was allocated to the MOH for the procurement of medicines related to COVID-19 treatment

Procurement

Medicines procured centrally at the MOH headquarters level through the **Emergency Procurement Procedure** to accelerate the availability of medicines. This special procedure was also applied to procure hand sanitizers to quickly overcome the stock-out condition in MOH facilities

Monitoring lists of key medicines, hand sanitizers and PPE & **pharmacovigilance**

Issues & challenges

Solution

Access to medicines for COVID-19 treatment

- As the usage of hydroxychloroquine (HCQ) increased, the product registration holder was unable to supply the medicine as required by the MOH
 - To ensure the adequate and continuous supply of hydroxychloroquine during this critical time, a local pharmaceutical manufacturer was engaged to produce HCQ locally after strict qualification assessment by the NPRA
- Unavailability of commercialized hydroxychloroquine sulphate suspension for children and adult patients
 - PSP had updated the formulation for hydroxychloroquine sulphate 25mg/ml suspension in the Pharmacy Information System (PhIS) to enable the facilities to prepare the suspension extemporaneously
- Fast-track approvals of products
 - The PSP also facilitated the WHO Solidarity Trial via fast-track approvals of investigational products (IPs) to be used in these clinical trials, including Remdesivir.
 - All IPs were successfully **evaluated within four working days** without jeopardizing the quality and adherence to the international regulatory requirements.
 - Assurance of quality and safety of all foreign and local products whether for procurement or donations were also verified through the registration status of drugs and cosmetics notification.

Issues & challenges

Solution

Supply Chain

- Supply chain management is very crucial during COVID-19 pandemic
 - Close monitoring on the stock status of medicine and related consumables e.g. PPE Tracker, PhIS Dashboard, Vaccine Management System (VMS)
 - Stock status at the suppliers' level was also being monitored, especially high usage items - immediate countermeasures can be taken to prevent stock disruptions to the MOH facilities.

Pharmacovigilance

- Most of the medicines and antivirals for the treatment of COVID-19 were used as off-label treatment
 - A special monitoring mechanism to supervise the utilization and conduct active surveillance on the safety profile of 15 types of medications that were used in the management of COVID-19 in 76 MOH hospital
 - These data were presented during the CPC PSP and MOH CPRC meetings every week.

Procurement

- The procurement of medicines during the pandemic was taxing and warranted lots of extra efforts mainly due to the travel restrictions that had affected the importation and logistics of medicines and medical supplies.
 - Inter-ministerial collaboration**
Inter-ministerial discussion and collaboration with the Ministry of International Trade and Industry (MITI) to obtain the approval for the pharmaceutical manufacturers and related companies to operate during the MCO.
 - Donations**
Donations from various parties. (e.g. Favipiravir and equipment cool box, temperature monitoring device from Japan, medical supplies from local companies)
 - G2G Agreement**
G2G engagement with Japan, India, China and Taiwan was facilitated through the MOH Policy and International Relations Division to allow the exportation of pharmaceutical products as well as active pharmaceutical ingredients (API) to Malaysia.

Lesson Learned & Future Perspectives



Efficient Supply Chain

The close monitoring of medicines stock and supply status during the COVID-19 outbreak was proven to be effective in allowing immediate actions to prevent stock-out situations in MOH facilities.



A structured early drug shortage warning system to detect and identify issues related to drug management should be developed.

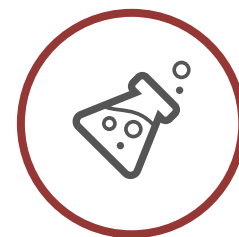


Use of Technology

Various monitoring mechanisms had helped the CPC PSP to acquire first-hand information to make important decisions related to crisis preparedness strategies promptly.



Access to real-time data is crucial to facilitate efficient decision making by the MOH.



Local API Manufacturing

During the COVID-19 pandemic, the availability of APIs in the country was affected when China and India tightened their control on API export.



Production of APIs in the country or region should be encouraged to reduce the dependency on other countries.



Strengthening Regulatory & Collaboration

Inter-ministerial collaboration and G2G agreement is crucial in ensuring sufficient supply of pharmaceutical. Fast track approval of product registration also plays vital role of medicines accessibility

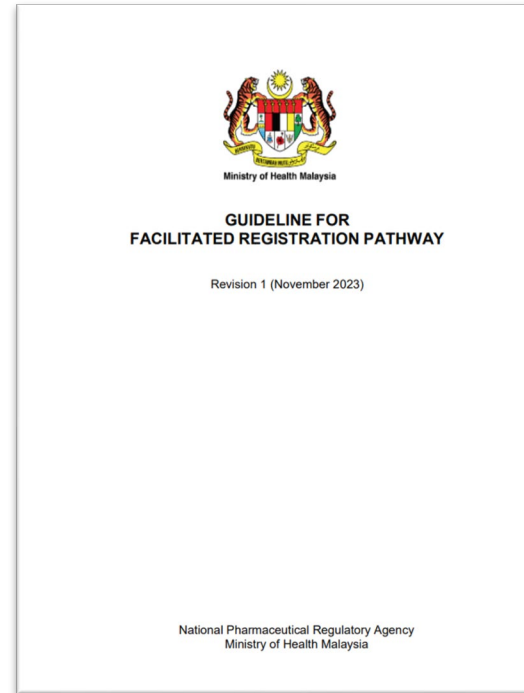


Strengthening regulatory systems is key to ensuring NPRA provides services for therapeutic substances approval that are of high quality, safe, and effective

Future Perspectives



- MNMP 2022-2026**
- Component 1:** Governance in Medicines
 - Component 2:** Quality, Safety and Efficacy of Medicines
 - Component 3:** Access to Medicines
 - Component 4:** Quality Use of Medicines
 - Component 5:** Partnership and Collaboration for Healthcare Industry



Guideline on Facilitated Registration Pathway (FRP) with the inclusion of procedures for:

- (i) WHO Collaborations Registration Procedure Pre-Q (CRP PreQ)
- (ii) WHO Collaborations Procedure by Stringent Regulatory Authority (CRP SRA)
- (iii) ASEAN Joint Assessment



Framework of the Regional Collaborative Strategy for ASEAN Drug Security and Self Reliance (ADSSR)

Strategy 5: *Strengthening procurement management and accountability*

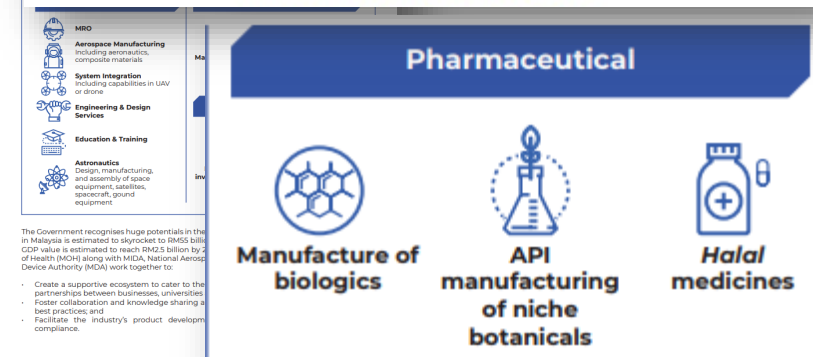
Initiative: *Pooled procurement of medicines among AMS*

Self-reliance



National Industrial Master Plan (NIMP) 2030

Figure 4.4: Key Growth Segments of Aerospace, Pharmaceutical and Medical Devices Sectors



The Government recognises huge potentials in the in Malaysia is estimated to skyrocket to RM55 billion in 2030. The Government recognises huge potentials in the in Malaysia is estimated to reach RM5 billion by 2030. The Government recognises huge potentials in the in Malaysia is estimated to reach RM5 billion by 2030.

Conclusions

The journey of handling COVID-19 pandemic crisis warrants great leadership, structured planning, excellent teamwork and undoubtedly, a lot of hard work.



The crisis preparedness at the PSP level was successfully carried out and the emerging issues were well managed.

Pharmacy personnel, from the top management at the headquarters and state health offices, to all pharmacy staffs at the front, had shown great commitment and pride in carrying out our responsibility in handling the COVID-19 pandemic.

With all the initiatives and strategies imposed, adequate access to medicines and pharmaceutical supplies needed for COVID-19 treatment and prevention was ensured.

In addition, the implemented strategies had also ensured the continuity of treatment for all our patients during the pandemic



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Thank You