KEMENTERIAN KESIHATAN MALAYSIA

PHARMACEUTICAL SERVICES PROGRAMME STRATEGIC PLAN 2021-2025

Program Perkhidmatan Farmasi
Pharmaceutical Services Programme

MOH/S/FAR/48.21(BP)-e

PHARMACEUTICAL SERVICES PROGRAMME STRATEGIC PLAN 2021-2025

PHARMACEUTICAL SERVICES PROGRAMME STRATEGIC PLAN, 2021-2025

ISBN 978-967-2854-15-9
eISBN 978-967-2854-16-6
MOH/S/FAR/48.21(BP)-e

Published by:
Pharmaceutical Services Programme
Ministry of Health Malaysia
Lot 36, Jalan Profesor Diraja Ungku Aziz,
46200 Petaling Jaya, Selangor.
T 603 7841 3200 F 603 7968 2222
Website: www.pharmacy.gov.my

©Ministry of Health, Malaysia

All rights reserved.
No part of this publication may be reproduced, stored or transmitted in any form or by any means whether electronic, mechanical, photocopying, tape recording or any storage and retrieval system without prior written permission from the publisher.

ISBN 978-967-2854-15-9
9 789672 854159

CONTENTS

FOREWORD BY
THE SECRETARY-GENERAL OF HEALTH iv
THE DIRECTOR-GENERAL OF HEALTH v
THE SENIOR DIRECTOR OF PHARMACEUTICAL SERVICES vi

EXECUTIVE SUMMARY vii

EDITORIAL BOARD viii

INTRODUCTION 2
VISION 2
MISSION 2
OBJECTIVES 2
RELATED ACTS AND REGULATIONS 3
SHARED VALUE 3
LEADERSHIP PRACTICES 3
ORGANISATION 4

ACHIEVEMENTS FROM THE STRATEGIC PLAN 2017-2020 5
THRUST 1: CUSTOMER ENGAGEMENT 6
THRUST 2: INNOVATION DRIVEN 10
THRUST 3: OPERATIONAL EXCELLENCE .. 22
THRUST 4: CAPABILITY BUILDING 30

ISSUES AND CHALLENGES 33

WAY FORWARD: STRATEGIC DIRECTION ... 44

THRUST 1: CUSTOMER ENGAGEMENT 45
STRATEGY 1: ENHANCE MULTISECTORAL AND INTERSECTORAL ENGAGEMENT TOWARDS BETTER HEALTH AWARENESS 45
STRATEGY 2: ENHANCE MULTI SECTOR ENGAGEMENT TOWARDS SAFE, EFFECTIVE AND QUALITY PRODUCTS 45
STRATEGY 3: ENHANCE VALUE PROPOSITION OF PHARMACY SERVICES 46
STRATEGY 4: INTENSIFYING THE ROLE OF PHARMACY SERVICES 46

THRUST 2: INNOVATION DRIVEN 47
STRATEGY 1: ENHANCING ICT-BASED SERVICE INNOVATIONS 47
STRATEGY 2: INTENSIFYING THE USE OF RESEARCH FINDINGS AND EVIDENCES IN POLICY DEVELOPMENT AND PRACTICE 50

THRUST 3: SUSTAINING OPERATIONAL EXCELLENCE 50
STRATEGY 1: STRENGTHEN GOVERNANCE AND REGULATORY CONTROL 50
STRATEGY 2: STRENGTHEN MONITORING OF SALES AND ADVERTISEMENT OF UNREGISTERED AND ADULTERATED PRODUCT 54
STRATEGY 3: ENHANCE ORGANISATIONAL EFFICIENCY 54
STRATEGY 4: ENHANCE ACCESSIBILITY OF PHARMACEUTICAL PRODUCTS 55
STRATEGY 5: ENHANCE EFFICIENCY AND OPTIMISING RESOURCES 56

THRUST 4: ENHANCING CAPABILITY BUILDING 57
STRATEGY 1: ENHANCE HUMAN RESOURCE COMPETENCY AND PERFORMANCE 57
STRATEGY 2: OPTIMISE HUMAN RESOURCE CAPACITY TO ENSURE CONTINUOUS SERVICE DELIVERY 58

STRATEGIC PLAN ALIGNMENT 59
THRUST AND STRATEGY 60
IMPLEMENTATION PLAN 61
MONITORING AND EVALUATION 78
CONCLUSION 79
GLOSSARY OF TERMS, ABBREVIATIONS AND ACRONYMS 80
CONTRIBUTOR 84

FOREWORD

THE SECRETARY-GENERAL OF HEALTH

I am pleased to note that the Pharmaceutical Services Programme is continually creating its Strategic Plan for the years 2021-2025. This framework, I believe, will serve as a guide for the Programme's future trajectory, particularly in terms of supporting Ministry of Health in serving the nation. The structure and direction for the Pharmacy Services Programme's strategic plan for the period 2021–2025 have been successfully designed holistically, considering current scenarios, including the concerns and challenges posed by the COVID-19 pandemic. This is a significant concern for the health sector, as the Pharmaceutical Services Programme plays a critical role in assuring the readiness of all pharmaceutical supplies and consumable needed, in responding to this pandemic.

This Strategic Plan is critical for the continued competitiveness, sustainability, and viability of pharmaceutical resources and services. The proposed approach is unambiguously consistent with existing policies. The strategic focus and activities planned are supposed to be implemented successfully and strategically in order to add value to the services supplied.

Finally, congratulations to all involved in realizing the continuity of this strategic plan and it is hoped that the Pharmacy Programme will remain outstanding as an important organisation in the Ministry of Health Malaysia as well as in the delivery of services to the people.

Dato' Mohd Shafiq bin Abdullah

FOREWORD
THE DIRECTOR-GENERAL OF HEALTH

The Ministry of Health is pleased to present the Pharmaceutical Services Programme Strategic Plan 2021-2025, which establishes a five-year roadmap for the Pharmacy Programme's future development. This framework provides the strategic vision, which is supported by core thrusts, strategies and initiatives that are synergistically moulded in order to accomplish the programme's vision and mission.

The framework addresses the need to provide sustainable, high quality pharmacy services in a complex and evolving environment. It clearly outlines the Programme's direction and establishes action priorities at regional, national and local levels.

Pharmacy services play an integral role in healthcare service delivery system. It provides a wide range of services spanning from primary and secondary care and enforcement of law that includes, but not limited to pharmaceutical products and cosmetics. Additionally, this pharmacy framework also supports the pharmaceutical industry by providing regulatory backbone to ensure further growth and expansion of this vital and dynamic sector. Greater collaboration and cooperation between various healthcare stakeholders will boost the country's economy and improve quality of life.

I wish to sincerely acknowledge the dedication and effort of all who have participated in the development of this plan under the leadership of the Senior Director of Pharmaceutical Services for the formulation of the 2021-2025 Pharmaceutical Services Programme Strategic Plan. I am certain that the success of the plan will have a positive impact on our robust healthcare system. Together we will strive towards improving the country's healthcare needs.

Tan Sri Dato' Seri Dr. Noor Hisham bin Abdullah

FOREWORD

THE SENIOR DIRECTOR OF PHARMACEUTICAL SERVICES

Pharmaceutical Services Programme is committed to advancing the national agenda in achieving better health for the nation. The Twelve Malaysia plan (2021-2025) with the theme to achieve "A prosperous, inclusive and sustainable Malaysia" has charted a path forward for the nation's health care system.

As with previous editions, The Pharmaceutical Services Programme's Strategic Plan 2021-2025 primarily facilitates a well-coordinated and streamlined implementation of initiatives to strengthen our health system and services further, firmly supporting the national agenda. It is imperative for us to develop a strategic plan to guide the organisation towards achieving a common goal. Key strategies are developed in conjunction with the overarching National Medicines Policy by analysing the current situation, strengths and weaknesses, and projecting future needs.

In this new term of the strategic planning period, the Pharmaceutical Services Programme will continue to focus on four main aspects:

- Strengthening the governance of Pharmacy Programme.
- Strengthening service delivery through innovation and technology,
- Strengthening the skills, expertise and human resource capacity, and
- Enhancing cooperation with stakeholders and empowering communities on the quality use of medicines.

Additionally, the strategies and initiatives outlined in this plan will also have an impact on the development of pharmacy services in the future. In carrying out this mission, every member of Pharmacy Programme should instil and uphold the shared values and leadership practices outlined in this document.

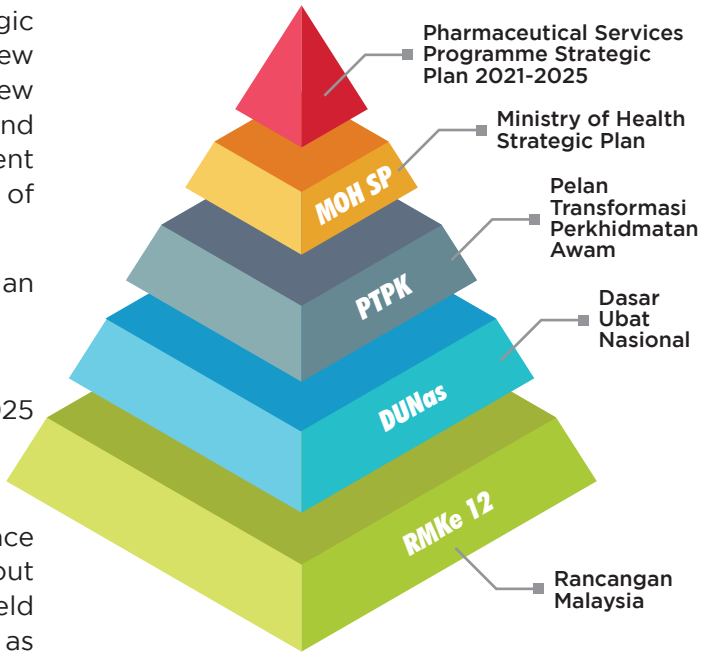
Finally, I would like to extend my earnest appreciation to all parties involved in the realisation of this strategic plan. I believe, with the collaborated effort from all, we will implement this plan successfully and overcome the challenges and issues in the future. Let us continue to work together as a team, with full cooperation and dedication from all levels. Together we can make significant progress and deliver outcomes that benefit to the health of the nation.

Norhaliza binti A.Halim

EXECUTIVE SUMMARY

Succeeding the Pharmacy Programme Strategic Plan 2017-2020, this new framework recorded new initiatives and revised strategies driven by new norms and foreseen challenges in the global and national pharmaceutical sector. The establishment of this framework is based on the fundamental of the country's health plans and commitments.

1. Working Papers of Twelfth Malaysian Plan 2021-2025
2. Health Services Transformation Plan
3. Ministry of Health Strategic Plan 2021-2025
4. Malaysian National Medicines Policy



This strategic document highlights performance from the previous Strategic Plan, discussed about issues and challenges in the pharmaceutical field in Malaysia, and envisioned the way forward as the organisation moves towards a post-crisis environment and confronts a new era of delivering services to the people.

Pharmaceutical Services Programme Strategic Plan 2021-2025 outlines a four-year strategic direction with main focus to:

- Introduce customers to better service experience and patients to applied community care
- Empower knowledge in medicines information and quality use of medicines
- Enable convenience and accessibility to pharmacy services through technology and innovation
- Strengthen legislation and regulation to safeguard medicinal products marketed to consumers
- Reform organizational structure for further performance and efficiency of the Programme
- Ensure affordability and reasonable pricing of medicines
- Develop training models and professional pathways to produce competent workforce

EDITORIAL BOARD

ADVISORY COMMITTEE

YBhg. Datin Dr. Faridah Aryani binti Md. Yusof
Senior Director
Pharmaceutical Services Programme

YBrs. Puan Norhaliza binti A Halim
Director
Pharmacy Policy and Strategic Planning Division

YBrs. Dr. Hasenah binti Ali
Director
National Pharmaceutical Regulatory Agency

YBrs. Puan A'tia binti Hashim
Director
Pharmacy Practice and Development Division

YBrs. Encik Roeslan bin Ishak
Director
Pharmacy Enforcement Division

EDITORS

Nur'Ain Shuhaila binti Shohaimi
Deputy Director
Pharmacy Policy and Strategic Planning Division

Bibi Faridha binti Mohd Salleh
Senior Principal Assistant Director
Pharmacy Policy and Strategic Planning Division

Leona Tan Sze Ping
Senior Principal Assistant Director
Pharmacy Policy and Strategic Planning Division

Mohd Azuwan bin Mohd Zubir
Senior Principal Assistant Director
Pharmacy Policy and Strategic Planning Division

Lau Ling Wei
Senior Principal Assistant Director
Pharmacy Policy and Strategic Planning Division

Izzati binti Mohd Farok
Senior Principal Assistant Director
Pharmacy Practice and Development Division

EDITORIAL COMMITTEE

Nurul Afifah binti Osman
Senior Principal Assistant Director
Pharmacy Board Malaysia Division

Grace Tan Poh Lian
Senior Principal Assistant Director
Pharmacy Practice and Development Division

Sharon Ong Chin Wen
Senior Principal Assistant Director
Pharmacy Practice and Development Division

Datcayani a/p Ramadoo
Senior Principal Assistant Director
Pharmacy Board Malaysia Division

Mohd Hazwan bin Md Ghazali
Senior Principal Assistant Director
Pharmacy Policy and Strategic Planning Division

Syazana Akmal binti Ahmad Kamal
Principal Assistant Director
Pharmacy Enforcement Division

Ng Wei Han
Senior Principal Assistant Director
National Pharmaceutical Regulatory Agency

Chew Huei Min
Principal Assistant Director
National Pharmaceutical Regulatory Agency

INTRODUCTION

OF THE BOOK

PHARMACEUTICAL SERVICES PROGRAMME STRATEGIC PLAN 2021-2025

INTRODUCTION OF THE BOOK

INTRODUCTION

The Pharmaceutical Services Programme is one of the programmes under the purview of the Ministry of Health, Malaysia. Since its establishment in 1951, Pharmaceutical Services Programme has gone through a series of transformation in order to ensure the services provided are in line with national transformation plans, on par with international standards and advancement of pharmaceutical industry.

The Programme ensures pharmaceutical products marketed in the country comply with standards, are safe, efficacious and of good quality. The Programme also plays a role to protect the nation through enforcement of relevant pharmaceutical law and legislation and ensuring rational use of medicines by both healthcare providers and consumers.

VISION

- Enhancing our nation's health through excellence in the practice of pharmacy

MISSION

- Uphold legislations and improve policies to ensure quality pharmaceutical products and services
- Ensure effective and responsive organisational systems towards sustainable quality services
- Build capabilities and professionalism through talent development and workforce empowerment
- Intensify collaboration towards best practices and standard

OBJECTIVES

PHARMACY POLICY AND STRATEGIC PLANNING DIVISION

- → Developing policies for the pharmaceutical sector in line with the needs of national healthcare
- → Ensuring excellent and efficient resources management

PHARMACY PRACTICE AND DEVELOPMENT DIVISION

- → Ensuring continuous access to the quality, safe and cost-effective medicines
- → Strengthening the quality and rational use of medicines towards better health
- → Enhancing pharmaceutical care services in line with the good standards and practices

PHARMACY ENFORCEMENT DIVISION

- → Ensuring all sales, supply, possession and advertising of substances, products and cosmetics are in compliance with the legal provision

NATIONAL PHARMACEUTICAL REGULATORY AGENCY

- → Ensure that products approved for the local market are safe and of quality and also to ensure that natural products and cosmetics are safe and of quality

PHARMACY BOARD MALAYSIA DIVISION

- → Ensuring the registration of pharmacists and body corporate complies with Registration of Pharmacists Act 1951 and its regulations
- → Setting standard for conduct, ethics, proficiency, education and training, and Continuous Professional Development (CPD)

RELATED ACTS AND REGULATIONS

- Poison Act 1952
  - » Poison regulations 1952
  - » Poison (Fees) Regulations 1983
  - » Poison (Psychotropic Substances) Regulations 1989
- Sale of Drugs Act 1952
  - » Control of Drugs and Cosmetics Regulations 1984
- Registration of Pharmacists Act 1951
  - » Registration of Pharmacists Regulations 2004
- Medicines (Advertisement and Sale) Act 1956
  - » Medicine Advertisements Board Regulations 1976
- Poison (Sodium Hydroxide) Regulations 1962
- Sale of Drugs (Certificate of Analysis) Regulations 1997

SHARED VALUE

Shared Values clarifies values we hold, what our organisation stands for, believes in and the behaviours on which we perform work and conduct ourselves.

PROFESSIONALISME

INTEGRITY

CUSTOMER CARE

TEAMWORK

EFFICIENT

LEADERSHIP PRACTICES

1. MODEL THE WAY

Leaders establish principles and create standards of excellence and then set an example for others to follow. Leaders also set interim goals so that people can achieve small wins as they work toward larger objectives.

2. INSPIRE A SHARED VISION

Leaders passionately believe that they can make a difference, envision the future and create an ideal and unique image of what the organisations can become.

3. CHALLENGE THE PROCESS

Leaders search for opportunities to change the status quo and look for innovative ways to improve the organisation.

4. ENABLE OTHERS TO ACT

Leaders foster collaboration and build spirited teams. They actively involve others and strive to create an atmosphere of trust and human dignity.

5. ENCOURAGE THE HEART

Leaders recognise contributions that individuals make and celebrate accomplishments of the team.

Reference: The 5 Practices of Exemplary Leadership® Model
- James M. Kouzes & Barry Z. Posner

ORGANISATION

The operational Ministry of Health is led by the Director General of Health. Pharmaceutical Services Programme is one of the programmes in the Ministry of Health, handling pharmaceutical and medicinal issues. The Programme is headed by a Senior Director. There are five (5) Divisions and each is led by a Director with several subdivisions executing functions of the Divisions. At the state level, there are fifteen (15) Pharmacy Divisions and two (2) Institutional Pharmacy Departments. The state Pharmacy Divisions oversee pharmacy services in the Ministry of Health's hospitals and clinics which deliver pharmaceutical care and operational services to patients. The structure of the whole Programme is displayed in the organigram below.

ACHIEVEMENTS

FROM THE STRATEGIC PLAN 2017-2020

PHARMACEUTICAL SERVICES PROGRAMME STRATEGIC PLAN 2021-2025

ACHIEVEMENTS FROM THE STRATEGIC PLAN 2017-2020

THRUST 1: CUSTOMER ENGAGEMENT

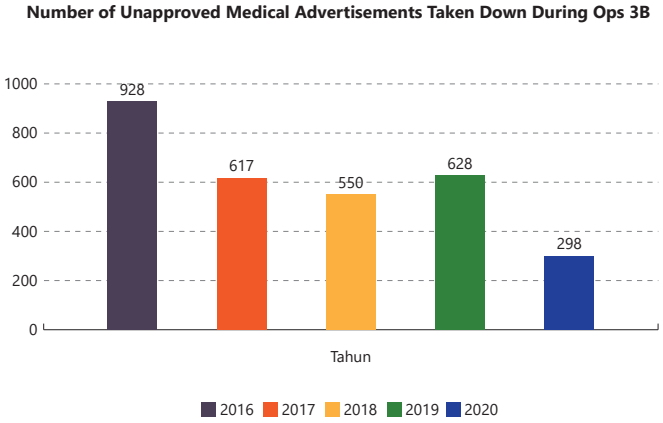
STRATEGY 1: ENHANCING MULTI SECTOR ENGAGEMENT TOWARDS BETTER HEALTH AWARENESS

Engagement with related sectors and stakeholders is an important element in making strategies effective and successful. This strategy focused on collaborating with agencies or groups that are directly dealing with consumers to advocate for quality use of medicines and combat prohibited medicine advertisements.

Engagement with Local Council and Local Media in Reducing Unapproved Medical Advertisement

Consumers, based on their demand and needs, have choices to decide on the selection of health products. Advertisement act as a medium to disseminate the information about the health products being advertised. Advertisements, on the other hand, can influence consumers in deciding on the choices of products. The two factors, i.e. consumers demand and need, together with the advertisement effect has impact on the sales and supply of health products. Today's world of advertising industry has undergone tremendous transformation from using conventional medium such as newspapers, magazines, TV and radio to something more sophisticated using the Internet technology. Online media or new media such as social media, e-commerce websites and even blogs are now the main/ primary choices for running the advertisements because it is fast, has interesting lights and sounds, and borderless coverage, hence reaching more audiences.

As of June 2020, a total of 141 engagements with the local state council (dialogue session and joint operation) throughout the country were conducted as an initiative to reduce unapproved medical advertisements in the traditional media. During the joint operation, illegal medicine advertisements in the form of banner, bunting and billboard (3B) were taken down. Dialogue sessions were held to provide awareness towards consumer safety.



Pharmacy Enforcement Division (PED), MOH, as well as State Enforcement Branch (SEB) also engaged with local RTM's radio station as part of the initiative to increase the awareness of advertising agency and broadcaster who are the responsible and accountable parties with regards to the content of the advertisements. From 2016 to 2018, PED and SEB managed to engage with all local RTM's radio station, the Ministry of Communications and Multimedia (KKMM) and Communications and Multimedia Commission (MCMC) in the effort to reduce unapproved medical advertisements in electronic media. With regards to the engagement with MCMC, PED has collaborated with them in developing 'Content Industry Reference: Health Claim Advertisement' as a reference to the MCMC licensee, particularly the broadcasting media as part of Standard Operating Procedure when dealing with medical advertisement matter. Through these engagement and dialogue sessions, PED was given the opportunity to use their platform to promote awareness to the consumers on the dangers and effects of buying unregistered health products through online platform. As a continuous effort, four (4) guidelines on Health Products Advertisements were published and disseminated to the respective target groups.

1. *Panduan Penyiaran Iklan Produk Kesihatan* (poster distributed to all broadcasters in 2017)

2. *Panduan Penyiaran Iklan Produk/ Perkhidmatan Kesihatan* (poster distributed to all Local Council in 2018)
3. *Panduan kepada Industri dalam Pengiklanan Produk Kesihatan* (booklet distributed to relevant stakeholders in 2018 and can be accessed at www.pharmacy.gov.my)
4. *Panduan kepada Selebriti dalam Pengiklanan Produk Kesihatan* (booklet distributed to relevant stakeholders in 2018 and can be accessed at www.pharmacy.gov.my)

As consumers shift to view content on new media screens, PED has developed strategies to monitor the marketing and advertising of unregistered health products. Currently, PED monitored 27 new media platforms which include Facebook, Twitter, blog, website, YouTube, Instagram, WeChat, Line, WhatsApp, Ubuy, EC21, TheMalaysianEdge, Alibaba, Pinterest, ezbuy, Carousel, ebay Malaysia, Google+, KakaoTalk, Lazada, Shopee, PrestoMall, Mudah.my, Qoo10 Malaysia, Jamumall, Lelong and Youbeli. This initiative will be expanded further where more media will be monitored, in line with the global development in the advertising landscape.

Annual dialogue sessions were held with e-marketplace platform providers since 2017 in discussing on the issues of online advertising and selling of health product, particularly in the e-marketplace. As part of the collaborative action, the e-marketplace providers are helping the PED in taking down advertisements that violate the laws and regulations.

NO.	E-COMMERCE	2017	2018	2019	2020 (until 30 June)	TOTAL
1	*Lelong.com.my*	110	343	337	133	**923**
2	*Shopee.com.my*	123	900	6424	2197	**9644**
3	*Qoo10.my*	242	645	712	207	**1806**
4	*Lazada.com.my*	145	1377	5979	633	**8134**
5	*PrestoMall (11street.my)*	214	585	326	441	**1566**
6	*Disini.my*	21	48	20		**89**
7	*Mudah.my*	125	332	832	106	**1395**
8	*Jamumall.com*	-	10	17	3	**30**
9	*Youbeli.com*	-	316	310	163	**789**
10	*Carousell*	3	888	856	187	**1934**
11	*Zalora*				5	**5**
12	*PG Mall*				9	**9**
13	*Hayib.com*				6	**6**
14	*EC21*	0	0	156	417	**573**
15	*ubuy*	0	0	51	309	**360**
16	*Ebay*	1	133	0	0	**134**
17	*ezbuy*	0	7	0	204	**211**
18	*Alibaba*	0	0	67	174	**241**
19	*Logon.my*	126	9			**135**
20	*Aladdinstreet.com*	38	0	-		**38**
21	*Amaxmall*	7	0	-		**7**
22	*Monspacemall*	7	15	-		**22**
23	*Myharakahbazaar*	2	0	-		**2**
24	*Gemfive*	15	-	-		**15**
25	*My fave (Groupon)*	0	-	-		**0**
TOTAL		**1179**	**5608**	**16087**	**5194**	**28068**

Number of advertisements with infringement taken down by e-marketplace platform providers since 2017

Engaging NGOs, Professional Society and Government Agency to Reach Specific Group Towards Quality Use of Medicines (QUM) & Customer Protection

The initiative focused on engagement with Non-governmental Organisation (NGOs), professional society and/or government agencies as a collaborative effort to educate and increase awareness on QUM. Within the area of health, it is a paradigm that has been widely promoted to solve our country's apparent lack of awareness. Pharmacists, as experts in medicines, play an essential role in educating the consumers regarding medicines use. Through time and effort, this initiative can build strong relationship based on trust between pharmacists and consumers. When conducted properly, it can harness NGOs and community collective power to support the effective delivery of health awareness programmes. There is a need for willingness by all stakeholders to build relationships, engage with each other and work towards common goals. Complementary collaborations can have multiple benefits, including enhancing government activities and better integration of national health policy at the community level. Identifying and utilising all stakeholders' strengths can create opportunities for further capacity-building and strengthen existing relationships.

From 2016 to 2020, Pharmaceutical Services Programme has collaborated with a total of nine (9) agencies as such:

2016
- Malaysian Pharmacy Students' Association (MyPSA)

2017
- Pharmaniaga Berhad *(Skuad Operasi Sihat)*

2018
- *Pertubuhan Bekas Pelajar Maktab Rendah Sains MARA* (ANSARA Malaysia)

2019
- Mass Rapid Transit Corporation Sdn. Bhd.
- Ministry of Women, Family and Community Development
- New Straits Time Press (M) Berhad (Metro Ahad and New Straits Time)

2020
- Antidoping Agency Malaysia (ADAMAS), Nu Ideaktiv Sdn. Bhd. *(Mingguan Wanita)*

STRATEGY 2: ENHANCE VALUE PROPOSITION OF PHARMACY SERVICES

Pharmacy services have transformed and evolved over the past years from traditionally fulfilling medicine prescription to patient-oriented care working in collaboration with other healthcare providers to a service which may enable pharmacists all over the world to prescribe and manage therapy. Strategies have been identified to enhance the value of pharmacy profession and promote pharmacy services delivery.

World Pharmacist Day (WPD) is celebrated on the 25th of September each year to commemorate the pharmacists' roles and contributions to patients and community. This day gathered pharmacists from various sector throughout Malaysia to honour their profession and applaud for the invaluable services delivered. Meanwhile, in 2018 and 2019, pharmacists started to reach out to the society in this celebration day to introduce and promote pharmacy services in shopping mall and community hall. Health educational talks, information booths, health screening and etc. were conducted and received overwhelming responses from the public. In 2020, WPD was celebrated virtually due to COVID-19 outbreak. An opening ceremony was conducted at the headquarters level, joined by state pharmacy through online participation.

Know Your Medicines Programme (Program Kenali Ubat Anda) has been introduced as a national project with its own website to raise awareness on quality use of medicines. This programme indirectly helps to promote the roles and services of pharmacy to the community. Many activities are conducted in this programme such as exhibitions and talks, radio and television interviews, mass media promotion, home visits and etc.

CUSTOMER ENGAGEMENT								
The quality of the customer experience that emphasizes the positive aspects of the interaction with our organisation								
Strategy	**Initiative**	**Strategy/ Initiative Details**	**Performance Indicator (Quality, Quantity or Time)**	**Implementation Status**				**Remarks**
				2017	**2018**	**2019**	**2020**	
STRATEGY 1: Enhance Multi Sector Engagement Towards Better Health Awareness	**Initiative 1:** Engagement with local council in reducing unapproved medical advertisement	To conduct dialogue sessions followed by joint operations to withdraw illegal medicine advertisements under OPS 3B	Percentage of PBT covered (cumulative)	31% of local council covered	78.1% of local council covered	93% of local council covered	Till 30 June: 94% (141/ 151) of local council in Malaysia engaged	Engagement activities for the first 6 months of 2020 were postponed due to COVID-19
	Initiative 2: Engagement with local media in reducing unapproved medical advertisement	Engagement with local RTM's radio station through dialogue session	Percentage of local RTM's Radio Station covered	73% of local RTM's Radio Station covered	100% of local RTM's Radio Station covered	N/A	Till 30 June: 100% (15/15) of local RTM's radio station engaged	All local RTM's Radio Stations had been covered in 2018
	Initiative 3: Engaging NGOs/ professional society/ government agency to reach specific group towards quality use of medicines (QUM) & consumer protection	This initiative is focusing on engagement with NGOs/ professional society/ government agency as a collaborative effort to educate and increase awareness on QUM	Number of NGO/ society/ government agency engaged (cumulative)	1 collaboration (Cumulative: 2)	1 collaboration (Cumulative: 3)	4 collaborations (Cumulative: 7)	2 collaborations (Cumulative: 9)	1 collaboration in 2016

CUSTOMER ENGAGEMENT									
The quality of the customer experience that emphasizes the positive aspects of the interaction with our organisation									
Strategy	Initiative	Strategy/ Initiative Details	Performance Indicator (Quality, Quantity or Time)	Implementation Status					Remarks
				2017	2018	2019	2020		
STRATEGY 2: Enhance Value Proposition of Pharmacy Services	**Initiative 1:** Enhance promotion of pharmacy services	This initiative aims to promote the availability of pharmacy services in MOH facility in order to improve service uptake	Improvement in the community perception towards pharmacy services and professional image	Early phase of identifying survey type	Initiative discontinued since there are other activities to promote pharmacy visibility such as: World Pharmacist Day, Know Your Medicines Activities, Appearance of pharmacy activities in social media				

THRUST 2: INNOVATION DRIVEN

STRATEGY 1: IMPLEMENTATION OF INNOVATIVE PHARMACY SERVICE DELIVERY

Innovative pharmacy services have been introduced continuously throughout the years in line with needs and demands for more convenient services. The delivery of these services has received satisfactory response from patients and healthcare providers. Two (2) initiatives were planned under this strategy, namely the Integrated Drug Delivery System (IDDS) and Patients' Own Medicines (POM) programme as described below.

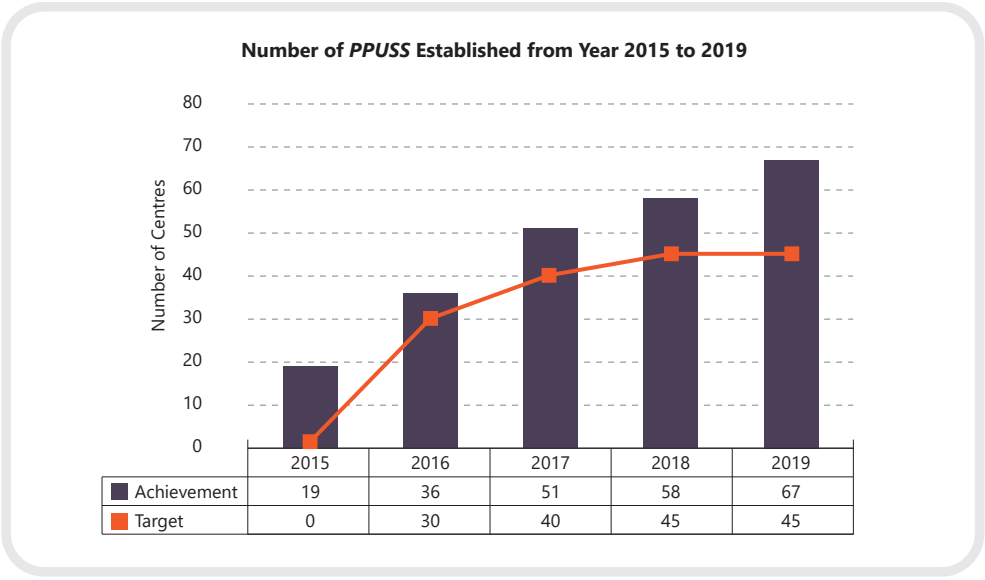
Expansion of Integrated Drug Delivery System (IDDS)

Pharmacy Value Added Services (VAS) have been implemented to address issues such as lengthy waiting times and patients congested at pharmacies, as well as patients' compliance in collecting their follow-up medications due to transportation issues and time constraints. VAS's key objective is to ensure patients have continuous access to their follow-up medication supply while also ensuring that they receive their medications consistently and at their convenience.

In 2019, 22.3 percent (3.08 million) of follow-up prescriptions were dispensed through VAS, which had facilitated patients with chronic illnesses to collect their follow-up medications. To aid the achievement of VAS's primary objective and to ensure that more patients benefit from this initiative, additional centres have been identified as dedicated ***Pusat Pembekalan Ubat Susulan Setempat (PPUSS).***

PPUSS are collection points for medicines that are located outside of the MOH hospitals and clinics which are available in strategic and convenient locations such as KOMTAR, Urban Transformation Centres (UTC), etc. This service enables patients to collect their medications at their preferred locations, obviating the need for unnecessarily frequent visits to healthcare facilities. Medications are prepared in advance before patients' arrival and will be dispensed through a variety of options, including directly at the counter, Locker4U, or drive-thru pharmacy.

In 2019, a total of 67 PPUSS were established, all with similar goal to increase patients' access to medications via VAS (figure below). The total number of prescriptions dispensed at these centres has significantly increased by 30 percent, from 76,593 in 2018 to 100,034 in 2019.

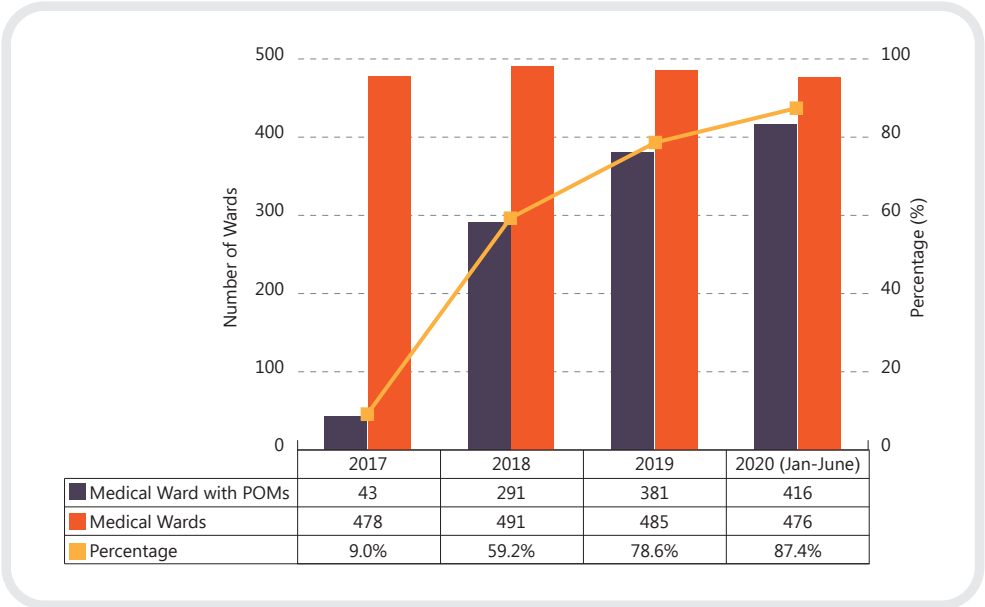


Increment of PPUSS from year 2015 to 2019

Medicines Optimisation

Patients' Own Medicines (POMs) was implemented in MOH facilities as an initiative to optimise medication use with the goals to improve patient treatment outcomes, avoid unnecessary medications, reduce wastage, and enhance medication safety. The programme encourages patients and caregivers to bring their own medications to the hospital during ward admission. With these medications, their healthcare providers are able to perform appropriate medication reviews and reconciliations in wards and upon discharge from the hospital.

A pilot study on the implementation of POMs in wards was conducted in 2017 for a three-month period, from January to March at 43 MOH facilities' medical wards with 1,384 patients enrolled. The study resulted in a total saving of RM106,394.76 of the cost of medicines. The POMs programme was therefore gradually introduced to all medical wards in all MOH facilities. In 2018, a target of 25 percent of medical wards in MOH facilities implementing the POMs programme was established. The target was increased to 50 percent in 2019 and to 75 percent in 2020. The majority of MOH facilities exceeded the target for POMs implementation in medical wards. The overall level of achievement at the national level is depicted in figure below.



Achievement of POMs programme from year 2017 to 2020

STRATEGY 2: ICT-BASED SERVICE INNOVATION

Apart from innovative delivery of pharmacy services, a strategy about innovative ICT-based service was also being exploited. This strategy talked about converting manual work into technology-based process, developing databases, implementing track and trace system and web-based management system.

Business Process Reengineering (BPR) of Manual Work Processes into Technology-Based Processes

This initiative aims to enhance service delivery efficiency by transforming manual work processes into web-based services and intends to support the Government Transformation Programme's (GTP), which aims to transform 95 percent of government services into online services by 2020. As of June 2020, 12 out of 14 manual work processes had been successfully converted to online services, with the remainders expected to be completed by the end of the year.

Integration of ICT-based systems

The rapid advancement of technology, particularly in the field of data science has ushered in a new era of organisational management, problem solving and strategic planning. Looking at the potential for intelligent system sharing, Pharmaceutical Services Programme (PSP) intends to implement a comprehensive data integration to improve data integration strategy in order to enhance data analysis activities that support decision-making and strategic planning process. PSP has responded to this call by establishing an initiative aims to integrate existing independent systems under PSP to improve systems efficiency and optimise data sharing.

Feasibility report was initiated in November 2017, followed by two (2) workshops conducted in 2018 to identify data for integration and flow between systems. The data integration platform known as Integrated Repository for Pharmacy Information Systems (IRIS) has been set up using open source software in 2019.

The initiative was completed in December 2019. All databases from the following systems were successfully connected to the IRIS platform:

- My.Pharma-C
- EDPF
- PRiSMA
- MERS
- Research
- QUEST3+
- PhIS/CPS

Due to system architecture constraints, two legacy systems, *Sistem Pengurusan Integrasi Kawalan Efektif Substans* (SPIKES) *and Sistem Pengurusan Iklan* (SPI), will not be integrated into IRIS. These systems, however, will be redeveloped into a new system called MyPRAISE and integrated with IRIS.

Implementation of Pharmaceutical Track and Trace System

Pharmaceutical Track and Trace System is implemented throughout the whole medicine supply chain from manufacturer to consumer. The objectives of this system are to strengthen regulatory activities through Global Standards, to optimise cost and operation efficiency, to enhance ecosystem of pharmaceutical sector and to improve patient safety.

A committee on developing this system had been established in 2017 with proposal presented and market survey and business model also implemented. This system would be developed as a public-private partnership project and the timeline to implement was extended to year 2023. There are many elements involved in order to make this system a reality, such as IT specifications and requirements, budget approval, regulatory review and stakeholders' engagement. As a continuity, stakeholders' engagement would be carried out through 2019 to 2023.

Optimisation of PhIS in MOH facilities

The Pharmacy Information System (PhIS) is a comprehensive web-based pharmacy management system that integrates pharmacy-related services intending to improve the monitoring of medicine procurement, supply, and use in government hospitals and health clinics. This system enables the sharing of patient drug profiles in order to provide seamless patient care and serves as a tool for making decisions regarding the country's medicines accessibility.

PhIS implementation started in 2014 in six (6) hospitals, one (1) district health office and 13 health clinics. By June 2020, PhIS & Clinic Pharmacy System (CPS) has been implemented at 1,248 MOH facilities nationwide. Reliability rates are measured based on system uptime nationwide, where the system records availability at a rate of 99.9 percent.

The following are the achievement rates for each module in terms of utilisation:

- Outpatient - 95.9 percent
- In Patient - 75.0 percent
- Inventory - 96.8 percent
- Counselling - 98.4 percent
- Manufacturing - 84.8 percent
- DICE - 90.2 percent
- Order Management (KPK) - 88.9 percent
- Ward Pharmacy - 94.3 percent
- MTAC - 96.5 percent
- TDM - 94.9 percent
- ADR - 99.0 percent

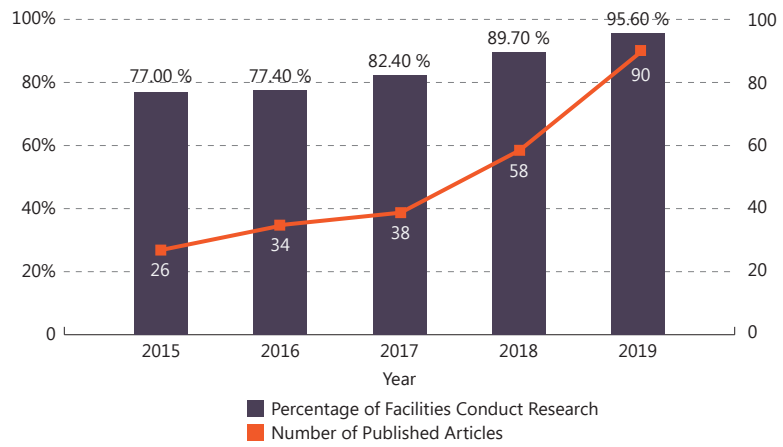
STRATEGY 3: ENHANCE RESEARCH, INNOVATION AND KNOWLEDGE SHARING

Enhancing research and advocating for knowledge sharing by providing clear guidance for studies particularly for policy-making decisions and also ensuring research studies reflect current health issues are crucial to help in attaining national health priorities and optimising time, effort and resources. This strategy comprised of two (2) initiatives as explained below.

Intensify Research and Innovation Based on Priority Areas Identified

This initiative focused on monitoring the percentage of pharmacy facilities within the MOH participated in research, the number of research presentations, and the number of articles published. The total number of active research projects reported nationally increased steadily from 729 in 2017 to 867 in 2019. Based on previous years' performance, the target is to have 95 percent of pharmacy facilities conducting research by 2020, with a 5 percent annual increment. With more participation of facilities, the PSP aims to publish at least 60 articles in journals or as technical reports by 2020. The number of articles published in 2019 exceeded the target of 60 set by the PSP.

Percentage of Facilities Conducting Research and The Number of Published Articles from 2015 to 2019



Intensify Knowledge Sharing in Research and Innovation through Multiple Platforms

i. Research Workshops and Training

At the national level, great efforts have been made to improve research performance through various educational workshops and training sessions. The PSP has organised a number of workshops, such as Advanced Biostatistics Workshop (2017), Systematic Review Workshop (2017), Good Clinical Practice Workshop (2019), and Manuscript Writing Workshop (2019), which were well attended by representatives across the country. These workshops aimed to strengthen pharmacy researchers' abilities to conduct high-quality research and to facilitate the dissemination of research evidence.

On the other hand, the Malaysian Alliance for Embedding Rapid Reviews (MAera) Workshop (2019) and the Secondary Data/ Database Research Workshop (2020) were organised to strengthen the analytical capabilities and capacity of officers in the PSP to conduct research at the national level using secondary data/ big data. It was hoped that these workshops would instill a culture of pharmacy research and help pharmacists improve the quality of their research.

ii. Publication of Malaysian Statistics on Medicines

The Malaysian Statistics on Medicines (MSOM) is a national-level medicine utilisation report published by the PSP. The MSOM reports total medicine used in the country as well as the pattern and trends of utilisation. It is produced to complement the efforts and outcomes of the National Medicines Policy (DUNas), which aims to ensure the citizens have equitable access to safe, effective, affordable and high-quality medicines, as well as to promote the rational use of medicines to improve the health of all Malaysians. Two (2) editions of MSOM were successfully published in 2017 and 2020, covering the statistics for the year 2011 to 2014 and 2015 to 2016, respectively.

iii. Publication of the Pharmacy Research Reports

The Pharmacy Research Reports is a peer-reviewed journal published by the PSP since 2018, as part of the efforts to enhance research and knowledge sharing and achieve the aims as stipulated in the Pharmacy Programme Strategic Plan 2017-2020. Increased dissemination of research findings aims to encourage pharmacists in the country to make decisions based on scientific evidence and to improve their practices and services. It is also hoped that this publication could spark new interests and encourage more pharmacists to be involved in pharmacy research. From 2018 to 2020, a total of 38 pharmacy research articles were published in the Pharmacy Research Reports.

The publication of Pharmacy Research Reports from 2018 to 2020

iv. The National Pharmacy Research and Development (R&D) Conference

The National Pharmacy R&D Conference is a prestigious event that is organised by Pharmacy Policy and Strategic Planning Division every two years as a platform for researchers to disseminate their research findings. In year 2018, a total of 114 researchers showcased their research findings at the 10th National Pharmacy R&D Conference. The conference was officiated by YBhg. Tan Sri Dato' Seri Dr. Noor Hisham bin Abdullah, Director General (DG) of Health, Malaysia, with the theme "Enhancing Access to Medicines Through Value-based Approaches". It was attended by more than 350 pharmacists, academicians, members of pharmaceutical industries and professional bodies from all over the country. Abstracts of the research presented in this conference were published as proceedings in the Malaysian Journal of Pharmacy 2018. Due to the unprecedented pandemic outbreak in year 2020, the 11th National Pharmacy R&D Conference that was scheduled in 2020 has been postponed to year 2021.

v. Pharmacy Research Priorities in Malaysia

The publication of the 'Pharmacy Research Priorities in Malaysia' intends to provide clear guidance for pharmacy research activities in generating useful evidence in line with the Malaysian National Medicines Policy. Prioritising pharmacy research is crucial for streamlining research efforts and maximising resources while achieving its main objective of bridging knowledge gaps and yielding more evidence to support service improvement and policy development.

The book was launched by YBhg. Tan Sri Dato' Seri Dr. Noor Hisham bin Abdullah, the DG of Health, Malaysia, at the 10th National Pharmacy R&D Conference on 8 July 2018 in Seremban, Negeri Sembilan. The DG of Health commended on the valuable support it will provide to Ministry of Health Strategic Plan 2016-2020 and the Pharmacy Programme Strategic Plan 2017-2020 in improving pharmaceutical services in the country.

Five (5) research priority domains have been identified which are:

1. Access to Medicines
2. Monitoring and Evaluation of Outcomes
3. Quality and Safe Use of Medicine and Sustainability
4. Optimisation of Therapy and Pharmacy Services Delivery
5. National Databases/ Big Data Analytics

These research priorities are applicable to all institutions or organisations in Malaysia that conduct pharmacy research. Therefore, all pharmacy and health researchers are encouraged to plan and design their studies in accordance with the outlined research priorities. The document will be reviewed and updated periodically to ensure it remains relevant to the country's evolving needs.

STRATEGY 4: ENHANCE BUSINESS PROCESS AND PRODUCT SAFETY

Privatisation of Pre-Registration Testing for Traditional Product

This initiative aims to recognise private laboratories with the capacities to perform testing for heavy metals, microbial contamination, uniformity of weight and disintegration, which are compulsory tests for traditional products registration as stated in the Drug Registration Guidance Document (DRGD), Appendix 5: Guideline on Registration of Natural Products. The target for this initiative is to have five (5) private laboratories recognised by year 2020.

- The list of Recognised Private Laboratories for Testing of Traditional Products is intended to facilitate those traditional product manufacturers which do not have quality control facilities or those who require testing services for their products. Application for recognition is on voluntary basis and those laboratories that complied with NPRA's requirement for testing of traditional products will be recognized.
- As of August 2020, 12 laboratories that have met the NPRA's requirements for traditional product testing, have been listed according to specific test and pharmaceutical dosage form. Of these, five (5) private laboratories are capable to conduct all four tests namely disintegration test, uniformity of weight test, microbial contamination test and heavy metal test. The list of recognised private laboratories is accessible on NPRA's website.
- The 344th Drug Control Authority (DCA) meeting on 30 April 2020 has agreed to accept the pre-registration traditional product testing results from the recognised private laboratories and from the manufacturers' laboratory effective 1 December 2020. With the issuance of the directive, NPRA will no longer conduct pre-registration testing for traditional products.

INNOVATION DRIVEN								
Translating ideas and innovations into services that create value for our customers								
Strategy	**Initiative**	**Strategy/ Initiative Details**	**Performance Indicator (Quality, Quantity or Time)**	**Implementation Status**				**Remarks**
				2017	**2018**	**2019**	**2020**	
STRATEGY 1: Implementation of Innovative Pharmacy Service Delivery	**Initiative 1:** Expansion of Integrated Drug Delivery System	This initiative aims to increase patient access to their medicine through value added service and ensuring continuity of their medication supply.	Number of new centres established (cumulative)	51 centres established (cumulative)	57 centres established (cumulative)	67 centres established (cumulative)	70 centres established (cumulative)	
	Initiative 2: Medicines Optimisation	This initiative focuses on patients and their experiences with the goals to help patients to improve treatment outcomes and avoid taking unnecessary medicines, reduce wastage as well as improve medication safety.	Percentage of medical wards implementing Patient's Own Medications (POMs) Programme	Pilot Study was conducted 9% of medical wards involved	59.2% of medical wards involved	78.6% of medical wards involved	Jan to June: 87.4% of medical wards involved	
			Number of facilities implementing Program Bekas Ubat	Pilot Study was conducted 17 facilities involved	17 facilities involved	Initiative discontinued (The pilot study result showed low retention rate of 37.3% for the programme, therefore this initiative was discontinued. The existing 17 facilities involved in the pilot study continue with the programme as it is.)		

INNOVATION DRIVEN								
Translating ideas and innovations into services that create value for our customers								
Strategy	**Initiative**	**Strategy/ Initiative Details**	**Performance Indicator (Quality, Quantity or Time)**	**Implementation Status**				**Remarks**
				2017	**2018**	**2019**	**2020**	
STRATEGY 2: ICT-based Service Innovation	**Initiative 1:** Business Process Reengineering (BPR) of manual work process to ICT-based	This initiative aims to improve efficiency of service delivery and to support the Government Transformation Programme (GTP).	Number of manual work process innovated	36% (5/14) of work processes completed	78% (11/14) of work processes completed	86% (12/14) of work processes completed	86% (12/14) of work processes completed	
	Initiative 2: Integration of ICT-based systems	This initiative focuses to integrate 5 existing independent systems to improve systems efficiency and optimise data sharing. The 5 systems are MyPharma-C, SPIKE, QUEST, MERS, PhIS/ CPS	Integration of the systems by year 2020	Proposal for the feasibility report was initiated in November 2017 A study on the need of integration between systems in MOH Pharmacy Programme will be conducted in 2 phases	2 workshops conducted to identify data for integration and flow between systems Integration point identified and to consolidate in a 'common data storage' This study shall be utilised during requirement evaluation for the integration activity	The data integration platform set up using open source software All databases from the following systems successfully connected to the platform: My.Pharma-C, EDPF, PRiSMA, MERS, Research, QUEST3+, PhIS	All databases from the following systems successfully connected to the IRIS platform: My.Pharma-C, EDPF, PRiSMA, MERS, Research, QUEST3+, PhIS/CPS	SPIKES will not be integrated into IRIS due to system architecture limitations. This system will be replaced by MyPRAISE and will integrate with IRIS.

INNOVATION DRIVEN								
Translating ideas and innovations into services that create value for our customers								
Strategy	**Initiative**	**Strategy/ Initiative Details**	**Performance Indicator (Quality, Quantity or Time)**	**Implementation Status**				**Remarks**
				2017	**2018**	**2019**	**2020**	
STRATEGY 2: ICT-based Service Innovation	**Initiative 3:** Implementation Pharmaceutical Track & Trace System	A system to improve patient safety and optimisation of logistic management.	1st phase Track & Trace System implemented by 2019	Proposal presented in DCA Meeting Jawatankuasa Sistem Track & Trace established Market survey and business model implemented	Pharmaceutical Track & Trace System presented to the MOH top management, pharmaceutical industry and in national conference. MOH Block Chain Pilot Study (Block Chain & Track & Trace System Application)	The system was agreed to be developed as a public-private partnership (PPP) project.	Allocation of RM1 million to implement preliminary parameters (pilot project) proposed. MyMediTRACE project presented. Seek approval from UKAS to implement the project through PPP	

<table>
<tr><th colspan="6">INNOVATION DRIVEN</th></tr>
<tr><th colspan="6">Translating ideas and innovations into services that create value for our customers</th></tr>
<tr><th rowspan="2">Strategy</th><th rowspan="2">Initiative</th><th rowspan="2">Strategy/ Initiative Details</th><th rowspan="2">Performance Indicator (Quality, Quantity or Time)</th><th colspan="3">Implementation Status</th><th rowspan="2">Remarks</th></tr>
<tr><th>2017</th><th>2018</th><th>2019</th><th>2020</th></tr>
<tr><td></td><td>Initiatives 4: Optimisation of PhIS in MOH facilities</td><td>PhIS is a web-based drug management system to be fully-utilised in all MOH facilities by year 2020.</td><td>Percentage of ARU (Availability, Reliability and Utilisation)</td><td colspan="3"><table>
<tr><td></td><td>2017</td><td>2018</td><td>2019</td><td>2020 (Jan to June)</td></tr>
<tr><td>Availability</td><td>90%</td><td>92%</td><td>95.6%</td><td>95.7%</td></tr>
<tr><td>Reliability</td><td>99%</td><td>99.9%</td><td>99.9%</td><td>99.98%</td></tr>
<tr><td colspan="5">Utilization (by module):</td></tr>
<tr><td>Outpatient</td><td>67%</td><td>89.76%</td><td>93.5%</td><td>95.9%</td></tr>
<tr><td>Inpatient</td><td>72%</td><td>72.98%</td><td>83.9%</td><td>75.0%</td></tr>
<tr><td>Inventory</td><td>87%</td><td>76.15%</td><td>89.6%</td><td>96.8%</td></tr>
<tr><td>Counselling</td><td>33%</td><td>88.11%</td><td>96.5%</td><td>98.4%</td></tr>
<tr><td>Manufacturing (extemporaneous)</td><td>35%</td><td>67.39%</td><td>86.3%</td><td>84.8%</td></tr>
<tr><td>Drug Information and Consumer Education (DICE)</td><td>12%</td><td>69.92%</td><td>88.6%</td><td>90.2%</td></tr>
<tr><td>Order Management (KPK)</td><td>17%</td><td>84.81%</td><td>93.4%</td><td>88.9%</td></tr>
<tr><td>Ward Pharmacy</td><td>40%</td><td>69.22%</td><td>89.8%</td><td>94.3%</td></tr>
<tr><td>MTAC</td><td>29%</td><td>80.18%</td><td>92.4%</td><td>96.5%</td></tr>
<tr><td>TDM</td><td>23%</td><td>77.32%</td><td>88.3%</td><td>94.9%</td></tr>
<tr><td>ADR</td><td>22.5%</td><td>87.32%</td><td>96.5%</td><td>99.0%</td></tr>
</table></td><td>Utilization data in 2017 was baseline</td></tr>
<tr><td>STRATEGY 3: Enhance Research, Innovation and Knowledge Sharing</td><td></td><td></td><td>Number of articles/ technical report published</td><td>38 articles published</td><td>Business Value Impact Assessment Workshop conducted</td><td>90 articles published</td><td>Jan-June: 33 publications</td><td></td></tr>
</table>

INNOVATION DRIVEN								
Translating ideas and innovations into services that create value for our customers								
Strategy	**Initiative**	**Strategy/ Initiative Details**	**Performance Indicator (Quality, Quantity or Time)**	**Implementation Status**				**Remarks**
				2017	**2018**	**2019**	**2020**	
STRATEGY 3: Enhance Research, Innovation and Knowledge Sharing	**Initiative 1:** Intensify research and innovation based on priority areas identified	To conduct research or innovation/ QA projects based on Pharmacy Programme Research Priority Areas Framework (Standard in 2015: 50%)	Percentage of pharmacy facilities within MOH conducting research or innovation/ QA projects	Research: 82.4%	Research: 89.7% QA: 36.3% KIK: 24.5% Innovation: 36.6%	Overall: 97.1%	Jan – June: Overall: 97.45%	
	Initiative 2: Intensify knowledge sharing in research and innovation through multiple platforms	This initiative aims to intensify knowledge sharing in research and innovation. Findings and reports are encouraged to be presented in various platforms.	Number of researches or innovation/ QA projects presented	Total presentation: 266 Research: 208 QA/ Innovation/ KIK: 58	Total presentation: 537 Research: 297 QA/ Innovation/ KIK: 240	Total presentation: 729 Research: 418 PIKF: 311 QA: 120 KIK: 68 Innovation: 114 Others: 9	Jan - Jun 2020: Total presentation: 63 Research: 50 QA: 1 KIK: 2 Innovation: 9 Others: 1	

INNOVATION DRIVEN								
Translating ideas and innovations into services that create value for our customers								
Strategy	**Initiative**	**Strategy/ Initiative Details**	**Performance Indicator (Quality, Quantity or Time)**	**Implementation Status**				**Remarks**
				2017	**2018**	**2019**	**2020**	
STRATEGY 4: Enhance Business Process and Product Safety	**Initiative 1:** Recognition of private laboratories (conducting test for traditional products)	This initiative aims to recognise private laboratories with the capacities to provide testing for heavy metal, microbial contamination, uniformity of weight, and disintegration.	Number of private laboratories recognised	13 laboratories	14 laboratories	12 laboratories	Jan-Aug: 12 laboratories	
	Initiative 2: Privatisation of pre-registration testing for traditional product	Privatisation of pre-registration testing for traditional products, will enable NPRA to redeploy resources for new services.	Registration testing for traditional products fully conducted by recognised private laboratories by 2020	N/A	Policy was presented in DCA 326 & Policy Meeting. In line with the decision of DCA 326, companies are given the options to send samples for pre-registration testing to NPRA or to any other listed panel laboratories.	Improvements of work process for Pelaksanaan Penggunaan Khidmat Luaran (Outsourcing) Bagi Pengujian Produk Semulajadi Pra-pendaftaran: Dialogue with Product Registration Holder, online public engagement session, dialogue with panel laboratories	DCA 344 agreed to accept results of pre-registration testing of traditional products from private laboratories that have been recognized by NPRA and quality control laboratories of local manufacturers effective 1 Dec 2020.	

THRUST 3: OPERATIONAL EXCELLENCE

STATEGY 1: IMPROVE ACCESSIBILITY OF PHARMACEUTICAL PRODUCTS

Implementation of Price Setting Mechanism

Implementation of the price-setting mechanism for medicines is one of the initiatives to improve the accessibility of pharmaceutical products in the country. Development of a mechanism for price-setting was initiated by this Programme through collaboration and cooperation with relevant authorities and stakeholders. Transparency in price information is fundamental in a duly established medicine pricing mechanism. This is consistent with the resolution "Improving the transparency of markets for medicines, vaccines, and other health products" as discussed at the 72nd World Health Assembly (WHA) held on 20th to 28th May 2019 in Geneva. The resolution urges the Member States to take an open approach to share price information, drug costs, patent status and product marketing approvals. The move will help strengthen the government's negotiating position and increase the country's ability to obtain affordable medicine prices in tackling rising healthcare costs.

In 2017, a task force was established to develop a concept paper on Medicines Pricing Mechanism. The committee has reviewed and discussed with relevant authorities on existing laws and legislation pertaining to price declaration under the Control of Drugs and Cosmetics Regulation 1984 (CDCR) and the Price Control and Anti Profiteering Act 2011 [Act 723] under the jurisdiction of the Ministry of Domestic Trade and Consumer Affairs (*Kementerian Perdagangan Dalam Negeri dan Hal Ehwal Pengguna*, KPDNHEP). Numerous engagement sessions with internal and external stakeholders have been held over the years to gather information and feedback on the best mechanism to be implemented in the country and potential impact on its stakeholders. Furthermore, the Health Advisory Council and a panel of experts were also being consulted on the medicines price concept.

Cabinet adopted the Memorandum on Medicines Price Control in April 2019. Regulatory Impact Analysis (RIA) for the proposal to implement medicines price controls under Act 723 has been completed and is currently being evaluated by the Malaysia Productivity Corporation (MPC). RIA is required to propose new regulations to ensure all available options have been thoroughly analysed for their effectiveness and that the best option is justified.

From 26 July to 26 August 2019, Unified Public Consultation (UPC) was conducted to solicit feedback on the proposal from all stakeholders and the public via a central online platform developed by MPC. UPC is an alternative channel that can be used in addition to face-to-face and personalised meetings with stakeholders. The Programme received overwhelming responses from the UPC platform. Hence, the Pharmaceutical Services Programme was awarded the recognition of Active Participation in Unified Public Consultation 2019 by MPC. As of 2020, a new Cabinet Memorandum has been prepared for approval by the current Cabinet.

Improving Access to Affordable Medicine through Patient Access Scheme (PASc)

Patient Access Scheme (PASc) was established to enable patients to gain access to medicines, particularly those that are high-cost or innovative medicines. The concept of PASc for the purpose of improving access to high cost medicines is not uncommon, as it has been widely practised in various countries to assist patients in receiving treatment at a lower and affordable cost.

Two (2) guidelines have been developed and distributed for this purpose:

1. Guidelines for Proposal Submission on Patient Access Scheme (PASc) Implementation in Ministry of Health, Malaysia
2. *Garis Panduan Pengendalian Ubat-Ubatan yang Ditawarkan secara Patient Access Scheme (PASc) di Fasiliti-fasiliti Kementerian Kesihatan Malaysia*

This initiative is designed to improve patient access to innovative and high-cost medicines through novel market access agreements. The scheme aims to provide equitable and affordable access to innovative drugs for patients with life-threatening or seriously debilitating condition with inadequate treatment options.

Since the PASc Submission Guideline published in 2018, PASC secretariat had received and processed a total of 17 proposals as of August 2020. 16 proposals are categorised as Complex Schemes, while one (1) is classified as Simple

Scheme. However, none of the PASc proposals were approved by the MOH Controlling Officer.

Number of PASc Proposals Received from 2018 to August 2020

	Year		
	2018	2019	2020
No. of PASc Proposals Received	6	6	5

STRATEGY 2: IMPROVE EFFICIENCY AND OPTIMISE EXPENDITURE

Utilisation of Local Pharmacoeconomic Data in the Selection of Medicines for Formulary Listing

It is essential to practice a fair and transparent medicines selection mechanism in accordance with the country's health needs. Selection of medicines into the Ministry of Health Medicine Formulary (MOHMF) is based on several criteria, including cost-effectiveness of the treatment. However, there is a dearth of local studies conducted by utilising local data to support the decision making. In an effort to encourage the conduct of local pharmacoeconomic studies, the Pharmacoeconomics Guideline for Malaysia was developed in 2012.

Under the Strategic Plan 2017-2020, initiatives were taken to update the 2012 guideline and to assess number of dossiers submitted with pharmacoeconomic studies. In December 2019, the Pharmacoeconomics Guideline for Malaysia (Second Edition) was successfully completed and distributed. It was made accessible online at www.pharmacy.gov.my.

Over the three (3) years period from 2017-2019, the percentage of dossiers received with pharmacoeconomic studies was 35.9 percent (baseline), 33.3 percent and 41.9 percent respectively. An increase in year 2019 was observed potentially due to multiple engagements done with the pharmaceutical companies who are the main stakeholders for formulary listing dossier submission. Nevertheless, it is important to highlight that pharmacoeconomic study does not apply to all medicines, limiting yearly achievement.

STRATEGY 3: STRENGTHEN MONITORING ACTIVITIES OF UNREGISTERED PRODUCTS

Expand the "Didik, Pantau dan Serbu" (DiPS) Approach to the Hotspot Areas

Recognising the negative implications of the sales of unregistered health products to consumer, DiPS initiative was developed. DiPS or "Didik, Pantau and Serbu" initiative is a systematic approach to reduce sales of unregistered products through awareness and surveillance amongst retailers. This initiative is focusing on the retailers that sell unregistered products in hotspot area. Hotspot area refers to an identified place that is closely monitored by the State Enforcement Branch. The hotspot areas include premises such as drug/ herbal/ cosmetics shop, night/ morning market, supermarket/ mart/ kiosk, pedestrian area, beauty centre/ spa and grocery store.

The initiative begins with awareness programmes designed to educate the retailers on the features of registered health products, and the requirements of the laws and regulations, etc. This is followed by monitoring and inspection to ensure that the sale and supply of health products and cosmetics done by the retailers are in accordance with the laws and regulations enforced. If any non-compliance detected, legal action would be taken against the respected retailers.

Since the initiative's inception in 2017, DiPS has contributed to 84.57 percent reduction of targeted premises selling unregistered health products. This significant achievement is an indicator to show that this initiative is positive, significant and has the potential to continue in the following years by further expanding the hot spot areas.

Monitoring Sales of Unregistered Products and Cosmetics in the Social Media and Instant Messaging Platforms

Irresponsible sellers may take the opportunity to use this medium for advertising and selling products that are deleterious and harmful to health. Most common is the advertisement and selling of unregistered health products. Unregistered health products never being evaluated by the authority for its safety, quality and efficacious. Thus, it is highly potential to cause risk and harmful effects on consumers.

Realising these, Pharmacy Enforcement Divisions (PED) has taken proactive actions through screening and monitoring unapproved medical

advertisements. Actions are taken on the sellers and advertisers of unregistered health products, which includes warnings and legal actions. Awareness sessions to consumers, sellers, advertising agencies and local authority on how to identify approved medical advertisements and registered health products were conducted from time to time.

Continuous awareness activities under the tagline *#biarbetuliklanni!* are also carried out by PED and CPF in raising awareness on the risk of buying medicine online to the public and online sellers. Multiple types of media are used to disseminate the information, such as in conventional way (car sticker, poster, brochure, talk, exhibition etc.) and digital medium (using Facebook Ads, Google Ads, digital screen in hotspot area and many others).

STRATEGY 4: STRENGTHEN GOVERNANCE AND REGULATORY CONTROL

Establishment of NPRA as a Certified Conformity Assessment Body (CAB)

The plan to establish NPRA as a certified Conformity Assessment Body (CAB) was introduced as Initiative 1, under Strategic Thrust 3 (Sustaining Operational Excellence), Strategy 4: Strengthen Governance & Regulatory Control, in the Pharmacy Programme Strategic Plan 2017-2020. This initiative aimed to enhance regulatory control and governance of NPRA in the field of medical device by pursuing certification as CAB by the Medical Device Authority (MDA), Malaysia in 2018.

NPRA managed to complete 'ISO 13485 with Directive 93/42/EEC and 98/79/EC Lead Auditor Training' in January 2017 as part of the pre-requisite criteria followed by the submission of a formal application to MDA in August 2017. NPRA was subsequently audited by MDA in November 2017, and a Corrective and Preventive Action (CAPA) report was submitted by NPRA to MDA within the same month.

However, MDA in February 2018, informed that based on opinion from the Legal Advisor of MOH, NPRA as a Government Agency does not fulfil the requirements under Act 737 and Medical Device Regulations 2012 and thus, it was inappropriate to certify NPRA as a CAB. Following this, the Senior Officer Meeting (SOM) in April 2018 had opted to discontinue this initiative.

Enhance Regulatory Control of Vaccine in the Aspects of Laboratory Testing

This initiative aims to enhance regulatory control of vaccines through collaboration with an identified partner in developing vaccine testing methods. This initiative aims to have three (3) vaccine testing methods developed by the year 2020.

The National Committee on Immunization and Policy Meeting decided that the development of vaccine potency test should be given priority. Based on the expertise and available facilities, these are the divisions under MOH that have been identified to be involved in the development of the vaccine potency test:

1. Disease Control Division
2. National Public Health Laboratory (NPHL)
3. Institute of Medical Research (IMR)
4. National Pharmaceutical Regulatory Agency (NPRA)

In this regard, the Technical Committee for Development of Vaccine Potency Testing was established in 2017 to ensure collaboration between divisions under the MOH to develop and strengthen the capacity for vaccine potency testing in Malaysia. The main responsibility of this technical committee is to identify and determine the types of vaccines and potency tests to be developed, to carry out method development for potency testing and to establish relevant guidelines and SOPs.

The roles of NPRA in this committee are as followed:

a) To share information on testing procedures, test specification and other information needed for conducting vaccine potency testing

b) To develop potency test methods and conduct potency testing on vaccine for post-market surveillance, complaint and lot release purposes

c) To decide regulatory action for noncompliance to lot release requirements or post-marketing surveillance activities

Currently, NPHL has the capacity to conduct potency tests for both BCG and MMR vaccines which was successfully developed in 2018, whereas NPRA was tasked with developing a

test for Aluminium content in Hepatitis B Vaccine which was successfully completed in 2019 and is currently working towards developing a potency test method for Hepatitis B vaccine which is targeted to be completed by December 2020.

Moving forward, this collaboration aims to develop more potency test methods on selected vaccines which will be identified by considering factors such as number of doses imported, National Immunisation Programme (NIP), Adverse Events Following Immunization (AEFI) and availability of resources and capacity.

STRATEGY 5: ENHANCE ORGANISATIONAL EFFICIENCY

Establishment of NPRA as a Statutory Body

This initiative was identified and proposed originally for NPRA to be more autonomous in terms of policy-decision making within the context of the medicines regulatory environment, as well as more flexible and efficient in operational decision-making.

In order to become a statutory body, an Act has to be established to govern the functions and duties to be carried out by NPRA. A Regulatory Impact Analysis (RIA) needs to be performed to identify and assess the expected effects of this proposal prior to the preparation and finalizing the Act to be tabled to the Parliament.

In April 2017, the concept paper as well as the Cabinet Paper (MJM) was prepared and presented to the top management of Pharmaceutical Services Programme (PSP), awaiting confirmation to present to the MOH top management.

However, in January 2018, the PSP received a memo from the Policy and International Relations Division (BDHA) under MOH requesting for all programmes and divisions to postpone any new policies, projects and government programs that would not be favourable to the *rakyat.* Hence, in line with this new policy, the PSP's Senior Officers Meeting 2/2018 on 3 April 2018 had decided to discontinue the proposal to establish NPRA as a statutory body and for the initiative to be dropped for now.

Establishment of PBMD as a Statutory Body

It is agreeable by the Pharmaceutical Services Programme that Pharmacy Board Malaysia Division (PBMD) should be restructured instead of forming a statutory body. Furthermore, till to date, the amendment of the Registration of Pharmacists Act 1951 is still not been finalised yet.

OPERATIONAL EXCELLENCE								
The element of organisational leadership that applies a variety of principles, systems, and tools toward the sustainable improvement of key performance metrics								
Strategy	**Initiative**	**Strategy/ Initiative Details**	**Performance Indicator (Quality, Quantity or Time)**	**Implementation Status**				**Remarks**
				2017	**2018**	**2019**	**2020**	
STRATEGY 1: Improve Accessibility of Pharmaceutical Products	**Initiative 1:** Implementation of Price Setting Mechanism	Price setting for medicines will be done through the development of a mechanism for price setting in cooperation with relevant authorities.	Medicines Price Setting Mechanism is implemented	Appointment of Task Force for the development of Concept Paper Engagement with private associations, public sector stakeholders, on medicine price declaration	Concept paper presented to MOH top management Medicine Pricing & Reimbursement Workshop MJM Medicines Price Control submitted to the relevant Ministries for comment	Pricing Mechanism presented to MOH top management Cabinet approved MJM on Medicines Price Control Meetings and engagements with relevant stakeholders Proposal for pre-impact study & framework of MedPrice prepared	Pricing Mechanism and new MJM presented to MOH top management KPDNHEP principally agreed with delegation of power of Deputy & Assistant Price Controller to MOH Pharmacy Officers, in accordance of Act 723 Stakeholder engagement sessions with government agencies and NGO New MJM forwarded to KPDNHEP	

OPERATIONAL EXCELLENCE								
The element of organisational leadership that applies a variety of principles, systems, and tools toward the sustainable improvement of key performance metrics								
Strategy	**Initiative**	**Strategy/ Initiative Details**	**Performance Indicator (Quality, Quantity or Time)**	**Implementation Status**				**Remarks**
				2017	**2018**	**2019**	**2020**	
STRATEGY 1: Improve Accessibility of Pharmaceutical Products	**Initiative 2:** Improving access to affordable medicines through Patient Access Scheme (PASc)	This initiative is designed to improve patient access to innovative and high cost medicines through novel market access agreement. Cost shall not become a barrier for a population to get the best treatment. The scheme shall provide equitable and affordable access to innovative drugs for patients with life threatening or seriously debilitating condition without adequate treatment options.	Guideline on Proposal Submission for PASc Implementation in Ministry of Health developed by 2018	Preparation of the draft of Guidelines on the Proposal Submission for PASc Implementation in Ministry of Health	Guideline developed and disseminated	4 PASc proposals from pharmaceutical companies were evaluated. JK Panel PASc Meeting was held on 1st of July 2019. None of the PASc proposals were approved.	As of June 2020, no PASc proposals have been approved. Preparation to review PASc submission guideline has begun. Plan to complete revision at the end of 2020.	
			Garis Panduan Pengendalian Ubat-Ubatan yang Ditawarkan secara PASc di Fasiliti-fasiliti KKM developed by 2019	Preparation of the draft of Garis Panduan Pengendalian Ubat-Ubatan yang Ditawarkan secara PASc di Fasiliti-fasiliti KKM	Relevant stake holders identified and preliminary engagement done Preparation of the guideline	Guideline has been distributed to all MOH facilities on 21st of October 2019	As of June 2020, no PASc proposals have been approved. Monitoring of PASc will start after PASc proposals have been approved and implemented.	
			Number of drugs approved for PASc (start to monitor in year 2019)	N/A	N/A	No PASc proposals have been approved in 2019	As of June 2020, no PASc proposals have been approved.	
STRATEGY 2: Improve Efficiency & Optimise Expenditure	**Initiative 1:** To promote the utilisation of local pharmaco-economic (PE) data in the selection of medicines	This initiative aims to encourage pharmaco-economic studies utilising local data	PE Guideline 2nd Edition published by 2019	Workshop to review PE Guideline has been conducted in Sept 2017	Draft PE Guideline 2nd edition completed	Draft has been finalised	PE Guidelines for Malaysia, Second Edition 2019 has been disseminated on 27 February 2020	The guideline is now available for reference at the Pharmaceutical Services Programme's official website: www.pharmacy.gov.my.
			Percentage of dossier received with PE study	35.9% (Baseline data)	33.33%	41.86%	21.05%	

OPERATIONAL EXCELLENCE								
The element of organisational leadership that applies a variety of principles, systems, and tools toward the sustainable improvement of key performance metrics								
Strategy	**Initiative**	**Strategy/ Initiative Details**	**Performance Indicator (Quality, Quantity or Time)**	**Implementation Status**				**Remarks**
				2017	**2018**	**2019**	**2020**	
STRATEGY 3: Strengthen monitoring activities of unregistered products	**Initiative 1:** Expand the "Didik, Pantau dan Serbu" (DiPS) approach to the hotspot areas	DiPS is a systematic approach to reduce sales of unregistered products through awareness and surveillance amongst retailers	Percentage of targeted premises selling unregistered drugs	63.29% reduction of targeted premises	65.57% reduction of targeted premises	79.57% reduction of targeted premises	92.57% reduction of targeted premises Till 30 June: 84.57% reduction of targeted premises selling unregistered health products	
	Initiative 2: Monitoring the sales of unregistered products and cosmetics in the social media and instant messaging platforms	This initiative aims to increase the monitoring the sales of unregistered pharmaceutical products in the social media and instant messaging platforms in order to curb the illegal sales practices.	The number of social media platforms and instant messaging (IM) platforms monitored	4 (Instagram, WeChat, Line, Whatsapp) 9 media platforms being monitored (cumulative)	5 (ezbuy, Carousell, ebay Malaysia, Google+, Kakao talk) 14 media platforms being monitored (cumulative)	5 (Ubuy, EC21, Alibaba, Pinterest, Malaysianedge) 19 media platforms being monitored (cumulative)	5 (iklanlah, Sekaki, Majalah, Bazariaonline, Secondhand.my) 24 media platforms being monitored (cumulative) Till 30 June: 27 new media platforms monitored??	
STRATEGY 4: Strengthen Governance & Regulatory Control	**Initiative 1:** Establishment of NPRA as a certified Conformity Assessment Body (CAB)	This initiative aims to enhance regulatory control and governance of NPRA in medical device.	Certified as a CAB by Medical Device Authority (MDA) by 2018	Completed Lead Auditor Training NPRA was audited by MDA CAPA report submitted to MDA	The application for registration of NPRA as a CAB was not approved	Initiative discontinued	Initiative discontinued	

OPERATIONAL EXCELLENCE								
The element of organisational leadership that applies a variety of principles, systems, and tools toward the sustainable improvement of key performance metrics								
Strategy	**Initiative**	**Strategy/ Initiative Details**	**Performance Indicator (Quality, Quantity or Time)**	**Implementation Status**				**Remarks**
				2017	**2018**	**2019**	**2020**	
STRATEGY 4: Strengthen Governance & Regulatory Control	**Initiative 2:** Enhance Regulatory Control of Vaccine in the Aspects of Laboratory Testing	This initiative aims to enhance regulatory control in vaccine through collaboration with identified partner in developing vaccine testing method	Vaccine testing method developed by 2018	Collaborating partner identified Laboratory facilities and equipment upgraded	MKAK has developed potency test for BCG and MMR Vaccines NPRA is developing test for Aluminium content in Hepatitis B Vaccine	NPRA is developing Potency Test method for Hepatitis B Vaccine and expected to complete by June 2020 NPRA has developed method for aluminium content in Hepatitis B vaccine	Due to the current pandemic, the shipment for testing kit and chemicals required for Hepatitis B Vaccine Potency Test method development was disrupted. Therefore, the method development is expected to complete by December 2020.	
STRATEGY 5: Enhance Organisational Efficiency	**Initiative 1:** Establishment of NPRA as a Statutory Body	This initiative focuses on enhancing NPRA efficiency through establishment as statutory body	Finalisation of bill	Draft Concept Paper presented Stakeholders engagement with industry, association, MOH and JPA Survey on the NPRA staff level of readiness conducted	Cabinet paper has been prepared and NPRA is awaiting confirmation from MOH top management on the future direction of this proposal	No further action for this initiative	Initiative discontinued	Although NPRA generates an increasing amount in revenue each year, the expenditure exceeds the revenue especially in terms of employee emoluments. This clearly shows that NPRA is still not able to sustain herself as a self-financing entity as well as a statutory body.
	Initiative 2: Establishment of LFM as a Statutory Body	This initiative focuses on enhancing LFM efficiency through establishment as statutory body	Finalisation of bill	Establishment of MPC Working Group	Postponed due to RUUF not gazetted yet	Initiative discontinued	Initiative discontinued	

THRUST 4: CAPABILITY BUILDING

STRATEGY 1: ENHANCE HUMAN RESOURCE COMPETENCY AND PERFORMANCE

This framework identifies career pathway and training for pharmacists in different settings or career options. Ten (10) components had been identified but only six (6) were drafted, therefore this initiative will be continued in the next term of Strategic Planning.

Expansion of Credentialing Activities

Credentialing is one of the activities under the Pharmaceutical Services Programme to recognise and identify pharmacists and pharmacist assistants who have expertise knowledge in particular field related to pharmacy. The area of practice includes pharmacy practice, pharmacy enforcement and regulatory pharmacy with a variety of modules to be recognised. Seven (7) new credentialing modules have been identified and 333 qualified pharmacists have been credentialed in these various fields.

Establishment of Subject Matter Expert (SME) Programme in Pharmacy Services

Three (3) new areas of SME for Pharmacy Programme have been approved by Public Service Department Malaysia (JPA):

1. Phase 1 Clinical Trial: First dose in Human
2. Pharmacotherapy: Cardiology (Anticoagulant)
3. Pharmacotherapy: Infectious Disease

Competency Dictionary and Evaluation of SSA (SME Special Assignment) for the three areas have been identified and developed. Seven (7) new credentialing modules have been identified and 333 qualified pharmacists have been credentialed in the various fields.

STRATEGY 2: OPTIMISE HUMAN RESOURCE CAPACITY TO ENSURE CONTINUOUS SERVICE DELIVERY

Develop Staffing Guidelines based on Facility Workload

Staffing Guidelines based on facility workload were developed for hospitals and health clinics using Workload Indicators for Staffing Need (WISN) method:

Staffing Guidelines based on facility workload using WISN method began to be developed since 2014, led by Planning Division, MOH. A template has been developed and data have been collected from states. 148 hospitals and 747 health clinics have been involved in the pilot project to develop these staffing guidelines.

CAPABILITY BUILDING								
Process of developing and strengthening the skills, abilities and resources that organisations need to adapt and thrive in a changing environment								
Strategy	**Initiative**	**Strategy/ Initiative Details**	**Performance Indicator (Quality, Quantity or Time)**	**Implementation Status**				**Remarks**
				2017	**2018**	**2019**	**2020**	
STRATEGY 1: Enhance Human Resource Competency and Performance	**Initiative 1:** Develop capability building framework (technical and management)	This initiative aims to develop a framework that offer an overview of the various career options along with education and training in pharmacy services	Capability Building Framework developed	N/A	10 components identified (functional & technical components)	6 out of 10 components have been drafted (60%)	Initiative to be continued in Pelan Strategik Program Perkhidmatan Farmasi 2021-2025	Generic component will be established by JPA/ KKM
	Initiative 2: Expansion of credentialing activity	Credentialing and Privileging (C&P) is a programme to credential qualified individuals in identified areas of practice Area of Practice (Bidang): Enforcement (Cyber Forensic), Clinical, Pharmacy Practice, R&D, Regulatory	Number of identified areas of practice established	No new module identified	Achievement 100% 5 new modules identified	Achievement 100% 2 new modules identified (Sterile Pharmaceutical Preparation & Chromatography & Spectrograph technique)	No new modules identified until June 2020	
			Number of qualified pharmacists being credentialed	54 qualified pharmacists credentialed	45 qualified pharmacists credentialed	188 qualified pharmacists credentialed 3 credentialing retention approved	No new credentialing applications approved until June 2020	
	Initiative 3: Establishment of Subject Matter Expert (SME) Programme in pharmacy services	Subject Matter Expert (SME) Programme is a form of recognition to an individual pharmacist who is an expert in a particular area/ field.	Establishment of Subject Matter Expert (SME) Programme in pharmacy services	3 areas submitted for approval	3 new areas of SME approved by JPA Competency Dictionary for the 3 areas of SME developed Evaluation of SME (SME Special Assignment) for the 3 areas identified	Bengkel SME Program Farmasi conducted to develop competency dictionary New area of SME proposed	New area of SME proposed: 1. Pharmaco-kinetics 2. Nuclear Pharmacy 3. Pharmaco-economics 4. Pharmaceutical & Herbal Drug Discovery & Delivery: Translational PKPD 5. Pharmacovigilance 6. Penilaian Teknologi Farmaseutikal 7. Endocrinology 8. Respiratory (All 8 areas proposed are still being reviewed)	

CAPABILITY BUILDING								
Process of developing and strengthening the skills, abilities and resources that organisations need to adapt and thrive in a changing environment								
Strategy	**Initiative**	**Strategy/ Initiative Details**	**Performance Indicator (Quality, Quantity or Time)**	**Implementation Status**				**Remarks**
				2017	**2018**	**2019**	**2020**	
STRATEGY 1: Enhance Human Resource Competency and Performance	**Initiative 4:** Enhance officers' capability to carry out analysis of digital evidence (Cyber Forensic Laboratory)	To conduct a special training with accredited forensic agency specifically on Computer and Mobile Forensic Tools.	Number of officers undergo training and certified	100% achieved	100% achieved	100% achieved (Web Reconstruction and Evidence Analysis Training)	100% achieved	
STRATEGY 2: Optimise Human Resource Capacity to Ensure Continuous Service Delivery	**Initiative 1:** Develop Staffing Guidelines based on facility workload	This initiative aims to come out with a standard staffing needs using WISN method	Staffing guidelines developed	2 WISN templates developed for hospital and health clinic 255 hospital and health clinic underwent testing with the templates	WISN template for NPRA to be finalised due to organizational restructuring of NPRA A workshop for Enforcement Pharmacy conducted and the WISN template to be finalised in early 2019	Bengkel WISN Pegawai Farmasi for state pharmacy division conducted WISN template for Enforcement Pharmacy developed	WISN template for state pharmacy division is being refined and will be finalised by the end of 2020	
	Initiative 2: Establish staffing needs of each selected MOH facilities based on workload	This initiative is to deploy the staffing guideline (WISN method) to all selected MOH facilities in identifying the staffing needs of each facility based on each individual workload.	The number of selected MOH facilities tested using WISN method (747 health clinics and 148 hospitals)	N/A	This indicator will be measured in 2019	Data analysis for hospital and health clinic facilities completed	Initiative to be continued in Pelan Strategik Program Perkhidmatan Farmasi 2021-2025	

ISSUES AND CHALLENGES

PHARMACEUTICAL SERVICES PROGRAMME STRATEGIC PLAN 2021-2025

MEDICATION LITERACY AND EDUCATION

Malaysia continues to see an increase in the prevalence of non-communicable diseases (NCD), which is now among the highest in the ASEAN. In Malaysia, one in every five adults has diabetes, and that sums up to 3.9 million population. According to the National Health and Morbidity Survey (NHMS) 2019, diabetes has increased in prevalence from 11.2 percent in 2011 to 13.4 percent in 2015 and 18.3 percent in 2019. Based on the findings from the National Survey on the Use of Medicines by Malaysian Consumers (NSUM), only 44 percent of Malaysian consumers are aware of proper use of medication. In light of the findings, communities and individuals must be empowered to act against NCD risk factors and to increase knowledge and understanding towards medications management which may aid them in achieving better health outcomes.

Malaysia is moving fast towards having an ageing population. Proliferation of elderly nursing homes or home care institutions are becoming significant in the society. Most institutions are in neglected conditions with inadequate care and facilities for the resident seniors. Whilst ensuring the safety of these elderly people, more attentions are also needed to deliver health care to them effectively. Lack of attention may result in mismanagement of medications at those homes and institutions and hence put their health at risk.

The number of pharmacists remained low in ratio to serve a population of 32 million in year 2020. Pharmacists are primarily employed in health care facilities, where they provide services such as dispensing and medication counselling. There are limited platforms to disseminate reliable information regarding medications to the general public. Consumer education and health literacy, which apply to healthy and unhealthy individuals, may be neglected in populations who seldom seek medical treatment.

Expanding the reach of the 'Know Your Medicine' (KYM) programme, particularly in rural areas, is thus a primary priority in improving health awareness. However, expanding coverage is not straightforward, and it is necessary to identify the economic, financial, geographic and social limitations affecting the dissemination of information. Nevertheless, through years of implementing the KYM programme, we gained an understanding from the consumers' perspective when it comes to utilising medications. Public engagement requires commitment, hard work, passion, cooperation and understanding from pharmacists as well as the community.

SALES AND ADVERTISEMENT OF UNREGISTERED AND ADULTERATED PRODUCTS

Before the Internet, healthcare providers, especially the general practitioners and community pharmacists are patients preferred and most trusted sources of information for health-related matters. Now, the Internet has disrupted this model. Many people are increasingly using the Internet as an alternative source of information to help manage their health because it is more convenient, cost-effective and time-saving. The rise in self-care and self-medication behaviour has led to an increase in purchase or demand for medicines and health products online, as well as from unlicensed premises such as herbal shops, kiosks, supermarkets, grocery stores and night markets. Although self-medication is a common practice globally that has been well recognized as an alternative option to relieve symptoms associated with minor illnesses, many possible risks have been attributed to this practice among the public. Consumers are at risk of purchasing unregistered medicines or medicines that may be contaminated and counterfeited. Consumers may also end up using medicines that are unsafe to take with other medicines or products that they are already using. Many people are not aware of the serious consequences of inappropriate self-medication. Therefore, there is a continuous need to monitor and combat the promotion and sales of unregistered medicines or adulterated products online and also at unlicensed premises through strict enforcement activities.

On the other hand, the high demand for medicines and healthcare products coupled with the increase usage of the internet provided opportunities for irresponsible group of people to advertise and sell unregistered products and poisons online. The proliferation and vastness of online platforms such as personal websites, blogspots, social media applications (e.g. *Facebook, Instagram, YouTube*) and e-marketplace sites (e.g. *Lazada, Shopee*) make it easier for sellers to promote and influence the public to buy their product which may put consumers' health at risk. With around 29 million Malaysian using the Internet and social media, it is an easy and cost-effective way for them to reach a fairly broad audience. The COVID-19 pandemic in 2020 has also caused some online sellers to take

advantage of the outbreak by exploiting the high market demand for health protection products. Online sellers who sell unregistered medicines and poisons are not only breaking the law but have little regard for the public's health and are only taking advantage of a major public health crisis to make a profit. This may lead to aggressive promotion of pharmaceuticals with questionable safety profiles, dissemination of misleading or unbalanced information about the risks and benefits of medications and inappropriate use of medicines. Engagement with online sellers and platform providers will need to be enhanced to increase their awareness and knowledge on the importance of promoting only safe, effective and quality products to consumers and also to highlight the serious consequences of misleading medicines advertisement.

MANUAL WORK PROCESSES AND LIMITED IT SUPPORT

As more people gain access to computers and the Internet, many organisations are transitioning to a digital platform, using the power of technology to improve their products and services offered and delivered to their clients or stakeholders. In the normal course of business, digital transformation is forward-thinking. However, in today's COVID-19 environment, digital transformation is imperative to adapt to the current environment and to meet stakeholders' expectations.

Business Requirement

Inefficient work processes such as taking a long time and using high resources, less effective monitoring, not customer-friendly and not in line with current needs the latest technological developments create an urgency to implement reformation in the implementation of work processes. At the moment, several online services have been developed to improve the quality of services to customers, but it is still seen as not comprehensive.

Infrastructure Availability to Support ICT Implementation

Limited infrastructure availability, including internet networks and electricity supply in some government facilities, also influences the implementation of systems. This issue was seen in the implementation of the PhIS & CPS system nationwide, where some facilities could not implement the system due to constraints of electricity supply and internet network. Besides that, low-capacity internet connection also impacts the performance of data sharing from facilities to data centres.

Cost of Development, Implementation and Maintenance

Implementation and maintenance of ICT infrastructure, including hardware, networks and applications, need to be carried out to ensure the continuity of services. The high cost of implementation and maintenance, mainly involving the old or end of life (EOL) infrastructure, requires a large budget allocation. Other factors such as implementation method, selection of technology etc., also contribute to the increase in implementation cost. For example, PhIS and CPS system architecture are not centralised, resulting in many servers required to host this application. Besides that, other ICT equipment such as computers and printers allocated at each facility across the country, further increases the maintenance costs. Detailed planning for the long term is essential to overcome this problem.

Security

Currently, the Pharmaceutical Services Programme (PPF) has ten core applications as well as several support applications that contain various government and customer confidential data. The ICT security aspect is crucial to avoid being exposed to disaster threats and treacherous acts. PPF must bear high costs in ensuring that ICT infrastructure is protected by acquiring security software and maintenance services. Existing infrastructure is also exposed to disaster as it is not equipped with Data Recovery Centre. Planning is ongoing to relocate the critical systems to the Public Sector Data Centre (PDSA) as a risk mitigation measure. In addition to that, existing backup systems need to be upgraded as a measure to reduce the impact of system and infrastructure failures, whether due to disasters or treacherous acts.

Skills and Competency in the Field of ICT

The availability of skilled resources in the ICT field is crucial to accommodate the workload and ensure the implementation of ICT initiatives runs smoothly and hence optimises the benefits to the government. Lack of skilled manpower leads to high dependency on outsiders, limiting the adaptable technology in the ICT ecosystem of an

organisation, besides less competitive costs to be borne by the government due to the use of closed source and proprietary technology.

Competency in ICT is also important in ensuring the sustainability of the system, especially those system developed internally. The rapid advancement of technology, especially in open source, has created a variety of cheap and easy alternatives, besides producing more skilled manpower in the development of application and technology internally. This provides an opportunity for the government to utilise existing resources to optimise the effectiveness of service delivery as well as obtaining greater value from the existing resources. A long-term plan is worthwhile to ensure the system's sustainability, with a particular emphasis on the development of training paths, recognition (credentialing), and privileges for specific areas of specialisation such as informatics, health informatics, and data science, in order to ensure the sustainability of government services in facing challenges in the future.

QUEST System

On the other hand, the existing NPRA's QUEST3+ online system needs to be enhanced due to the fact that some work processes are still performed manually, as well as to improve existing work processes. NPRA intends to develop the QUEST5 system across a five-year timespan (2021 to 2025) to address these related issues. However, the key challenges to this are budget constraints for technology upgrades, agile NPRA business process, rigid ICT implementation policy, multiple stakeholders involved with imbalance needs, and the need to safeguard big data within the QUEST3+ against cyber-attacks.

Special Drug Approval (SDA)

Special Drug Approval (SDA) is required to obtain, and utilise medicines that are not listed in the Ministry of Health Medicine Formulary (MOHMF), including registered and unregistered drugs for Ministry of Health (MOH) as well as non-MOH facilities. This approval is considered as the final alternative treatment for life-threatening conditions after all options available in the MOHMF, or registered medicines have been exhausted. The importation and usage of unregistered products for a life-threatening condition, may on application be exempted by the Senior Director of Pharmaceutical Services under Regulation 7(1) and 15(6) of the Control of Drugs and Cosmetics Regulations 1984.

Currently, most MOH facilities submit SDA applications via an online system (PhIS), whereas non-MOH facilities are still using manual application forms. A total of 3,526 applications processed in the year 2018 and 4,041 applications in 2019, with an increment of 14 percent was noted. Based on the number of applications received as of September 2020, an additional 10 to 20 percent increment will be expected this year.

Gaps in Monitoring PRP Performance through PRiSMA

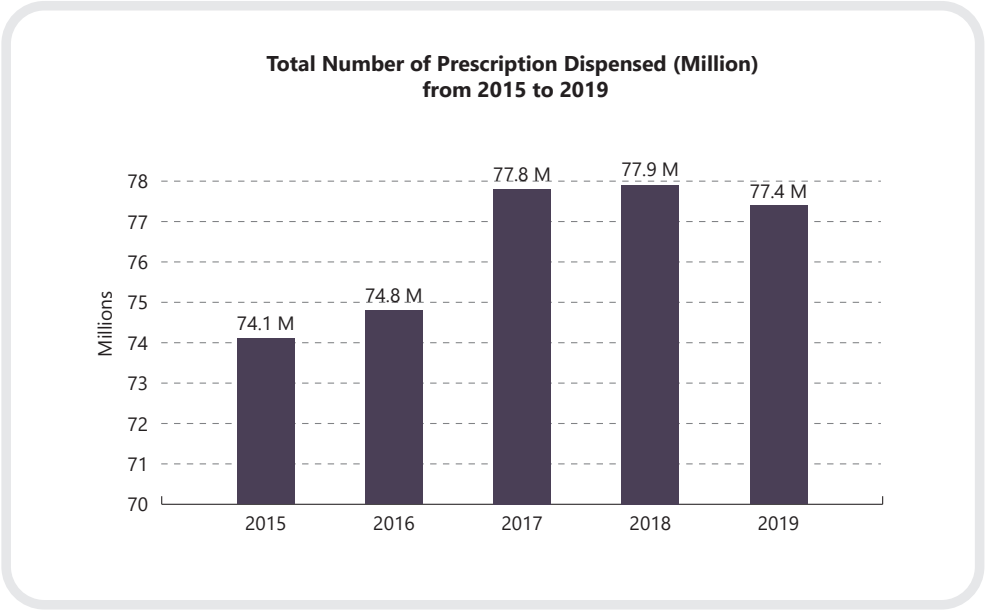
Currently, there is no systematic monitoring of the Provisionally Registered Pharmacist (PRP) training due to no specified Standard Operating Procedure (SOP) for the process of obtaining final appraisal of the logbook from the preceptors up to the process in which PRP uploads the given marks to the *Pharmacist Registration Management System* (PRiSMA) upon submitting the application to be registered as a Fully Registered Pharmacist (FRP). With the existing system, there is room for the PRP to falsify the final appraisal of the logbook. The process of obtaining the final appraisal and signatures from the principal preceptor and the master preceptor sometimes is time-consuming which may delay the process of applying for the FRP registration.

Manual Sanction Documentation

The Pharmacy Board of Malaysia has the authority to penalized registered pharmacists or bodies corporate that violate the Registration of Pharmacists Act (ROPA) 1951. All sanctions shall be documented to ensure that they are in accordance with the Board's decision. Currently, the penalty record is kept manually. It is quite challenging for Pharmacy Board Malaysia Division (PBMD) to provide information on the list of pharmacists and bodies corporate that the Board has sanctioned, the types of sanctions imposed, and any associated expenses. Statistic reports for reference purposes may also take longer time to be created.

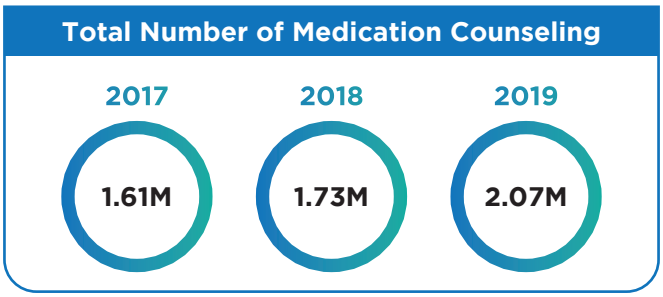
OBSTACLES IN MEDICATION COUNSELLING

The number of patients who received treatment at public health facilities is constantly increasing. As such, the number of prescriptions received at the pharmacy is also demonstrating an increasing trend. The number of prescriptions received and dispensed in inpatient and outpatient settings has increased from 74 million prescriptions per year in 2015 to approximately 77 million prescriptions in 2019.



Number of Prescriptions Dispensed in MOH Health Facilities (2015 to 2019)

At the same time, the number of patients receiving medication counselling at the pharmacy has also increased tremendously from 1.61 million patients in the year 2017 to 2.07 million patients in 2019.



Number of Patients Counselled by Pharmacists from year 2017 to year 2019

A solid foundation of trust between the patient and pharmacist is crucial to ensure effective communication during counselling sessions. Patients need to spend time with the pharmacist to receive explanations and instructions about their medication regimen, as well as an opportunity to ask additional questions and clarify any drug-related concerns with the expert. However, time is a significant impediment to providing effective medication counselling in the pharmacy.

Frequently, patients must arrive early at the hospital to attend doctor's appointment before proceeding to the pharmacy to collect medication and attend a medication counselling session. Long waiting time in the doctor's clinics renders the patients impatient and unwilling to commit additional time to counselling sessions. It may be viewed as an inconvenience or trouble to patients when pharmacists wish to retain them for further explanation following counter dispensing. Constantly they need to rush off for other errands, such as returning to work or running family errands. At times, family member collects medication on behalf of the patients. Without the patients' presence, effective medication counselling cannot be done.

The high workload in pharmacy is also another challenge in expanding the medication counselling services. With an increased volume of prescriptions and variety of services available, pharmacists need to prioritise their work, such as reducing patients waiting time in collecting the medications, ensuring zero dispensing errors, and facilitate VAS.

Alternatively, pharmacists give out medication counselling appointments for patients who are unable to stay back for counselling after collecting medications or those who need their caretaker or family members to attend together for more elaborate sessions. The response, on the other hand, has always been discouraging.

During the COVID-19 pandemic, new standard operating procedures were implemented to ensure the safety for both patients and health care professionals. Patients are encouraged to spend as little time as possible in health facilities to minimise the risk of transmission. Additionally, medication collections were accomplished by subscribing to one of the VAS offered by the pharmacy to reduce further the frequency of patients returning to the health facilities. Medication counselling services were badly affected due to patients' unwillingness to spend additional time with healthcare professionals and the hassle associated with the additional safety measures required to provide medication counselling face-to-face.

INCREASE DEMAND FOR EVIDENCE-BASED PRACTICE

Pharmacy is a very dynamic profession and the role of pharmacist is expanding beyond supply and dispensing of medicines. Research is a disciplined and methodical way of seeking answers. When a research paper is published, it is also subject to greater critical scrutiny in terms of its credibility, trustworthiness, validity, reliability and rigour. Personal experience and personal opinion are insufficient for policymakers to support their decisions in the delivery of pharmaceutical care. Evidence-based practice (EBP) is an emerging trend and gaining popularity due to its potential to effectively provide better pharmaceutical care. In order to be relevant, information presented to policymakers should be based on high quality research. Pharmaceutical Services Programme aspires to generate more information using local data from Malaysia. Therefore, there is a great demand to encourage pharmacists to conduct research and establish evidence-based practice.

GAPS IN LEGISLATION AND REGULATION

Controlled Drugs

Life without the Internet has become unimaginable in this millennial age. The rapid advancement in technology has led to the rise in online sales of medicines and healthcare products and the development of online pharmacies, including the use of e-prescriptions which require new sets of laws to regulate them. Another example is the growing interest in kratom plants, which resulted in the detection of loopholes within the existing law regulating psychoactive plants. Currently, the existing law does not sufficiently regulate the appropriate handling of kratom plants. In addition to that, there has also been a surge in enquiries from the public in relation to the cultivation and use of cannabis which needs to be addressed with laws in place. Many existing laws and legislations which were enacted in the 1950s have not been updated in tandem with the latest technology and developments in the pharmaceutical industry.

Registration of Pharmacist

The Registration of Pharmacists Act (ROPA) 1951 is an act related to the establishment of the Pharmacy Board and the registration of pharmacists. The Act was enacted 1952 and was based on the requirements for the registration of pharmacists and bodies corporate during that time. It also enforced the disciplinary action on pharmacists and bodies corporate. Due to the fact that the Act was passed more than half a century ago, many of the provisions are obsolete in light of current legal requirements and unable to fulfil the demands of stakeholders. Among the areas involved are the use of technology, pharmacists and pharmacy technologists' registration, and pharmacy practices.

Clinical Trial

Currently, Malaysia does not have specific legal provisions to regulate commercial and non-commercial clinical research. This situation has created a less conducive clinical research ecosystem to promote clinical research in Malaysia. Also, the establishment of the Clinical Trial Act is one of the requirements under the WHO Global Benchmarking Tool to show the maturity of a drug regulatory agency. Apart from that, current legal provisions are very limited in governing the conduct of clinical research in Malaysia. This situation results in the regulatory authority not having the power to stop or suspend the clinical research if there are issues that affect safety and the fundamental rights of subjects involved in clinical research as enshrined in the Declaration of Helsinki and international regulatory requirements. The proposed Clinical Trial Act can also ensure the

protection of subjects involved in clinical research as well as ensuring that Malaysia complies with international regulatory requirements.

Cosmetics

After more than a decade of implementation of the notification system for cosmetic products started in 2008, number of non-compliant cosmetics is still significant, especially among the small-medium companies (SMEs); and this includes repeated offenders. One of the proposed solutions is to penalise the offenders in the form of compound. However, the proposed compound has to be introduced first in the existing regulations i.e. Control of Drug & Cosmetic Regulations 1984 and it takes time to be enforced. Meanwhile, compliance shall be strengthened through a series of training sessions for the targeted cosmetic industries.

Vaccine Testing

NPRA collaborates with other government institutions under the Ministry of Health in developing potency test methods for vaccines. The development of Vaccine Potency Test method is expensive especially in obtaining reference materials of a specific antigen tested. Aside from this, there is a need to acquire a certain amount of experience and build up on expertise in specialized areas as well as to bridge the gaps which is essential for improving the existing laboratory setting/ practices required for the testing of vaccines.

Quality Control Testing of Traditional Products

The registration of traditional products has been enforced in Malaysia since 1992 followed by the implementation of the requirement of Good Manufacturing Practice (GMP) compliance for traditional manufacturers in 2000. The registration process involves evaluation of documentary evidence and product testing based on samples obtained pre- and post-registration. Since then, traditional medicines have made significant contributions to the health care in Malaysia. However, due to rapid development of the traditional medicine industry both locally and globally, regulators are currently faced with challenges in the form of authentication, adulteration, contamination, misleading therapeutic claims as well as counterfeit products.

Application for recognition of private laboratories by NPRA is based on voluntary basis. With the new directive taking effect from 1 December 2020, NPRA anticipates more private laboratories to be listed in the panel of laboratories for traditional product testing. The recognition of private laboratories is an on-going activity and the list of recognized laboratories is dynamic depending on the number of new applications and renewals after the expiry of the three (3) years validity period.

At present, evidence for safety and quality such as disintegration, microbial and heavy metal tests are required for finished products. However, minimum documents or criteria are required to prove the authenticity and identity of herbal raw materials and finished products. These requirements are not enforced currently as there are limitations on both regulators and industry in analysing or interpreting the tests and results.

Regulatory Control of Medicinal Gases

Medicinal gases (MG) are any gas or mixture of gases intended for the administration to patients for medicinal purposes (e.g. anaesthetic, therapeutic, diagnostic or prophylactic). According to Sale of Drugs Act 1952, MG qualifies as drug. MG products should be registered as pharmaceutical products. MG classified as a pharmaceutical product is a gas or gas mixtures which mode of action is achieved primarily based on pharmacological, immunological or metabolic action in or on the body.

Issues addressed in regulating MG are lack of knowledge and experience in regulatory control of MG. Additionally, there are differences in practicing GMP compliance among MG industries in Malaysia such as implementation of pharmaceutical quality system, documentation, facilities and etc.

Product Safety Monitoring and Vigilance

Currently, the PRHs activities pertaining to safety management of registered medicinal products are uncoordinated and have yet to be effectively monitored by the authority. This encompasses the preparation of Risk Management Plan (RMP) to mitigate the risk for local setting and the submission of Periodic Benefit Risk Evaluation Report (PBRER) for high risk products such as biologics and New Drug Products (NDPs).

There are also huge gaps between the pharmacovigilance systems practised among

the PRHs, particularly between the multinational companies and local generic companies. This was apparent from the findings of the PV inspection pilot study conducted by NPRA in 2018 to 2019. One of the main factors could be the depth of understanding of the PV requirements. Multinational companies are often more advanced in terms of product safety management compared to local generic companies and have guidance from the parent companies located in developed countries that have established PV practices in place. As for the local companies, even though they are keen to improve their pharmacovigilance systems, they often have limited resources to seek assistance from PV experts and have lack of guidance in fulfilling local PV requirements.

Besides that, it is also noted that there is much improvement needed in the quality of ADR/AEFI reporting made by pharmaceutical companies as compared to the reporting made by the healthcare professionals. ADR/AEFI reports received from PRHs often lack details that are important for conducting causality assessment of the reports. This situation may hinder the complete and accurate evaluation on the risk-benefit balance of the registered medicinal product.

Time and Temperature Sensitive Products (TTSPs)

The current understanding by the local industries regarding the regulatory expectations of TTSPs by the relevant authority may not be aligned with the actual compliance requirements of the relevant authority, particularly pertaining to the aspect of Good Distribution Practice (GDP). A good understanding on GDP requirements translates into good adherence to the GDP compliance requirements which in turn is crucial in ensuring a high level of supply chain integrity.

ACCESS TO PHARMACEUTICAL PRODUCTS

Medicines Price Mechanism

The Pharmaceutical Services Programme faces several challenges in developing and establishing price mechanism for medicines. Numerous responses indicate that the pharmaceutical industry does not favour the proposal or its amendments although consumers do. The proposed implementation of medicines price mechanism will be in phases. The best mechanism that suits each phase will be developed through consultation and engagement with related agencies and stakeholders. However, the collaboration with agencies lacks consumer empowerment on medicines price information at the public level.

Currently, there is a lack of a comprehensive and fully integrated medicine price database with product registration, procurement and external price databases. As a result, access to current and reliable sources of medicine information is limited, which will impede actionable decisions at procuring medicine at the best price. Lack of integration also drives ineffective price analysis and obstructs medicine price monitoring activities. Since 2012, the public can access the latest medicine price information via Consumer Price Guide platform, available at the Programme's website www.pharmacy.gov.my. However, this platform is less user-friendly and need enhancement according to current developments. Without a comprehensive medicine price database, the Programme may not be able to establish an effective medicine price mechanism for the country.

Challenges in Medicines Dispensing and Value-Added Services

Based on the 2019 National Health Morbidity Survey (NHMS), the prevalence of three (3) major non-communicable diseases (NCDs) in Malaysia showed an increasing trend from previous years where 18.3 percent are diabetes, 30 percent with hypertension and 38.1 percent with high cholesterol in year 2019 (NHMS 2019). The increasing number of prescriptions received in Ministry of Health (MOH) facilities can also be seen from year to year. In 2019, outpatient pharmacies in facilities under MOH received 60.9 million prescriptions compared to 52.2 million prescriptions in 2016, which is a 16.6 percent increment. Approximately 30 percent of the total prescriptions received were repeated prescriptions for patients with chronic diseases such as diabetes, hypertension, and high cholesterol.

In Malaysia's public healthcare settings, patients with chronic diseases are scheduled for an appointment with their doctors at intervals of 3 to 6 months. They will be given prescriptions for the same duration. However, these medicines are only supplied on a monthly basis. This policy is similar to practice in most countries, was implemented to ensure quality use of the medicines, enabling pharmacy to monitor for any side/ adverse effect and also to reduce any wastage.

Due to these challenges, issues regarding congestion at pharmacy counter, long waiting time, patient's inconveniences such as travelling cost and time, parking at facilities and others have been occurred from time to time. The Ministry of Health (MOH) has implemented Value-Added Services (VAS) such as Integrated Medicine Dispensing System (*Sistem Pendispensan Ubat Bersepadu, SPUB*); Pharmacy Appointment System; Drive-Through Pharmacy; Medicines by Post (*Ubat Melalui Pos, UMP*) and Locker4U, to ease patients in refilling their prescriptions every month at their own convenience, and with less hassle.

Since 2012, VAS has been tracked nationally as a Key Performance Indicator (KPI) to ensure the success and quality of the service offered. In 2015, the establishment of *Pusat Pembekalan Ubat Susulan Setempat* (PPUSS) was designated as one of the new Health Minister's key performance indicators. PPUS applies the concept of VAS for medicines collection and is located outside of the main MOH hospital and health clinic. This ensures a better access for patients to their medicines supply as it is nearer to their home or office and operates outside regular working hours.

Nevertheless, despite tremendous efforts to promote and provide VAS, the uptake of these services seems to have reached a plateau. In the existing practice, patients need to register at the pharmacy counter to opt for the service. Any changes after the registration need to be communicated through phone calls between the pharmacy staffs and patients. This could be seen as a burden to the patients as more time needs to be spent at pharmacy counter and to contact the pharmacy if they wish to change their appointment date or type of VAS. With the rapid advancement of technology and the increasing usage of smartphones, the present conventional method of enrolling for VAS was seen as outdated, may not be convenient and less user-friendly. There are demands for e-pharmacy services because patients find it more convenient, cost-efficient, and time-saving.

Year	2016	2017	2018	2019
Number of refill prescriptions dispensed via VAS (million)	2.16	2.72	2.97	3.98
Number of refill prescriptions received (million)	11.82	15.87	17.28	17.85
Percentage of refill prescriptions dispensed via VAS (%)	18.3	17.1	17.2	22.28

Uptake of VAS from year 2016 to 2019

Challenges in Procurement of Medicines

Generally, Ministry of Health (MOH), University Teaching Hospital (*Hospital Pengajar Universiti, HPU*) under the Ministry of Higher Education (MOHE) and Ministry of Defence (MINDEF) each carry out the procurement of medicines separately even if it may be the same product or item for medical purposes. Therefore, to optimize the expenditure and savings to the Government, and in line with the "Do More with Less" policy, MOH believes that pooled procurement of medicines should be implemented with MOHE and MINDEF as these Ministries are also involved in procurement for their respective health facilities and have the same aspiration which is to achieve quality goals for health care. Ministry of Finance Malaysia (MOF) has approved the application for the implementation of pooled procurement for MOH, MOHE and MINDEF which would be a pilot project involving 85 medicines through the open tender method.

Although the approval for implementation of pooled procurement has been obtained from the MOF, there are some issues and challenges that need to be addressed to ensure the process of pooled procurement runs smoothly. At the initial stages, MOH faced great challenges where there was no clear Standard Operating Procedures (SOP) to manage this initiative. On top of that, the procurement system used by each *HPU* is different from that used by MOH & MINDEF who are using the *ePerolehan* (eP) system. In addition, the terms in the contract agreement also need to be standardized and agreed upon by the three ministries. The process of reviewing the terms of the contract agreement is a time-consuming process because it needs to incorporate input from all ministries. These are among the biggest challenges that were faced during the initial stages of doing the pooled procurement.

Due to manpower constraints within the Pharmacy Practice and Development Division and the Procurement and Privatization Division which serves as the main secretariat, both parties view this start-up process as a significant challenge in ensuring the pooled procurement process and also the tender process of other non-pool procurement remain unaffected.

Currently, 20 pooled procurement tenders have been finalised. With the Standard Operating Procedures for the Pooled Procurement for MOH, MOHE and MINDEF which was issued on 5th August 2020 in place, MOH hopes that coordination between the three (3) ministries will be more orderly in managing the pooled procurement tenders.

HUMAN RESOURCE COMPETENCY AND EFFICIENCY

Developing A Talented Health Workforce

While many organisations now look at talent development as a just-in-time function or a perk for high performers, this new world will increase the need for talent development to be truly global, strategic, and predictive of future corporate global needs, all to ensure that we are creating global talent development initiatives that are filling future talent gaps. To develop a pool of talented pharmacists, many factors need to be considered, such as funding, training options, workplace environment, job satisfaction, workload burden, and many more factors that will affect the planning and development of the talent. Nevertheless, retaining talented, skilful, and younger employees are becoming another issue and challenge for organisations. Thus, a clear, well-planned leadership structure, good succession plan, and framework need to be constructed to overcome all these challenges.

Skills and Expertise

Highly skilled human capital is required to support the further development of the organisations. One of the biggest challenges in maintaining organisations' success is keeping their human capital updated with the current technologies, strengthening their skills, and motivating them to give their best to the organisations. Workforce training and development becomes a major issue. A robust competency framework needs to be developed to ensure the necessary skill for every individual in the organisation is being considered.

Capabilities and Professionalism

Using an empowerment approach to building capability focuses on identifying workforce strengths, increasing stakeholders' capacity to identify their needs, documenting the impact of the programmes, and increasing the degree of control the agency staff have over their initiatives. According to Page & Czuba (1999), empowerment is a multi-dimensional social process that helps people gain control over their own lives. It is a process that fosters power (that is, the capacity to implement) in people, for use in their own lives, their communities, and in their society, by acting on issues that they define as important. At the same time, the development of talent or a highly skilled workforce is essential to helping organisations make the shift towards higher-value and knowledge-intensive activities which are the benchmark of advanced institutions. On the other hand, capability building, and professionalism of pharmacists are becoming crucial as the profession itself has evolved significantly. Pharmacists should be prepared with not just the knowledge but also with skills and a good attitude. Professional development is relevant for all pharmacists to generate their talent and capabilities. As pharmacy practice continues to progress, so do the requirements for continuing education. Continuing education is evolving into more complex, competency-based education, in which every pharmacist should incorporate the application of knowledge and demonstration of skills in their daily practice.

Leadership Development

The workforce is ageing quickly, leading many organisations and human resource teams to consider putting formal succession plans together with standard competency for generating talent in place and begin more emphasis on developing future leaders. The organisations grow and expand, thus developing quality leaders has become a significant initiative. Successful organisations that work on leadership development will also make well-planned strategies with better employee retention. It is known that poor leadership has become one of the main factors that triggers employees for leaving their jobs. The workforce also requires a more active leadership role in decisions within their jobs, which usually necessitates training. Unfortunately, organisations sometimes struggle to come up with the budgets and funding necessary for strong workforce training and development programmes that emphasise talent

grooming, talent pool, leadership, and growth. In this case, the organisations must strategically plan to optimise the budget given, the well-planned and structured leadership training together with Capability Building Framework for talent development.

Capacity Building for Evidence Based Medicine (EBM) and Budget Impact Analysis (BIA)

Optimal drug decision making is crucial to ensure maximised resources and efficiency. Specific tools are needed to guide drug decision-making, which is done at various levels (micro and macro) in the Ministry of Health. Application of Evidence-Based Medicine (EBM) and Budget Impact Analysis (BIA) principles can assist in ensuring optimal decisions. This approach is important considering the current constraints in healthcare resources.

It is important to note that there is wide variation of level of skills available and the extent of application of EBM/ BIA approach in drug decision making in MOH facilities. Regardless, there is a need to create awareness on the role of EBM/ BIA as well as to provide technical skills in EBM/ BIA to encourage its application across various pharmacy services in MOH.

Currently EBM/ BIA training is only provided as yearly training for pharmacists but not in a structured programme which is vital to ensure continuous and standardized EBM/ BIA applications at the MOH facilities. Therefore, to address this issue, one of the focuses in the upcoming Strategic Plan is to establish a structured and progressive training programme in EBM and BIA for pharmacists.

Human Resource Capacity Optimisation

Among the main challenges encountered by MOH are inadequate post, delayed employment and unemployment of new graduates. In tandem with the development of pharmacy services, increased workload, and number of facilities due to increase of patients, the number of pharmacists required in the Ministry of Health Malaysia has grown throughout the years. Following the government's decision on the public service size control policy, application for new posts is not allowed except by trade-off and redeployment method with no additional financial implications. In order to ensure continuous delivery of continuous service, task execution has to be carried out using the number of existing workforces. Therefore, a structured and strategic plan is crucial to ensure proper projection and distribution of pharmacists' workforce, as well as efficient utilization of human resource can be achieved.

WAY FORWARD

STRATEGIC DIRECTION

PHARMACEUTICAL SERVICES PROGRAMME STRATEGIC PLAN 2021-2025

WAY FORWARD: STRATEGIC DIRECTION

THRUST 1: CUSTOMER ENGAGEMENT

STRATEGY 1: ENHANCE MULTISECTORAL AND INTERSECTORAL ENGAGEMENT TOWARDS BETTER HEALTH AWARENESS

Engaging NGO, professional societies, government agencies to reach specific groups toward Quality Use of Medicines

Pharmaceutical Services Programme has made effort and opportunity to collaborate with various public and private agencies, which may have greater capacity, platform and accessibility to increase the dissemination of information on medicines. Utilising such knowledge and skills could improve the planning and development process of programmes, and the fundamental knowledge on the quality use of medicines. These agencies have conducted health programmes at the national level, expanded access to rural areas and populations, and advocated quality use of medicines issues to a broad audience.

The Know Your Medicines (KYM) Programme would also cover vulnerable communities such as the elderly, women, haj pilgrims and disabled individuals, particularly those with hearing, vision, and communication impairment. Extending the programme to these communities will enable them to obtain necessary information and benefit from the activities. This group of people are also in need of information on medicines. Extending the programme towards the group will allow them to benefit from the activities conducted.

STRATEGY 2: ENHANCE MULTI SECTOR ENGAGEMENT TOWARDS SAFE, EFFECTIVE AND QUALITY PRODUCTS

Engaging Online Sellers and Platform Providers through Awareness Activity to Increase their Awareness and Knowledge on Registered Products

The Pharmacy Enforcement Branch has developed several strategic initiatives to reduce unapproved medical advertisements, sales of unregistered health products and unnotified cosmetics. The strategy will emphasise the engagement with relevant stakeholders to increase their awareness and knowledge of registered products, thus, promoting the sale of safe, effective and quality products for consumers.

Collaboration with Relevant Associations in Promoting Regulatory Compliance for Cosmetic Products

Cosmetics should comply with the stipulated regulations and guidelines. To increase the regulatory compliance level of cosmetics, National Pharmaceutical Regulatory Agency (NPRA) has planned to collaborate with cosmetic associations for series of training that will be conducted for the cosmetic notification holders. The training will be participated by selected notification holders. The selection criteria are based on post-market surveillance (PMS) history. The outcome of the training will be measured through the level of the product's compliance. Training progress and the outcome are subjected to yearly review.

Further details are as followed:

Year 2021:

i. **Number of training sessions conducted**

   NPRA will conduct 4 series of training yearly for a period of 5 years (year 2021 to 2025). Hence, the total number of trainings planned throughout the 5 years period are 20 series.

ii. **Percentage of compliance (increasing trend)**

   Compliance level of the cosmetics screened by both Cosmetic & Surveillance Section is targeted to reach 60 percent. Currently, the compliance level is below 50 percent.

   Numerator: number of compliant cosmetics
   Denominator: total number of cosmetics screened

Year 2022 to 2024:

As the trainings progress, more companies will be trained. Hence, the compliance level is expected to increase every year by 5 percent.

Year 2025:

After 5 years of training, compliance level is expected to reach 80 percent. This plan will be further reviewed and data will be used to improvise the cosmetic regulatory system.

STRATEGY 3: ENHANCE VALUE PROPOSITION OF PHARMACY SERVICES

Enhance Pharmaceutical Care and Awareness on Medicines towards Specific Groups

Moving forward, the Know Your Medicine (KYM) Programme will continue with more alternatives in public engagement to ensure the successful dissemination of information across the nation. A patient has to be informed on acceptance of disease instead of in state of denial. That is why continuity of care is important when a patient is discharged from health care facilities and returns to the community. In order to ensure that they manage to take care of themselves, pharmacists play an important role in educating and maintaining patient's health.

The Pharmacist Integrated Community Care (PICC) Programme is introduced and aimed to educate diabetic patients on diabetes care and medicine compliance. Patients' expectations towards pharmacy services are no longer restricted to clinical skills and knowledge, but there is an increasing demand for mutual respect, clear communication, and behaviour that portrays high standards of professional probity. This provides an opportunity for pharmacists to work with patients and develop effective patient care relationships for optimal therapeutic outcomes.

STRATEGY 4: INTENSIFYING THE ROLE OF PHARMACY SERVICES

Enhance the Role of Pharmacists in the Provision of Healthcare Services

By using social media and mass media, as compared to the previous practice, the area of information distribution is wider as it covers both patients in healthcare facilities and healthy individuals in the community. Initiatives to engage local councils and local media through dialogue sessions via radio stations are organised to disseminate medicine information to educate and increase health care awareness. Through this, the public is better equipped with the knowledge to protect themselves from being misguided by myths on social media.

THRUST 2: INNOVATION DRIVEN

STRATEGY 1: ENHANCING ICT-BASED SERVICE INNOVATIONS

Enhance Utilisation of IRIS to Facilitate Decision Making and Knowledge Sharing

Following of PPF's success in establishing the Integrated Repository of Information System (IRIS) as a data lake platform that collects data from various information systems under the programme, the next challenge is to ensure that the data can be utilised and protected as an important asset of the organisation. The development of data governance policies helps to establish efficient and consistent data management, handling and protection practices.

PPF aims to utilise the data collected by the IRIS through the production of data analysis reports to help improve planning and decision making. In addition, PPF also intends to expand the use of data collected by IRIS for research and development by encouraging the use of digital data from IRIS for research purposes.

Business Process Reengineering (BPR) Of Manual Work Process to ICT-Based System

The implementation of business process reengineering (BPR) provides an opportunity to identify weaknesses and improving existing processes to increase the efficiency and the value of the services operated.

QUEST3+

QUEST3+ began its development in 2015, starting with the cosmetic module which was the first module to be launched in August 2016, followed by the rest of the modules beginning from January 2017 onwards. QUEST3+ uses PHP language for the application framework combined with MySQL Database and consolidates the data from QUEST2 & QUEST3 through a series of data migration processes. The current key stakeholders involved are the Competency Development Division and Pharmaceutical Services Programme under the Ministry of Health (MOH), the Malaysian Administrative Modernization and Management Planning Unit (MAMPU), pharmaceutical & cosmetic industries, healthcare professionals and consumers.

In the year 2021, NPRA plans for two Milestones, i.e. Milestone One (1) to 20 percent progress of budgetary and procurement process for new QUEST system and Milestone Two (2) to five (5) percent progress of new QUEST system project sign-off. This sums up to 25 percent cumulative progress. Securing a budget at the beginning of a project ensures that NPRA minimises budget constraint issues, which if not tackled, would inevitably hinder any kind of technology updates and upgrades.

In the year 2022, NPRA will proceed with Milestone Three (3), which contributes to 25 percent progress of the project, bringing it to a total of 50 percent cumulative progress (half of total project). This milestone involves coming up with three (3) documents i.e. Foundation of Business Process Reengineering (BPR) Document for new and existing work processes, Foundation of User Requirement Specification (URS) and Foundation of Software Design Document (SDD) Development for the new QUEST system.

In the year 2023, NPRA will prepare for Milestone Four (4) which will be the development of new QUEST5 system. This adds up to a total of 60 percent cumulative progress. In 2024, Milestone Five (5) will enable for User Assessment Test (UAT) and Final Acceptance Test (FAT). At this stage, NPRA will be inching closer to project completion with an expected contribution of 75 percent cumulative progress. By 2025, the project will conclude with 100 percent cumulative progress and NPRA will be ready for full implementation of the new QUEST5 system as well as the warranty period.

Special Drug Approval (SDA)

The Pharmaceutical Services Programme continuously looks into ways to enhance and strengthen work processes associated with applications for importing unregistered products and ensuring optimal resources utilisation in MOH facilities. Given the growing volume of applications received each year, the way forward is for all facilities to submit applications online to expedite the process while increasing transparency and integrity. This initiative will be integrated into the Pharmacy Enforcement Division system, MyPRAISE, with input from all relevant stakeholders, which are the Royal Malaysian Customs Department, the

Pharmacy Enforcement Division, the Malaysian Medical Council (MMC), the Association of Private Hospitals Malaysia (APHM) and the Pharmacy Information Management Section. Utilising an integrated online system will increase efficiency, security and accessibility. For instance, if the Pharmacy Enforcement Division, MOH and the Royal Malaysian Customs Department are able to online access the Unregistered Drug Import Permit, costs for printing manual documents and postages can be reduced and loss or forgery of import permit can be prevented. Additionally, all statistical data will be fully automated with continuous analysis.

Rapid Development of Technology and Increase Demand in Digitalized Services

The Pharmacy Enforcement Division must continue to refine its operations through developing and upgrading its digital processes, such as making improvements to the online platform for license, permit, authorization and advertisement approval applications. This would enable applicants to submit applications and make payments with more ease and speed while ensuring transparency of the procedures. Fast approval and accessibility to data will increase efficiency, prevent corruption, and reduce the officers' burden and workload. Stakeholders' expectations are constantly changing, and they will continue to expect these digital offerings, which emphasize the importance of investing in a secure online service system now rather than later. As an effort to ease and facilitate the work process for the stakeholders and the providers, a consumer-friendly system is targeted to be developed in stages beginning 2021 and completed by 2025. This system will allow license, permit, approval applications etc. via online. The new system will ease the process, and is faster and more economical.

Implementation of Pharmaceutical Track and Trace System

Pharmaceutical Track and Trace System support all stakeholders in the pharmaceutical supply chain to comply with the country's specific legal requirements on serialisation, tracking and tracing, and regulatory reporting of pharmaceutical products.

The main objective of the Pharmaceutical Track and Trace System solution and architecture is to ensure patient safety by safeguarding the pharmaceutical supply chain, enable traceability and visibility of pharmaceutical products in the market, and combating counterfeit and unregistered products. This objective can be achieved by establishing a system that tracks the end-to-end movements of drugs from manufacturer to end-user through the use of unique package coding and identification.

To ensure smooth implementation of the system, work processes and current system requirements need to be streamlined and improved. This includes the implementation of requirement analysis, process engineering and system integration activities.

Expanding and Optimising IT System

Expansion of PRiSMA system to include new module on monitoring of PRP performance (PRP appraisal by preceptor)

The addition of a new module to the *Pharmacist Registration Management System* (PRiSMA), for monitoring PRP performance will enable preceptors to key-in the PRP's marks into the system without physically transferring the log book from the PRP to the preceptors and vice versa. The marks entered by the preceptors upon completion of each training module can also be viewed by the master preceptor and the Pharmacy Board Malaysia Division (PBMD). This will assist in the monitoring of the PRP's performance, and based on that performance, the preceptors can make better informed decisions about the PRP's training, such as whether or not the PRP's training should be extended. Since the marks will be entered by the preceptors, the possibility of the PRP falsifying the marks is minimised. Additionally, the new system can shorten the time needed to complete the entire process and serve as a platform for effective communication between the PRP, preceptors and the PBMD.

Expansion of PRiSMA system to include new module on Offence & Punishment Registry

The newly proposed online system for Offence and Punishment Registry Module will be incorporated as one of the modules within the *Pharmacist Registration Management System* (PRiSMA). Thus, this will benefit the Pharmacy Board Malaysia Division (PBMD) in capturing all relevant necessary information pertaining

to complaints against pharmacists and bodies corporate and sanction meted out by the Board. The information will be captured and directly linked to PRiSMA and such information will be checked against any application for registration or renewal of the annual certificate. It will assist the PBMD in ensuring that all applications are thoroughly evaluated. Furthermore, statistical reports can be generated quickly and decisions on registration can be made on a timely basis.

Development of Virtual Online Platform for Pharmacy Services

Virtual Counselling (Virc-Rx)

The responsibilities of a pharmacist vary among different areas of practice and work settings. Their roles cover a broad range of activities including dispensing medications, monitoring patient's disease progress, educating patients on medication, and providing advice to other healthcare professionals on drug-related issues. Medication counselling and educating patients remains the pivotal role in the pharmacist profession.

Effective medication counselling not only facilitates clearer and better understanding of medication, but also improves patients' willingness to comply with their medication regime, thus improving adherence, which positively impacting their clinical outcome. During a medication counselling session, a pharmacist needs to prevent and solve drug-related problems, and optimise drug therapy while involving patients in decision-making. However, pharmaceutical care extends beyond this session, where it involves assessment, monitoring, documenting care and progress, and follow-up care.

The challenges and current pandemic situation have urged Pharmaceutical Services Programme to move towards the direction of providing counselling services via online methods. During COVID-19 pandemic, some facilities have taken the initiative to reach out to patients to provide virtual counselling either by phone calls or through online platforms such as Google Meet or Skype Meeting. These methods open up a new era in the provision of pharmaceutical care delivery.

By providing virtual counselling, patients can have access to medication education at their own convenience. Location will not be restricted to pharmacy at health facilities only, but can be at home, or together with family member even those who are at work.

The strategic plan's primary objective for this initiative is to build an online system with educational / instructional modules that patients can access and download information related to their disease and treatment. Additionally, the system will incorporate an appointment system with a limited number of slots for counselling session that can be booked every day. Patients can self-register for available slots in order to receive counselling from the pharmacist.

As to ensure the development of this platform can be done systematically and standardised across MOH facilities, a guideline must be established. At this point, Pharmaceutical Services Programme is currently drafting a guideline for virtual counselling that describes the criteria of patients' recruitment, working procedures, technology requirements, and documentations. Moving forward, PSP will form a task force to develop the related educational contents that will be used for medication counselling. There have been 17 counselling modules identified and the contents of which will be reviewed by expert groups.

This initiative will be continuously monitored and improved following the advancement of technology. Pilot and feasibility studies will be conducted in phases before expansion to all facilities in Malaysia.

Delighting Customer Experience by Developing Apps to Empower Patient/ Caregiver (Personalised)

Following the demand for e-pharmacy service, Pharmaceutical Services Programme (PSP) is planning to create a smart solution for patients who could be set to interact with live databases stored in PhIS and CPS. This smart solution will enable patients to monitor the supply and consumption of their prescribed medicines using their smartphone. At this point of writing, PSP has developed the new system, MyUBAT (as the first phase of this smart solution) in which includes a mobile application and web-console system, to allow patients to register for VAS to get their medication supply. This method is more cost-effective and time-saving compares to conventional methods in which patients need to

register at the pharmacy counter. This enhances the accessibility of patients to register for VAS as well as providing a personalised experience to patients for follow-up medication collection (e.g. modifying date of appointment at patient's convenience). This smart solution will begin with the implementation of MyUBAT in all health facilities, focusing on Ubat Melalui Pos (UMP) and Pharmacy Appointment System, followed by expansion scope of service in drive-through and Locker4U. Further enhancement of MyUBAT will provide drug information and counselling tips to the patients as well as improving the communication between patient and pharmacist.

STRATEGY 2: INTENSIFYING THE USE OF RESEARCH FINDINGS AND EVIDENCES IN POLICY DEVELOPMENT AND PRACTICE

Recognising a need to enhance the quality of research, the Pharmacy Policy and Strategic Planning Division will continue the effort to publish the Malaysian Statistics on Medicines (MSOM), Pharmacy Research Reports and to organise the National Pharmacy R&D Conference.

As a way forward, the Pharmacy Policy and Strategic Planning Division aimed to engage more with diverse organisation on, engage in secondary data analysis and venture into more broad issues particularly that involving policies.

With more scientific publications emerging every year, the Pharmacy Policy and Strategic Planning Division also aim to facilitate engagements between researchers and policy-makers. It is hoped that with this new strategy, culture in conducting quality research will greatly enhance and transform the pharmaceutical sector towards universal excellence.

THRUST 3: SUSTAINING OPERATIONAL EXCELLENCE

STRATEGY 1: STRENGTHEN GOVERNANCE AND REGULATORY CONTROL

Amendment of the Existing Law and Regulations for the Betterment of Pharmaceutical Services

The Pharmacy Enforcement Division (PED) serves to ensure that all sales, supplies, possessions and advertising of medicines and healthcare products are in compliance with related Pharmacy laws in the country. Strategies have been put in place to ensure the laws and regulations enforced are up to date and in line with the current development. This includes revisiting and revising the laws from time to time. Updated laws and regulations are more dynamic, practical and able to facilitate in many aspects.

On the other hand, the amendment of the Registration of Pharmacists Act (ROPA) 1951 is to facilitate the current and emerging new legal requirements. Hence, it will uphold the Act relevancy and to ensure that it is in tandem with the current practice. The process of amending the current law and its regulations will involve all relevant stakeholders to ensure that it is comprehensive, addresses all issues pertaining to pharmacist registration and practise; and incorporates perspectives from diverse sectors. Several new areas will be covered, including pharmacy practise and pharmacy technologist governance.

Develop Clinical Trial Research Legal Framework

There will be two approaches towards realising the governance of clinical trials in Malaysia. The first approach is for the Clinical Trial Act to include the following:

i. Intervention-based clinical research conducted in Malaysia.
ii. The Act will focus on the conduct of quality clinical research, protection of human rights, security, data integrity and well-being of subjects involved in clinical research.
iii. Incorporation of existing guidelines such as Malaysian Good Clinical Practice (GCP) Guideline, Malaysian Guideline on Application of Clinical Trial Import License (CTIL) / Clinical Trial Exemption (CTX), National Stem Cell and Gene Therapy

Guideline, Guideline on Notification of Exemption from Registration of Medical Devices, etc.

It is also proposed that the following stakeholders be involved in the enactment of the Clinical Trial Act:

i. National Regulatory Agencies, i.e., National Pharmaceutical Regulatory Agency (NPRA), Medical Device Authority (MDA), Food Quality Control Division (BKMM), Health and Medical Practice Branch (CKAPS).
ii. Academicians from Universities or higher institutes of learning.
iii. Local ethics committees either those that have been registered or unregistered with the Drug Control Authority.
iv. Researchers, including physicians and scientists.
v. Professional organisations, i.e., Malaysian Pharmacists Society (MPS), Malaysian Medical Association (MMA).
vi. Legal advisers, Ministry of Health (MOH).
vii. Pharmacy Legal and Enforcement Division, MOH.

In addition, the legislative enforcement approach will be based on the type of intervention, relevant ethics committees, professional bodies and authorities (in the event of criminal conduct).

In the event of the first approaches may not be feasible due to the complexity in harmonising numerous acts and regulations from various regulatory agencies in the country, other alternative approaches are proposed, which include the following:

i. Incorporating the Malaysian Good Clinical Practice Guidelines in the amended Sales of Drugs Act 1952 or under Regulation 29 of Control of Drugs and Cosmetics Regulations 1984.
ii. Limiting the governance of clinical trials to only products registrable by NPRA that are involved in intervention-based clinical research conducted in Malaysia.

For this alternative approach, the following stakeholders will be involved in the enactment of the Act:

i. NPRA
ii. Academicians from Universities or higher institutes of learning.
iii. Local ethics committees that have been registered with the Drug Control Authority.
iv. Researchers, including physicians and scientists.
v. Legal advisers, MOH.
vi. Pharmacy Legal and Enforcement Division, MOH.

As a summary, the establishment of the Clinical Trial Act in Malaysia is an integral part of ensuring that all relevant authorities and ethics committees in Malaysia have a broad oversight towards the conduct of clinical trials and could take legal actions in the event of frauds and misconducts. Furthermore, this gazettement will be in-line with international requirements as recommended by WHO towards a mature regulatory authority.

Development of Quality Control Test Method for Registered Vaccines

The target of this initiative is to have cumulatively seven (7) test methods developed by 2025, which will be used for monitoring quality of registered vaccines. The National Public Health Laboratory (NPHL) is responsible to develop potency test methods for four (4) types of vaccine namely MMR, BCG, Diphtheria, Tetanus & Acellular Pertussis vaccine and Measles & Rubella vaccine. NPRA is given the task to develop potency test methods for three (3) types of vaccines namely Hepatitis B, Meningococcal and Pneumococcal vaccines. From 2018 to end of 2020, three (3) potency test methods are targeted to be developed (MMR, BCG and Hepatitis B vaccines). NPRA will continue to collaborate with the National Public Health Laboratory (NPHL) through the Technical Committee Development of Vaccine Potency Testing to develop potency testing methods for identified vaccines. Aside from potency tests, NPRA will develop other test methods necessary for vaccines quality monitoring such as appearance, identity, specific safety tests and for certain products, thermostability test.

Strengthening Quality Control Testing for Natural Products

Following on from the success of 2017-2020 Strategic Planning, this initiative has been carried

forward to the next phase of 2021-2025 Strategic Planning under Strategic Thrust 3: Sustaining Operational Excellence, Strategy 1 Strengthen Governance and Regulatory Control, Initiative 4 whereby the scope of recognition activity will be extended to those private laboratories which are able to comply with NPRA's requirement for conducting identification and authentication test for herbal raw materials. The target of this initiative is to recognize four (4) private laboratories by 2025.

The listing of recognized private laboratories for testing of herbal raw materials is to facilitate those traditional product manufacturers without quality control facilities or those who require testing services for their products by ensuring raw materials used in traditional products are identified and authenticated before the products are released to the market.

To ensure that this initiative is successful, training for regulators will be carried out regularly to enhance their current knowledge and understanding. Awareness sessions with private laboratories are also important to ensure that there are suitable testing facilities available that can support the new testing requirements for raw materials and finished products. Prior to full implementation of this new requirement, a feasibility study involving the relevant stakeholders shall be conducted following the awareness sessions.

Strengthen Regulatory Control of Medicinal Gases in Malaysia

Medicinal gases are now more widely used for adequate medical interventions mainly in hospitals and healthcare centres, provided their important role in healthcare. Therefore, there is a need to strengthen regulatory control of medicinal gases through licensing and registration activities to ensure quality, safety and efficacy of the products. NPRA has taken the initiative that aims to strengthen regulatory control of medicinal gases in Malaysia through licensing & registration activities which includes comprehensive plans and actions for five years.

As a legislative act and reference for regulators and industries, directive and guideline will be issued in the first year of our strategic direction Additionally, at least one training for regulators and industries will be conducted in the same year and another training in the following year. Our target in the second year is to inspect at least one MG manufacturer and subsequently to license the inspected manufacturer in the following year. Finally, to register at least three products within three years (third, fourth and fifth year).

Registration requirements/ Guideline

As MG is controlled as various categories in other countries, information on regulatory control of MG from various parties such as local industries, international practices and guidelines has been gathered and reviewed. Based on these information and further discussion among regulators, a suitable guideline on registration of MG will be developed. The guideline will be used as reference and will facilitate the industries through understanding the registration procedures and requirements, which will ensure a more efficient registration process.

Training for regulators and industries

Sharing of current manufacturing knowledge and practices from the industries will be done through training of MG to enhance the understanding of regulator in the aspect of registration, inspection and quality control. On the other hand, regulator will identify the level of understanding of the MG industries on the registration requirements in Malaysia. As such, training provided for both, regulator and the medicinal gas industries will be more effective and beneficial.

GMP Compliance

A MG product must be manufactured at a licensed manufacturing facility that complies with the PIC/S standard of Good Manufacturing Practice (GMP). This requirement is mandatory for a MG product registration. Due to differences in practicing GMP compliance among MG industries in Malaysia, these gaps can be identified through GMP inspection activities.

Strengthening Product Safety Monitoring and Vigilance

Pharmacovigilance (PV) is defined by the World Health Organization (WHO) as the science and activities relating to the detection, assessment, understanding and prevention of medicine-related problems. National Pharmaceutical Regulatory Agency (NPRA) has been appointed as WHO Collaborating Centre in the Regulatory Control of

Pharmaceuticals in May 1996 and has been acting as the national pharmacovigilance centre to collect and collate Adverse Drug Reaction (ADR)/ Adverse Event Following Immunisation (AEFI) reports from healthcare professionals, product registration holders (PRHs) and consumers ever since.

The Malaysian Pharmacovigilance Guidelines has been issued out by the NPRA to guide PRHs to fulfil their pharmacovigilance obligations. In this guideline, every PRH is responsible for establishing an appropriate system of Pharmacovigilance (PV) in the company. PV system refers to a system used by the PRH to fulfil the pharmacovigilance tasks and responsibilities outlined in national regulations and is designed to monitor the safety of registered medicinal products as well as to detect any changes in the benefit-risk balance. A basic PV system should be comprised of elements such as ADR/AEFI data management, procedures for signal detection, data evaluation and decision making related to safety issues, risk-management, PRH's action plan to protect public health, communication with stakeholders and to have in place audit procedures in order to measure the outcome of pharmacovigilance activities within the company. Having a PV system in place will help to strengthen the responsibility and liability held by the company for its products on the market.

Good Pharmacovigilance Practice (GVP) inspection is one of the regulatory activities that is practised by the more established regulatory agencies to keep track of PRHs' post-marketing vigilance activities. An effective pharmacovigilance system of PRH is crucial in ensuring product safety.

Good Pharmacovigilance Practice (GVP) Inspection is one of the regulatory activities that has been planned earlier under the National Medicine Policy (DUNas) in order to strengthen regulatory practices in Malaysia. Additionally, as NPRA strives to reach WHO maturity level 4 (regulatory system operating at advanced level of performance and continuous improvement), GVP inspection is an important indicator (Vigilance 03) set in the Global Benchmarking Tool utilized by the World Health Organization (WHO) to evaluate national regulatory systems around the world that will need to be implemented.

The main aim of the GVP inspection is to ensure that the PRHs comply with the pharmacovigilance requirements as outlined in the Malaysian Pharmacovigilance Guidelines. Currently, the Malaysian Pharmacovigilance Guidelines is being revised to include a specific section on GVP inspection. The PRHs and stakeholders will be consulted on the final draft of the new guideline. The circular to announce the requirement for GVP inspection is expected be issued in the first quarter 2021 followed by a series of seminars which will be arranged specifically for PRHs to raise awareness on the new Malaysian Pharmacovigilance Guideline particularly on the GVP inspection requirements. Subsequently, the first GVP inspection has been planned to take place in the fourth quarter of 2021. Thereafter, GVP inspections will be conducted regularly based on yearly targets determined by risk-based evaluations.

Strengthen the Enforcement of GDP Routine Inspection on Importers and Wholesalers Handling Time and Temperature Sensitive Products (TTSP)

The advancement in the global supply chain of pharmaceutical industry is growing progressively at a tremendous pace, with increasing emphasis on the importance of appropriate handling of cold chain products (also known as Time & Temperature Sensitive Products, TTSP by the World Health Organization, WHO). The usage of TTSPs has increased over the past few years with the strengthening of public health services in our country as well as the growing health awareness amongst Malaysians.

TTSPs comprise of a wide range of general pharmaceuticals, vaccines and blood/ plasma products, which must be stored within a defined storage temperature range in order to ensure that its safety, efficacy and quality are preserved up until the point of administration to the end users. As the name implies, TTSPs are sensitive to changes in storage time and temperature, therefore the handling of these products is extremely crucial whereby inappropriate handling can result in cold chain failure that could potentially cause harm to the end users.

National Pharmaceutical Regulatory Agency (NPRA) has tabled out a strategic plan to strengthen the governance and regulatory control of GDP amongst the local industries that hold import/ wholesale/ manufacturer's license of registered products, including TTSPs. Such

initiatives as proposed are aimed at strengthening the enforcement of routine GDP inspection of the importers and wholesalers that handle TTSPs.

Beginning in the year 2017, efforts have been taken by NPRA to establish control over the importers/ wholesalers of TTSPs in Malaysia, with the primary focus on vaccine and plasma products. The inspection of TTSP facilities at that time was reactively executed whereby inspection was only conducted upon receipt of written application from the license holder. Nevertheless, TTSPs available in Malaysia are not limited to vaccine and plasma products only and therefore NPRA has identified the importers and wholesalers of TTSPs (including general pharmaceuticals) through an e-engagement session with the local industries.

The objectives of this initiative are as followed:

1. To ensure that the identified importers/ wholesalers who handle TTSPs have the appropriate facilities to receive, store and distribute TTSPs.
2. To ensure that the identified importers/ wholesalers of TTSPs comply with the requirements laid down in the Guidelines of Good Distribution Practice.
3. To ensure that the quality, efficacy and safety of TTSPs will be preserved up until the point it reaches consumer/ end user.

The percentage of identified importers and wholesalers inspected by NPRA serves as the Performance Indicator of this initiative, whereby inspection of all of the identified premises have been planned for completion by 2025. The following table indicates the achievement target set from 2021 to 2025:

Performance Indicator	Target				
	2021	2022	2023	2024	2025
Percentage of identified importers and wholesalers inspected by NPRA	10%* of total identified premises inspected	35%* of total identified premises inspected	60%* of total identified premises inspected	80%* of total identified premises inspected	100%* of total identified premises inspected
*Note: The percentage depicted represents the cumulative percentage achieved over a period of 5 years from 2021 to 2025.					

It is critical to establish proper control over importers/ wholesalers of TTSPs in Malaysia in order to ensure a high level of regulatory compliance by relevant entities operating cold chain facilities. Importers/ wholesalers that handle TTSPs must have the appropriate facilities to receive, store and distribute TTSPs. In addition, the importers/ wholesalers of TTSPs must be able to demonstrate a high level of compliance towards Good Distribution Practice (GDP) requirements so as to ensure that the quality, efficacy and safety of TTSPs are preserved up until the point of administration to the end users.

STRATEGY 2: STRENGTHEN MONITORING OF SALES AND ADVERTISEMENT OF UNREGISTERED AND ADULTERATED PRODUCT

In effort to curb unapproved medical advertisements and sales of unregistered health products and unnotified cosmetics, the Pharmacy Enforcement Branch has formulated strategic initiatives. The strategy will focus on strengthening the enforcement activities on monitoring sales and advertisement of unregistered products, adulterated products and unnotified cosmetics in the hotspots area as well as in new media platform, including e-marketplace, websites and social media.

STRATEGY 3: ENHANCE ORGANISATIONAL EFFICIENCY

Organisational Reform of Pharmacy Board Malaysia Division

The Pharmacy Board Malaysia Division (PBMD) governs the pharmacy profession for Malaysia. PBMD functions are extensive and elaborative, including registration and deregistration of pharmacists and Bodies Corporate, accreditation, and recognition of Pharmacy Undergraduate Programme by Higher Educational Providers, approval of premises for provisional training and conducting Qualifying Examination to

Practice Pharmacy nationwide for the purpose of pharmacist registration.

These functions are currently being handled by two (2) existing branches with the assistance of six (6) sections within PBMD with limited human resources. Although PBMD is a professional body that regulates activities for the whole nation, it does not have any representative at state level. In addition to that, PBMD is also intended to expand its scope and function efficiently at an excellent pace. To materialise these, PBMD needs to be restructured and expanded.

The restructuring of the Pharmacy Board Malaysia Division (PBMD) with the addition of three (3) more branches and eight (8) more sections will enable PBMD to deliver functions efficiently to the whole nation. Among the initiatives that can be materialised via restructuring PBMD is:

i. To enhance the collaboration between government bodies and private institution
ii. To have a direct liaison with MOH legal advisors to accelerate processes involved in handling legislative issues within PBMD
iii. To manage Pharmacy Technologist profession including accreditation and recognition of pharmacy technologist Diploma Programme
iv. To manage registration and deregistration of Pharmacy Technologists (*subject to Registration of Pharmacist Act 1951 amendment)

Acquiring Global Standard National Regulatory Authority (NRA)

Medical products regulation and regulatory activities are becoming more and more globalised. An ongoing initiative at World Health Organization (WHO) aims at establishing and implementing a framework for evaluating and designating national regulatory authorities (NRAs) that meet a defined criterion as WHO-Listed Authorities (WLAs). The designation of a regulatory authority as a WLA ultimately promotes access and supply of safe, effective, and quality medicines and vaccines. Currently, NPRA is undergoing a self-assessment exercise using the Global Benchmarking Tool (GBT) in preparation for official benchmarking by WHO. The WHO GBT incorporates the concept of maturity level (ML), allowing WHO to assess the overall maturity of the regulatory system on a scale of one (1) (existence of some elements of the regulatory system) to four (4) (operating at advanced level of performance and continuous improvement). Becoming WHO Listed Authorities (Maturity Level-4) would ensure that the regulatory system practised here in Malaysia is comprehensive, transparent and in line with WHO standards.

One of the areas which can be improved in NPRA is the promotion of Good Regulatory Practice (GRP). National Regulatory Agencies (NRAs) should promote, establish and apply GRP principles to the regulation of medical products in different functions and areas. The principles on which regulatory systems may be established and by which they may be evaluated are legality, impartiality, consistency, proportionality, flexibility, effectiveness, efficiency, clarity and transparency.

Good Review Practice (GRevP) is an integral part of overall good regulatory practices and focuses on regulatory works of medical product review aspect. GRevP is a documented best practice for any aspect related to the process, format, content, and management of a medical product review. The objective of GRevP is to help achieve timeliness, predictability, consistency, transparency, clarity, efficiency, and high quality in both the content and management of reviews. This is done through the development of review tools (for example, standard operating procedures (SOPs) and templates) and reviewer learning activities (for example, training courses, mentoring, orientation packages and discussion sessions). To promote continuous improvement, all aspects of GRevP should be continuously evaluated and updated. Hence for year 2021 to 2025, the targeted number of NPRA staff receiving training on GRevP is two (2) officers per year, number of training of trainers (ToT) sessions conducted to promote awareness concept of GRevP is two (2) sessions per year and percentage of staff trained and qualified as product evaluator is 100 percent each year.

STRATEGY 4: ENHANCE ACCESSIBILITY OF PHARMACEUTICAL PRODUCTS

Develop and Establish Medicines Price Mechanism

Engagement with numerous stakeholders, innovation in ICT-based services, and sustaining operational excellence throughout the implementation process are the primary strategies in developing the pharmaceutical price mechanism. Expanding existing inter-

agency collaboration in the Know Your Medicine Programme is one of the initiatives to improve engagement with many stakeholders. To ensure that engagements are optimal, awareness efforts will be monitored and assessed. All the feedback will be considered for the improvement of the mechanism.

The Medicine Price Mechanism essentially requires ICT based service innovation for rapid and efficient access to medicine price information. Thus, there is an indispensable initiative to develop comprehensive medicines price system and mobile application to enhance price transparency information for the relevant agencies and the public. By the end of 2025, Pharmaceutical Services Programme expects to establish a comprehensive medicine price data and a synchronized mobile application that allows to look over the price of medicines and monitor the pricing of medicine all year round. Based on the two initiatives discussed above, we expect to establish a medicine price mechanism that provides people with transparency and affordable prices.

By implementing the medicine price mechanism, legal actions can be taken onto those selling the medicine exceeding the gazetted price. The legal incentive would drive the pharmaceutical market to be fairer to consumers. Pharmaceutical Services Programme will closely evaluate the implementation of the medicines price mechanism and its impact on all the stakeholders and the health care system to improve and sustain its operational excellence.

STRATEGY 5: ENHANCE EFFICIENCY AND OPTIMISING RESOURCES

Enhancing Medicines Optimization Programme

One of the pharmacists' roles is to continuously monitor prudent use of medicines by patients to ensure 'no shortage no wastage'. With increasing NCD and prescriptions over the years, MOH has spent RM 2.8 billion on medications (including vaccines). In order to avoid wastage of medications, one of the initiatives being implemented is the Patients Own Medicines (POMs) programme at In-patient Pharmacy in all MOH facilities (under Strategic Plan 2017-2020).

Based on the initiative of Patients Own Medicines (POMs) programme at In-patient Pharmacy in all MOH facilities, it is known that the main benefit in conducting POMs is savings in drug costs. Drug budgets may have substantial reductions when all or most of the POMs are used in the hospital. Thus, it is expected that expanding the POMs programme at the outpatient pharmacy setting can also aid in reducing the medicines wastage, other than optimizing the use of prescription drugs in the outpatient pharmacy.

Concerns about the practice of verifying and using POMs are that it can be time consuming and prone to error. To conduct POMs in outpatient pharmacy setting, few issues and key challenges need to be identified such as ongoing patient education to ensure patients bring their own medications upon admission, time required for medication reconciliation and management, and issues related to increasing waiting time during dispensing (due to filling of medication against the medicines brought by the patients). Thus, the suggestion to implement POMs programme in outpatient pharmacy setting is timely. The five (5) years duration will include strategies on developing guidelines, conducting pilot study to ensure the feasibility of the programme in the outpatient pharmacy setting and conducting the programme by phases before expanding it to all facilities in Malaysia.

Optimization of Resources through Strategic Procurement of Medicines

Based on the approval from MOF, a total of 85 medicines have been listed for pooled procurement. The process of initiating pooled procurement started in October 2018 and up to date, a total of 20 drug tenders from pooled procurement have been finalized. All three ministries are expected to optimize their expenses using pooled procurement tenders to generate savings from bulk purchases through this initiative.

Besides that, a Cost Savings Report will be prepared based on finalised pooled procurement tenders. This initiative is planned to ensure that all 85 items gazetted in the approval are implemented successfully. Furthermore, if this initiative is found to be cost-effective and beneficial to the Government, it is proposed that the Standard Operating Procedures of Pooled Procurement for MOH, MOHE and MINDEF be improved based on the implementation of current tenders so that more pooled procurement will be implemented more systematically. It is also anticipated that the number of medicines procured through this method will be increased in the future.

THRUST 4: ENHANCING CAPABILITY BUILDING

STRATEGY 1: ENHANCE HUMAN RESOURCE COMPETENCY AND PERFORMANCE

Development of the Capability Building Framework

This initiative aims to develop a framework that offers an overview of the various career options, education and training. To utilise pharmacists to their full potential as drug custody and advanced practitioners, the development and global acceptance of standardised competencies, which pharmacists are required to meet, is essential. A competent pharmacist will be able to provide the highest quality of healthcare to their patients, with a lower rate of medication errors, leading to increased health outcomes and patient satisfaction. Additionally, a pharmacist who possesses the qualities of competence and capability will allow other healthcare professionals to recognise the expertise of advanced practise pharmacists.

The development of the Capability Building Framework, also known as Training Road Map (TRM), will be useful for the inevitable progression of the pharmacy profession toward advanced practice. Pharmacists later will continue to improve their expertise and value to the healthcare workforce. Before improved competence and recognition of advanced pharmacy practice can be achieved, more standard competency requirements must be established. There are still several barriers to overcome before pharmacists can be recognised as advanced practitioners. Still, overall, the benefits of creating a competency framework for advanced practice outweigh the challenges that may be faced along the way.

Expansion of Subject Matter Expert (SME) Programme

Advancement and specialisation are frequently used interchangeably in some jurisdictions. There have been attempts to define these two concepts clearly. The term "specialist" is protected in this country under the General Order for the Government Civil Servants and can only be used by designated healthcare practitioners such as doctors and dentists. Due to the exclusion of pharmacists from this group, more generic terms such as "area of focus", "area of expert practice", or "defined area of practice" is used, further complicating global understanding in this area. Subject Matter Expert (SME) is officially used to acknowledge and recognise an expert in the Civil Services for areas of special interests after a circular issued by the Public Service Department Malaysia in 2016. The Pharmaceutical Services Programme has identified three areas of focus for MOH Pharmacists in 2018. Many more areas will be identified in the future, along with the career advancement opportunities for the professions.

Recognition through Credentialing and Privileging

Credentialing has also become one of the specific interests for healthcare professionals including pharmacists in this country. In a wider context, credentialing has become one of the important prerequisites for healthcare professionals to practice their technical skills. Within this context, credentialing is used as an umbrella term to encompass processes to ensure that individuals have complied with accepted standards, therefore acting as an evaluation of a professional's training, experience, and competence. According to the UK Department of Health (2010), there is evidence supporting the notion that "credentialed" healthcare practitioners, including pharmacists, tend to be associated with the provision of a higher quality of patient care (including complex care), improved clinical outcomes, and an increase in patient safety as compared to non-credentialed or non-board-certified practitioners. This initiative ensures enhanced patient care and optimal medication outcomes.

Furthermore, according to the Council on Credentialing in Pharmacy (2014):

"These credentials include earning an accredited professional pharmacy degree and a license awarded upon successful completion of a national postgraduate examination administered by the National Association of Boards of Pharmacy on behalf of state boards of pharmacy".

Establish a Structured and Progressive Training Programme in EBM and BIA for Pharmacist

As a way forward, one of the focuses in the upcoming Strategic Plan is to establish a structured and progressive training programme in EBM and

BIA for pharmacists. This training programme targets pharmacists at all organisational levels (State, Hospitals and Health Clinics) and is guided by a standardised Training Module. The training programme will encompass "Training of Trainers" by zones followed by training of pharmacists at the State and facility level. A registry of trained pharmacists will be maintained with structured monitoring of their EBM / BIA activities to promote the capacity building of pharmacists.

STRATEGY 2: OPTIMISE HUMAN RESOURCE CAPACITY TO ENSURE CONTINUOUS SERVICE DELIVERY

Develop Guideline to Justify Staffing Needs

According to the indicator of outcome-based budgeting (OBB) 2020, 98 percent of hospitals and 94 percent of health clinics achieved an optimal percentage of filling post. Therefore, the staffing guidelines can be used in mapping the pharmacist's post in MOH facilities in identifying the staffing need of each facility, thus in order to optimise human resource capacity.

STRATEGIC PLAN ALIGNMENT

This strategic plan was developed with a view to the future direction of Pharmacy Programme in aligning with the needs and the current situation of the government's plans. The fundamentals of this strategic plan are based on:

a) Eleventh Malaysian Plan
   - Achieving universal access to quality healthcare

b) Technical Working Group Papers of Twelfth Malaysian Plan

c) Health Services Transformation Plan
   - Develop talented health workforce
   - Strengthen health policies and public organizational capacity
   - Enhance health services delivery
   - Intensify health collaboration
   - Inculcate corporate culture values

d) Ministry of Health Strategic Plan 2021-2025
   - Restructure healthcare system
   - Strengthen health funding
   - Strengthen health awareness and community empowerment
   - Leverage technology into healthcare

e) Malaysian National Medicines Policy
   - Improve health outcomes of Malaysians by promoting equitable access to essential medicines, promoting rational use of medicines and ensuring quality, safety, effectiveness and affordability of medicines

THRUST AND STRATEGY

CUSTOMER ENGAGEMENT **The quality of the customer experience that emphasises the positive aspects of the interaction with our organisation**			
Enhance Multi Sector Engagement Towards Better Health Awareness	Enhance Multi Sector Engagement Towards Safe, Effective and Quality Products	Enhance Value Proposition of Pharmacy Services	Intensifying the Role of Pharmacy Services
INNOVATION DRIVEN **Translating ideas and innovations into services that create value for our customers**			
Enhancing ICT-based Service Innovations		Intensifying the Use of Research Findings and Evidences in Policy Development and Practice	
SUSTAINING OPERATIONAL EXCELLENCE **The element of organisational leadership that applies a variety of principles, systems and tools toward the sustainable improvement of key performance metrics**			
Strengthen Governance and Regulatory Control	Strengthen Monitoring of Sales and Advertisement of Unregistered and Adulterated Product	Enhance Organizational Efficiency	Enhance Accessibility of Pharmaceutical Products	Enhance Efficiency and Optimising Resources
ENHANCING CAPABILITY BUILDING **Process of developing and strengthening the skills, abilities and resources that organisations need to adapt and thrive in a changing environment**			
Enhance Human Resource Competency and Performance		Optimise Human Resource Capacity to Ensure Continuous Service Delivery	

IMPLEMENTATION PLAN

CUSTOMER ENGAGEMENT				
The quality of the customer experience that emphasises the positive aspects of the interaction with our organisation				
Strategy	**Initiative**	**Strategy / Initiative Details**	**Performance Indicator**	**Target by Year 2025**
STRATEGY 1: Enhance Multi Sector Engagement towards Better Health Awareness	**Initiative 1:** Engaging NGO, professional societies, government agencies to reach specific groups towards Quality Use of Medicines	Enhance inter-agency collaboration towards effective Quality Use of Medicines amongst the elderly, women, Hajj Pilgrims and visually impaired community etc. through the 'Know Your Medicines Programme'	Number of agencies engaged and collaborated	14 engagements (cumulative)
			Percentage of consumer understanding towards proper use of medicines	Minimum 80%
			Percentage of *Perkhidmatan Farmasi* Home Care (PFHC) Coverage for Homecare Institution Registered under *Jabatan Kebajikan Masyarakat*	Increasing trend
		Expanding inter-agency collaboration towards medicines price mechanism through 'Know Your Medicines Programme'	Number of awareness activities done to promote on medicines price mechanism	15 activities (cumulative)

CUSTOMER ENGAGEMENT				
The quality of the customer experience that emphasises the positive aspects of the interaction with our organisation				
Strategy	**Initiative**	**Strategy / Initiative Details**	**Performance Indicator**	**Target by Year 2025**
STRATEGY 2: Enhance Multi Sector Engagement towards Safe, Effective and Quality Products	**Initiative 1:** Engaging online sellers and platform providers through awareness activity to increase their awareness and knowledge on registered products	Engagement will be focusing on two main stakeholders in the health products online sale which are online sellers and the platform providers through awareness activities	Number of awareness activities conducted towards online sellers and platform providers	150 activities (cumulative)
			Number of online awareness campaign contents created on social media channels	42 new contents created (cumulative) Estimated views: 80,000 Estimated subscribers: 2,500
	Initiative 2: Collaboration with relevant associations in promoting regulatory compliance for cosmetic products	To establish collaborative efforts in providing professional trainings for the cosmetic industries	Number of training sessions conducted	20 sessions (cumulative)
			Percentage of compliance	80% (increasing trend)
STRATEGY 3: Enhance Value Proposition of Pharmacy Services	**Initiative 1:** Enhance promotion of pharmacy profession and services	Activities based on outcome of survey/ situational analysis. Specify activities based on survey	Number of activities done	Increasing trend
		Enhance the role of pharmacists in the provision of healthcare services through engagement with stakeholders based on targeted issues	Number of engagements done	5 engagements (cumulative)
	Initiative 2: Enhance pharmaceutical care and awareness on medicines towards specific groups (e.g. diabetes, hypertension and other NCDs)	Implementation of Pharmacy Integrated Community Care (PICC) Programme focusing on diabetes. PICC aims to educate diabetes patients on diabetes care and medicines compliance	Number of PICC activities conducted	Addition of minimum 1 community per state compared to previous year
			Percentage of patients having diabetes under control by achieving target HbA1c value after completing PICC session	Increasing trend

CUSTOMER ENGAGEMENT				
The quality of the customer experience that emphasises the positive aspects of the interaction with our organisation				
Strategy	**Initiative**	**Strategy / Initiative Details**	**Performance Indicator**	**Target by Year 2025**
STRATEGY 4: Intensifying the role of pharmacy services	**Initiative 1:** Enhance the role of pharmacists in the provision of healthcare services	Dissemination of medicine information by pharmacist through social media and mass media	Number of medicine information shared on social media and mass media	100 information shared per year
		The primary function of a press release is to quickly publicize information on the achievement of operation activity that may have a significant impact or be of particular interest to a large group of consumers. These activities will also promote the role of Pharmacy Enforcement Division through mass media coverage in a high impact channel or news	Number of Press Release on Operation Activity	1 press release per year
	Initiative 2: Enlightening the public on the current pharmacy policy, services, and achievements	Dissemination of articles in mass/ social media related to current pharmacy policy, services, and achievements	Number of articles disseminate through mass or social media	Increasing trend

INNOVATION DRIVEN				
Translating ideas and innovations into services that create value for our customers				
Strategy	**Initiative**	**Strategy / Initiative Details**	**Performance Indicator**	**Target by Year 2025**
STRATEGY 1: Enhancing ICT-based Service Innovations	**Initiative 1:** Enhance utilisation of Integrated Repository of Information System (IRIS) to facilitate decision making or knowledge sharing	Utilizing the data collected by the Integrated Repository of Information System (IRIS) platform to improve service delivery and decision making	Number of requests for data usage from IRIS	Increasing trend
	Initiative 2: Business Process Reengineering (BPR) of manual work process to ICT-based system	The existing QUEST3+ online system needs to be improved as there are work processes in NPRA still being carried out manually as well as improving existing work processes. NPRA intends to develop the QUEST5 system to address related issues. The new online system (QUEST5) includes: • 9 new modules to be included • 11 existing modules in QUEST3+ to be improved	Development of new online system (QUEST5)	100% Milestone Six (6) (25% progress): Full implementation Warranty period (100% cumulative progress)
		Development of Pharmacy Enforcement Online Application & Management System (MyPRAISE) The objective of this system is to prepare an online platform for license/ permit/ authorization/ advertisement approval application and online payment for the benefit of our client (easy and fast transaction)	Number of modules developed in MyPRAISE system	10 modules developed (cumulative)
		Improving current business process and system to accommodate Track & Trace and electronic medical record (EMR) requirement (PhIS, QUEST5, HIS)	Quality: Progress	Integration with Track & Trace System (2024)

INNOVATION DRIVEN				
Translating ideas and innovations into services that create value for our customers				
Strategy	**Initiative**	**Strategy / Initiative Details**	**Performance Indicator**	**Target by Year 2025**
STRATEGY 1: Enhancing ICT-based Service Innovations	**Initiative 2:** Business Process Reengineering (BPR) of manual work process to ICT-based system	Develop comprehensive medicines price system and app to enhance price transparency information	Medicines price system and app established	Establishment of system and app & integration with other relevant system (e.g. QUEST5 - price and PRH info)
	Initiative 3: Implementation of Pharmaceutical Track and Trace System	Pharmaceutical Track & Trace System supports all stakeholders in the pharmaceutical supply chain to comply with country specific legal requirements on serialization, tracking and tracing and regulatory reporting of pharmaceutical products. The main objectives of this system solution and architecture are to ensure patient safety, securing pharmaceutical supply chain, enable traceability & visibility of pharmaceutical products in the market and to combat counterfeit and unregistered products. These objectives can be achieved by having a system that monitors the end-to-end movements of drugs from manufacturer to the end user by using codification and identification of packages of drugs.	Implementation of Pharmaceutical Track & Trace System by 2023	Expansion of Pharmaceutical Track & Trace System in phases (Government Health Clinics)
	Initiative 4: Expanding and optimising IT system	Expansion of Pharmacist Registration Management System (PRiSMA) to include new module on monitoring of PRP performance (PRP appraisal)	Establishment of PRP performance monitoring module	Go-live PRP performance monitoring module in liberalised facilities (2023)
		Expansion of PRiSMA system to include new module on Offence & Punishment Registry	Establishment of Offence & Punishment Registry module	Go-live Offence & Punishment Registry module (2022)

INNOVATION DRIVEN				
Translating ideas and innovations into services that create value for our customers				
Strategy	**Initiative**	**Strategy / Initiative Details**	**Performance Indicator**	**Target by Year 2025**
STRATEGY 1: Enhancing ICT-based Service Innovations	**Initiative 5:** Development of virtual online platform for pharmacy services (e.g., counselling)	Enhance accessibility of patients to medication counselling services through virtual online platform	Development of a virtual platform for medication counselling	Expansion of virtual platform for medication counselling to all hospitals and type 1 & 2 health clinics
		Medication Counselling Modules: • Devices (e.g., patches) • Special drugs (e.g., pessary, enema, eye/ ear drop, HRT, suppositories) • Diabetes Mellitus • Cardiology • Nephrology • Respiratory • Quit Smoking Pharmacotherapy • RVD • Psychiatry • Pain management • Oncology • Haematology • Rheumatology • Hepatology • Neurology • Dermatology • Home Parenteral Nutrition	Number of medication counselling modules prepared	17 modules prepared (2023) Review counselling modules: • Expansion of topics • Renew module contents
			Percentage of facilities providing medication counselling using virtual platform developed	All hospitals and type 1 & 2 health clinics
	Initiative 6: Delighting customer experience by developing apps to empower patient/ caregiver (personalised)	Enhance accessibility of patients to register for pharmacy value added service. MyUBAT application provides a personalised experience to patients for drug collection (e.g., modifying date of appointment at patient's convenience)	Expansion of MyUBAT module coverage	Expansion of module in MyUBAT to include (2023): • Counselling tips • Drug information • ADR • Side Effects • Allergies
			Percentage of patients registered with MyUBAT (No. of patients using MyUBAT apps/ Total no. of patients registered with MyUBAT)	Increasing trend

INNOVATION DRIVEN				
Translating ideas and innovations into services that create value for our customers				
Strategy	**Initiative**	**Strategy / Initiative Details**	**Performance Indicator**	**Target by Year 2025**
STRATEGY 2: Intensifying the use of Research Findings and Evidence in Policy Development and Practice	**Initiative 1:** Encouraging quality & innovation projects and pharmacy research in the identified priority areas	Setting research priorities to streamline and provide a well-planned guidance in conducting pharmacy research & quality projects	Publication of Pharmacy Research Priorities in Malaysia (2nd Edition)	Publish report findings
			Priority areas for quality & innovation projects document developed	Publish report findings
	Initiative 2: Enhancing the utilisation of quality & innovation projects and pharmacy research findings in policy development and practice	Providing multiple platforms for research evidence sharing with policy makers	Number of research or quality & innovation projects presented to policy makers	20 projects (cumulative)
			Number of rapid reviews conducted	19 rapid reviews (cumulative)
			Number of articles published	375 articles (cumulative)

SUSTAINING OPERATIONAL EXCELLENCE				
The element of organisational leadership that applies a variety of principles, systems and tools toward the sustainable improvement of key performance metrics				
Strategy	**Initiative**	**Strategy / Initiative Details**	**Performance Indicator**	**Target by Year 2025**
STRATEGY 1: Strengthen Governance and Regulatory Control	**Initiative 1:** Amendment of the existing law and regulations for the betterment of pharmaceutical services	Amendment of existing law to: • Facilitate the use of cannabis and cannabis resin for medical purposes • Expand the control of drug and provide for power of the officer in relation to enforcement, inspection, and investigation of drug • Expand the control of advertisement to medicines, services, medical devices, cosmetics, and online sales involving agencies under MOH • Expand the scope of the Act which covers new activities (e.g., practice of pharmacy, registration of pharmacy technologist, power of the Board) to ensure its relevancy and in tandem with the current practice	Number of stakeholder's engagement conducted	1 engagement conducted
			Number of draft bill or regulation submitted to PUU/AGC	1 draft bill or regulation submitted
		Development of new Pharmacy Act relating to the consolidation of Poisons Act 1952 and Sale of Drugs Act 1952	Draft bill submitted to PUU/ AGC	Draft bill submitted to PUU/ AGC
	Initiative 2: Develop clinical trial research legal framework (i.e., Clinical Trial Act)	It is proposed that this Clinical Trial Act include the following: • Intervention-based clinical research conducted in Malaysia • The Act focuses on the conduct of quality clinical research, protection of human rights, security, data integrity and well-being of subjects involved in clinical research	Approval of Bill in Parliament & establishment of Clinical Trial Act	Bill approved in Parliament & Clinical Trial Act established

SUSTAINING OPERATIONAL EXCELLENCE **The element of organisational leadership that applies a variety of principles, systems and tools toward the sustainable improvement of key performance metrics**				
Strategy	**Initiative**	**Strategy / Initiative Details**	**Performance Indicator**	**Target by Year 2025**
STRATEGY 1: Strengthen Governance and Regulatory Control	**Initiative 2:** Develop clinical trial research legal framework (i.e., Clinical Trial Act)	• Incorporation of existing guidelines such as Malaysian GCP Guideline, Malaysian Guideline on Application of CTIL / CTX, National Stem Cell and Gene Therapy Guideline, Guideline on Notification of Exemption from Registration of Medical Devices, etc.	Approval of Bill in Parliament & establishment of Clinical Trial Act	Bill approved in Parliament & Clinical Trial Act established
	Initiative 3: Development of quality control test method for registered vaccines	This initiative aims to strengthen laboratory capability in performing quality control testing for registered vaccines through development of more testing methods for the purpose of vaccines quality monitoring.	Number of test method developed by NPRA and NPHL (cumulative since 2018)	7 test methods developed (cumulative)
			Number of related training on the identified test method for relevant officers	At least 1 training session per year
	Initiative 4: Strengthening Quality Control testing for Natural Products	This initiative is to strengthen the requirement stated above by ensuring raw materials used in natural products are identified and authenticated before products are released to market.	Number of trainings for regulators and/ or industries	3 trainings (cumulative) (2023)
			Number of private laboratories recognised (conducting identification and authentication test for herbal raw material)	4 private laboratories recognised (cumulative)
			Policy paper approved by DCA (implement / enforce the requirement to submit COA of raw material with specified test during product registration)	Policy paper presented and approved by DCA Issuance of directive

SUSTAINING OPERATIONAL EXCELLENCE **The element of organisational leadership that applies a variety of principles, systems and tools toward the sustainable improvement of key performance metrics**				
Strategy	**Initiative**	**Strategy / Initiative Details**	**Performance Indicator**	**Target by Year 2025**
STRATEGY 1: Strengthen Governance and Regulatory Control	**Initiative 5:** Strengthen Regulatory Control of Medicinal Gases in Malaysia	This initiative aims to strengthen Regulatory Control of Medicinal Gases in Malaysia through licensing & registration activities.	Number of training for regulators & industry	At least 1 training per year (2022)
			Number of medical gases manufacturer licensed	At least 1 new MG manufacturer licensed (2023)
			Number of medical gases products registered	At least 1 new medical gases product registered
	Initiative 6: Strengthening product safety monitoring and vigilance through the implementation of Good Pharmacovigilance Practice (GVP) Inspection of product registration holders (PRH)	GVP inspection is aimed to ensure compliance of the PRH towards pharmacovigilance requirements as outlined in the Malaysian Pharmacovigilance Guidelines as well as other post-registration requirements imposed by the Drug Control Authority (DCA). In addition, GVP inspection is also aimed to strengthen the safety monitoring of the registered product through an effective pharmacovigilance system of the PRHs. In Malaysia, GVP inspection is planned on a list of PRH that have been identified through a risk-based assessment.	Percentage of total PRH identified (through risk-based assessment) inspected by NPRA (from year 2022 onwards)	40% of the total PRH identified (risk-based list)
	Initiative 7: To strengthen the enforcement of GDP routine inspection on the importers and wholesalers who handle Time & Temperature Sensitive Products (TTSP)	This initiative is: • To ensure the identified importers/ wholesalers who handle TTSPs has the appropriate facilities to receive, store and distribute TTSPs • To ensure the identified importers/ wholesalers of TTSPs comply to the requirement stated under the Guidelines of Good Distribution Practice • To ensure the quality, efficacy and safety of TTSPs will be preserved until the point it reaches consumer/ end user	Percentage of identified importers and wholesalers inspected by NPRA	100% of total identified premises inspected

SUSTAINING OPERATIONAL EXCELLENCE **The element of organisational leadership that applies a variety of principles, systems and tools toward the sustainable improvement of key performance metrics**				
Strategy	**Initiative**	**Strategy / Initiative Details**	**Performance Indicator**	**Target by Year 2025**
STRATEGY 2: Strengthen monitoring of sales and advertisement of unregistered and adulterated product	**Initiative 1:** Extent the "Didik, Pantau and Serbu (DIPS)" approach to the premises at the hotspots area	Premises that have been selected to be monitored by the State Branch that sell unregistered products. These premises are located in the attraction area of sales of unregistered products	Percentage of reduction of identified premises selling unregistered products	15-20% reduction of targeted premises selling unregistered products (Cumulative 95-100% reduction)
	Initiative 2: "Broken Window" initiative to overcome illegal online sales	This initiative will be implemented through 2 strategies: • To develop quality intelligence information through: » Screening of advertisement & sales of illegal products/ cosmetics online. E.g., advertisement on e-commerce and social media. » Profiling & information mining. Collection of relevance information pertaining to illegal advertisement and sales. » Social engineering & verification of quality intelligence information developed. • To organise successful operation based on the quality intelligence information. Measured by percentage of successful operation organized based on quality intelligence information developed.	Number of quality intelligence information developed for enforcement action	1,000 quality intelligence information developed (cumulative)
			Percentage of operation successfully conducted based on Broken Window information developed	80%

SUSTAINING OPERATIONAL EXCELLENCE				
The element of organisational leadership that applies a variety of principles, systems and tools toward the sustainable improvement of key performance metrics				
Strategy	**Initiative**	**Strategy / Initiative Details**	**Performance Indicator**	**Target by Year 2025**
STRATEGY 2: Strengthen monitoring of sales and advertisement of unregistered and adulterated product	**Initiative 3:** Strengthening of enforcement activities towards sales and advertisement of unregistered and adulterated products in new media	Formulating new guideline and standard operating procedure (SOP) of enforcement activities involving sales and advertisement of unregistered and adulterated products in new media.	Number of investigation of new cases involving sales and advertisement of unregistered and adulterated products in online media conducted	45 cases (3 investigation cases conducted per state)
		Increase monitoring on sale and advertisement in new media.	Compliance of e-marketplace providers in removing the identified medicine advertisements in their platform upon request by Pharmacy Enforcement Division	90%
			Percentage of compliance to the content removal request sent by Pharmacy Enforcement Division to Social Media in Malaysia	90%

SUSTAINING OPERATIONAL EXCELLENCE **The element of organisational leadership that applies a variety of principles, systems and tools toward the sustainable improvement of key performance metrics**				
Strategy	**Initiative**	**Strategy / Initiative Details**	**Performance Indicator**	**Target by Year 2025**
STRATEGY 3: Enhance organizational efficiency	**Initiative 1:** Organizational reform of Pharmaceutical Services Programme	In line with national policy on optimization of human resources in public services, Pharmaceutical Services Programme take the initiative to reform the structural and operational of the organisation to ensure the efficiency and continuity of pharmaceutical services. This initiative includes the expansion of role and function of divisions under the PSP in accordance with current healthcare policy and demand.	Restructuring of Divisions under the Pharmaceutical Services Programme	Review target based on the decision by MOH/ JPA/ Policy (2023)
	Initiative 2: Becoming WHO Listed Authority-Maturity Level 4	To meet the standard set in WHO Global Benchmarking Tool (GBT) in becoming WHO Listed Authorities-Maturity Level 4, preparing Road Map towards official benchmarking of WHO GBT	Promoting Good Registration Management (GRM), (Good Registration Practice) through indicators as below: Number of staff receiving training on GRevP (i.e from APEC initiatives, etc)	10 officers (cumulative)
			Number of training of trainer (TOT) sessions conducted to promote awareness on concept of GRevP	10 sessions (cumulative)
			Percentage of staff trained and qualified as product evaluators	100%

SUSTAINING OPERATIONAL EXCELLENCE				
The element of organisational leadership that applies a variety of principles, systems and tools toward the sustainable improvement of key performance metrics				
Strategy	**Initiative**	**Strategy / Initiative Details**	**Performance Indicator**	**Target by Year 2025**
STRATEGY 4: Enhance accessibility of pharmaceutical products	**Initiative 1:** Develop and establish medicines price mechanism	First Phase (2021-2022): The medicines price mechanism involves "controlled medicines" involving of innovative and generic drugs, which are registered by a single product registration holder. Subsequent Phase (2023-onwards): Medicines price Mechanism expanded to other Controlled Medicines	Medicines Price Mechanism gazettement established	Implementation of Medicines Price Mechanism
			Percentage of gazetted medicines price inspected by enforcement state branch	Increasing trend
			Publication of Impact study 2020-2025	Post implementation study of medicines price mechanism Publication of Impact study 2020-2025
STRATEGY 5: Enhance efficiency and optimising resources	**Initiative 1:** Enhancing medicines optimization programme	Enhancing POMs programme to Outpatient Pharmacy. This initiative focuses on patients and their experiences with the goals to help patients to improve treatment outcomes and avoid taking unnecessary medicines, reduce wastage as well as improve medication safety	Percentage of facility implementing POMs at outpatient pharmacy	100% of State Hospital + KK Type 1 100% of District Hospital + KK Type 2 and 3
	Initiative 2: Optimization of resources through strategic procurement of medicines	Assessment of Pooled Procurement between Ministry of Health, Ministry of Education (MoE) and Ministry of Defence (MoD) for contract items	Publication of pool procurement analysis report	Publish pool procurement analysis report for total 85 items (2023)
			Implementation of renewal contract of Pool Procurement	Implementation of renewal contract of Pool Procurement

SUSTAINING OPERATIONAL EXCELLENCE				
The element of organisational leadership that applies a variety of principles, systems and tools toward the sustainable improvement of key performance metrics				
Strategy	**Initiative**	**Strategy / Initiative Details**	**Performance Indicator**	**Target by Year 2025**
STRATEGY 5: Enhance efficiency and optimising resources	**Initiative 3:** Enhancing pharmacy facilities and infrastructure	To initiate the direction and policy of the pharmacy facilities project under RMK. To create a blueprint document that contain policy and guideline of pharmacy infrastructure projects	Development of blueprint document (Progression of developing document)	Mid-term review of document
			Percentage of new pharmacy development/ renovation projects comply to blueprint document	60%

ENHANCING CAPABILITY BUILDING				
Process of developing and strengthening the skills, abilities and resources that organisations need to adapt and thrive in a changing environment				
Strategy	**Initiative**	**Strategy / Initiative Details**	**Performance Indicator**	**Target by Year 2025**
STRATEGY 1: Enhance Human Resource Competency and Performance	**Initiative 1:** Develop capability building framework (technical & management)	This initiative aims to develop a framework that offer an overview of the various career options along with education and training.	Implementation of Training Road Map (TRM)	Implementation of TRM outcome covers all components below: Generic (developed by JPA) Functional Technical
		Enhancing Pharmacists Assistant competency through a more structured, systematic and comprehensive training through TRM components. Aim: • To provide qualified, capable and competent staff • Providing direction for career advancement	Number of Pharmacists Assistant undergoing TRM	60 Pharmacists Assistant trained Setting criteria for Pharmacists Assistant's career advancement pathway based on TRM
	Initiative 2: Increasing the number of Pharmacists Assistant with Advanced Diploma	Enhancing Pharmacists Assistant competency through a more structured, systematic and comprehensive training through Advanced Diploma Aim: • To provide qualified, capable and competent staff • Providing direction for career advancement	Number of Pharmacists Assistant awarded with Advanced Diploma	10 Pharmacists Assistant with Advanced Diploma
	Initiative 3: Recognition of Pharmacists Assistant through C&P	Increasing number of skilled Pharmacists Assistant in the field of Sterile Pharmaceutical Preparations	Number of Pharmacists Assistant approved for C&P	5 Pharmacists Assistant approved for C&P

ENHANCING CAPABILITY BUILDING				
Process of developing and strengthening the skills, abilities and resources that organisations need to adapt and thrive in a changing environment				
Strategy	**Initiative**	**Strategy / Initiative Details**	**Performance Indicator**	**Target by Year 2025**
STRATEGY 1: Enhance Human Resource Competency and Performance	**Initiative 4:** Expansion of Subject Matter Expert (SME) Programme	SME is a form of recognition to an individual pharmacist who is an expert in a particular area/ field. Approved SME fields: • Pharmacotherapy: Anticoagulant • Pharmacotherapy: Infectious Disease • Regulatory pharmacy: First in Human (FIH)/ First Dose in Human (FDIH)	Number of new SME field established	1 new SME programme established (2024)
	Initiative 5: Establish a structured and progressive training programme in EBM and BIA for pharmacist	Establish a structured and progressive training programme in EBM and BIA for pharmacist at various organizational levels to ensure EBM/BIA skill development which is essential to guide optimal drug decision making. Development of this skill and its application in pharmacy services can help optimize resource use and improve efficiency	Number of trainings conducted in EBM & BIA	1 session per facility (Training at hospitals & primary care clinics)
			Number of pharmacists trained	10 per facility
STRATEGY 2: Optimise Human Resource Capacity to ensure continuous service delivery	**Initiative 1:** Develop guideline to justify staffing needs	Staffing needs Guideline develop • Hospital • KK • JKN • IPKKM	Staffing Needs Guideline published	Completion of integration to i-HRx

MONITORING AND EVALUATION

Monitoring is routine tracking of key elements of programmes. It contributes to evaluation, shows where to focus and follows measure over time to make sure it is on track and on target. Monitoring for this strategic framework will be conducted in an indicator-based approach. Performance indicators were developed with annual targets for each initiative in the strategic plan. A performance indicator is a variable measuring important dimensions of system performance. It must be easy to understand, useful, reliable, and valid. Besides that, S.M.A.R.T. principles are also being used for developing these indicators, where the indicators shall be specific, measurable, achievable, realistic, and timely.

Evaluation is periodic assessment of changes in results and effectiveness of strategies. It relates programme outputs to outcomes and interprets measurements. Progress of the strategy and initiatives, together with outputs of performance indicators collected at the monitoring level, are used as sources of analysis in evaluation process. Evaluation stage includes examining the underlying foundation of a strategy, comparing actual results with expected outcomes, and taking corrective measures to ensure achievement conforms to plans.

The monitoring and evaluation activity will be a continuous process throughout the term of this Strategic Plan from 2021 to 2025. A mid-term review will be conducted to produce evaluation report with remedial actions and presented to top management to decide measures for improvement. A full-term review will be carried out in the last year of the term to assess the overall performance of this Strategic Plan and finally to propose for strategic framework for the next term.

2021	2022	2023	2024	2025
→ Roll out of Strategic Plan → Start off monitoring of implementation	→ Continue monitoring and start evaluation of implementation progress	→ Continue monitoring and evaluation activity → Mid-term review	→ Continue monitoring and evaluation activity	→ Continue monitoring and evaluation activity → Full-term review

CONCLUSION

The Strategic Plan is developed based on the first Strategic Plan and its past performance in the last five (5) years. This Strategic Plan has taken a wholesome approach and will spearhead the direction of the Pharmaceutical Services Programme in another upcoming five (5) years, carrying an improved and more strategised blueprint for the future of the Programme. The implementation of the initiatives under the four (4) thrusts and thirteen (13) strategies shall enable the Programme to achieve its goals and aspirations to improve the nation's health status.

GLOSSARY OF TERMS, ABBREVIATIONS AND ACRONYMS

3B	Banner, Bunting, Billboard
A&P	Pharmacy Practice and Development Division
ADAMAS	Antidoping Agency Malaysia
ADR	Adverse Drug Reaction
AEFI	Adverse Events Following Immunization
ANSARA	MRSM Malaysia Student Association
APEC	Asia-Pacific Economic Cooperation
APHM	Association of Private Hospitals Malaysia
ARU	Availability, Reliability and Utilisation
ASEAN	Association of Southeast Asian Nations
BCG	Bacille Calmette-Guerin
BDHA	*Bahagian Dasar dan Hubungan Antarabangsa*
BIA	Budget Impact Analysis
BKMM	Food Quality Control Division
BPR	Business Process Reengineering
BSM	*Bahagian Sumber Manusia* (Human Resource Department)
C&P	Credentialing and Privileging
CAB	Conformity Assessment Body
CAPA	Corrective and Preventive Action
CDCR	Control of Drugs and Cosmetics Regulation
CKAPS	*Cawangan Kawalan Amalan Perubatan Swasta*
CoA	Certificate of Analysis
COVID-19	Coronavirus Disease 2019
CPF	*Cawangan Penguatkuasaan Farmasi*
CPS	Clinic Pharmacy System
CTIL	Clinical Trial Import License
CTX	Clinical Trial Exemption
DCA	Drug Control Authority
DG	Director General
DICE	Drug Information and Consumer Education
DiPS	*Didik, Pantau dan Serbu*
DPSF	Pharmacy Policy and Strategic Planning Division
DRGD	Drug Registration Guidance Document
DUNas	*Dasar Ubat Nasional* (National Medicines Policy)
EBM	Evidence-based Medicines
EBP	Evidence-based practice
EDPF	*Sistem Data Penguatkuasaan Farmasi*
EMR	Electronic Medical Record
ENF	Pharmacy Enforcement Division
EOL	End of Life
eP	*ePerolehan*
FAT	Final Acceptance Test

FDIH	First Dose in Human
FIH	First in Human
FRP	Fully Registered Pharmacist
GBT	Global Benchmarking Tool
GCP	Good Clinical Practice
GDP	Good Distribution Practice
GMP	Good Manufacturing Practice
GRevP	Good Review Practice
GRM	Good Registration Management
GRP	Good Regulatory Practice
GTP	Government Transformation Programme
GVP	Good Pharmacovigilance Practice
HbA1c	Haemoglobin A1c
HIS	Hospital Information System
HKL	Hospital Kuala Lumpur
HOAG	Hospital Orang Asli Gombak
HPU	University Teaching Hospital/ *Hospital Pengajar Universiti*
HQ	Headquarters
HRC	Hospital Rehabilitasi Cheras
HRT	Hormone Replacement Therapy
ICT	Information and Communications Technology
IDDS	Integrated Drug Delivery System
IKN	*Institut Kanser Negara*
IMR	Institute of Medical Research
IPKKM	*Ibu Pejabat Kementerian Kesihatan Malaysia* (Ministry of Health Headquarters)
IRIS	Integrated Repository of Information System
IT	Information Technology
JK	*Jawatankuasa* (Committee)
JKN	*Jabatan Kesihatan Negeri* (State Health Department)
JPA	*Jabatan Perkhidmatan Awam* (Public Service Department)
KIK	*Kumpulan Inovatif dan Kreatif*
KK	*Klinik Kesihatan* (Health Clinics)
KKMM	*Kementerian Komunikasi dan Media*
KPDNHEP	*Kementerian Perdagangan Dalam Negeri dan Hal Ehwal Pengguna* (Ministry of Domestic Trade and Consumer Affairs)
KPI	Key Performance Indicator
KPK	*Ketua Pengarah Kesihatan*
KYM	Know Your Medicine
LFM	*Lembaga Farmasi Malaysia*
MAera	Malaysian Alliance for Embedding Rapid Reviews
MAMPU	Malaysian Administrative Modernization and Management Planning Unit
MCMC	Malaysian Communications and Multimedia Commission
MDA	Medical Device Authority
MERS	Medication Error Reporting System
MG	Medicinal Gases
MJM	*Memorandum Jemaah Menteri*
MKAK	*Makmal Kesihatan Awam Kebangsaan*

ML	Maturity Level
MMA	Malaysian Medical Association
MMC	Malaysian Medical Council
MMR	Measle, Mumps and Rubella
MoD/ MINDEF	Ministry of Defense
MoE	Ministry of Education
MOH/ KKM	Ministry of Health/ *Kementerian Kesihatan Malaysia*
MOHE	Ministry of Higher Education
MOHMF	Ministry of Health Medicines Formulary
MPC	Malaysia Productivity Corporation
MPS	Malaysian Pharmacists Society
MRSM	*Maktab Rendah Sains MARA*
MSOM	Malaysian Statistics on Medicines
MTAC	Medication Therapy Adherence Clinic
MyPRAISE	Pharmacy Enforcement Online Application & Management System
MyPSA	Malaysian Pharmacy Students' Association
NaOH	Sodium Hydroxide
NCD	Non-communicable Diseases
NDP	New Drug Products
NGO	Non-governmental Organisation
NHMS	National Health Morbidity Survey
NIP	National Immunization Programme
NPHL	National Public Health Laboratory
NPRA	National Pharmaceutical Regulatory Agency
NSUM	National Survey on the Use of Medicines
OBB	Outcome-based Budgeting
PASc	Patient Access Scheme
PBMD	Pharmacy Board Malaysia Division
PBRER	Periodic Benefit Risk Evaluation Report
PBT	Local Authority
PDSA	Public Sector Data Center
PE	Pharmacoeconomics
PED	Pharmacy Enforcement Division
PFHC	Perkhidmatan Farmasi Home Care
PhIS	Pharmacy Information System
PHP	Hypertext Preprocessor
PICC	Pharmacy Integrated Community Care
PIKF	*Perkembangan Infrastruktur dan Kualiti Farmasi*
PKPD	Pharmacokinetic pharmacodynamic
PMS	Post-Marketing Surveillance
POM	Patients Own Medicines
PPP	Public-Private Partnership
PPUSS	*Pusat Pembekalan Ubat Susulan Setempat*
PRH	Product Registration Holder
PRiSMA	Pharmacist Registration Management System
PRP	Provisional Registered Pharmacist
PSP/ PPF	Pharmaceutical Services Programme/ *Program Perkhidmatan Farmasi*
PUU/ AGC	*Penasihat Undang-undang* (Attorney General's Chamber)

PV	Pharmacovigilance
QA	Quality Assurance
QUEST	Online System for Product Registration, Cosmetic Notification, Licensing and Market Sampling
QUM	Quality Use of Medicines
R&D	Research and Development
RIA	Regulatory Impact Assessment
RMK12	Twelfth Malaysian Plan / *Rancangan Malaysia ke-12*
RMP	Risk Management Plan
ROPA	Registration of Pharmacists Act
RP2	Rolling Plan 2
RTM	*Radio Televisyen Malaysia*
RUUF	*Rang Undang-undang Farmasi*
RVD	Retroviral Diseases
S.M.A.R.T.	Specific, Measurable, Achievable, Realistic, and Timely
SDA	Special Drug Approval
SDD	Software Design Document
SEB	State Enforcement Branch
SME	Small and Medium Enterprises
SME	Subject Matter Expert
SMS	Short Message Service
SODA	Sale of Drugs Act
SOM	Senior Officer Meeting
SOP	Standard Operating Procedures
SPI	*Sistem Pengurusan Iklan*
SPIKES	*Sistem Pengurusan Integrasi Kawalan Efektif Substan*
SPUB	*Sistem Pendispensan Ubat Bersepadu*
SQL	Structured Query Language
SSA	SME Special Assignment
TDM	Therapeutic Drug Monitoring
ToT	Training of Trainers
TRM	Training Road Map
TTSP	Time and Temperature Sensitive Products
UAT	User Assessment Test
UK	United Kingdom
UKAS	*Unit Kerjasama Awam Swasta*
UMP	*Ubat Melalui Pos*
UPC	Unified Public Consultation
URL	Uniform Resource Locator
URS	User Requirement Specification
UTC	Urban Transformation Centres
VAS	Value-added Services
WHA	World Health Assembly
WHO	World Health Organization
WISN	Workload Indicators for Staffing Need
WLAs	WHO-Listed Authorities
WPD	World Pharmacist Day

CONTRIBUTOR

NATIONAL PHARMACEUTICAL REGULATORY AGENCY

YBrs. Dr. Hasenah binti Ali
Director

YBrs. Dr. Roshayati Mohamad Sani
Deputy Director

Dr. Noraida Mohamad Zainoor
Senior Principal Assistant Director

Puan Nik Juzaimah binti Juhari
Senior Principal Assistant Director

Dr. Zaril Harza Zakaria
Senior Principal Assistant Director

Encik Kobu Thiruvanackan
Senior Principal Assistant Director

Puan Karen Wong Yoke Sim
Senior Principal Assistant Director

YBrs. Puan Basariah binti Naina
Deputy Director

YBrs. Puan Rosilawati binti Ahmad
Deputy Director

Dr. Azuana Ramli
Senior Principal Assistant Director

Puan Nik Shamsiah binti Nik Salleh
Senior Principal Assistant Director

Puan Nur Azimah binti Mohd Taman
Senior Principal Assistant Director

Puan Sarawani binti Hassan
Senior Principal Assistant Director

Puan Zeti Hulwani binti Baba
Senior Principal Assistant Director

PHARMACY PRACTICE AND DEVELOPMENT DIVISION

YBrs. Puan A'tia binti Hashim
Director

Puan Rohana binti Hassan
Deputy Director

Puan Fatkhiah binti Haji Khalil
Deputy Director

Puan Rozita binti Mohamad
Deputy Director

Puan Norhuda binti Mohd Tajuddin
Deputy Director

Puan Munira binti Muhammad
Deputy Director

PHARMACY ENFORCEMENT DIVISION

YBrs. Encik Roeslan bin Ishak
Director

Puan Latifah binti Haji Idris
Deputy Director

Puan Saleha binti Abd Rahman @ Ngah
Deputy Director

Encik Mokhtar bin Abdullah
Deputy Director

Encik Adnan bin Salimin
Deputy Director

Encik Mohd Zawawi bin Abdullah
Deputy Director

PHARMACY POLICY AND STRATEGIC PLANNING DIVISION

YBrs. Puan Norhaliza binti A Halim
Director

Puan Ezatul Rahayu binti Anuar
Deputy Director

Puan Zarina binti Rosli
Deputy Director

Dr. Abdul Haniff bin Mohamad Yahaya
Deputy Director

Puan Nurhairani binti Abdul Latif
Deputy Director

Encik Mohd Hazwan bin Md Ghazali
Senior Principal Assistant Director

PHARMACY BOARD MALAYSIA DIVISION

Puan Noraini binti Mohamad
Deputy Director

Puan Siti Aisah binti Bahari
Deputy Director

NOTES

NOTES

NOTES

KEMENTERIAN KESIHATAN MALAYSIA

PROGRAM PERKHIDMATAN FARMASI

Lot 36, Jalan Profesor Diraja Ungku Aziz,
46200 Petaling Jaya, Selangor Darul Ehsan.

03-7841 3200

www.pharmacy.gov.my

Program Perkhidmatan Farmasi KKM