MALAYSIAN NATIONAL MEDICINES POLICY (MNMP)

Dasar Ubat Nasional (DUNas)

MINISTRY OF HEALTH MALAYSIA

First Term Performance Report (2007-2011)

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ABBREVIATIONS

ADR	Adverse Drug Reaction
AEFI	Adverse Event Following Immunisation
APPL	Approved Product Purchase List
ASEAN	The Association of Southeast Asian Nations
BE	Bioequivalence
BIMST-EC	Bay of Bengal Initiative for Multi Sectoral Technical and Economic Cooperation
CMA	Compliance Monitoring Authority
CPD	Continuing Professional Development
CP	Compliance Data
CRC	Clinical Research Centre
CRO	Contact Research Organization
DCA	Drug Control Authority
DE	Data Exclusivity
DUNas	Dasar Ubat Nasional
EDQM	European Directorate for the Quality of Medicines
GCP	Good Clinical Practice
GDP	Good Distribution Practice
GGM	Good Governance for Medicines
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GSP	Good Storage Practice
IRP	International Reference Price
KPI	Key Performance Indicator
MAB	Medicines Advertisement Board
MAD	Mutual Acceptance Data
MOH	Ministry of Health
MPR	Median Price Ratio
MSH	Management Sciences for Health
MTAC	Medication Therapy Adherence Clinic
NCE	New Chemical Entity
NEDL	National Essential Drugs List
NPCB	National Pharmaceutical Control Bureau
OECD	Organisation for Economic Cooperation and Development
OTC	Over-The-Counter
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PMAS	Post Marketing Surveillance Alert System
PSD	Pharmaceutical Services Division
QC	Quality Control
QUM-C	Quality Use of Medicines - Consumer
RAS	Rapid Alert System
RRP	Recommended Retail Price
SPOC	Single Point of Contact
UHC	Universal Health Coverage
WHO	World Health Organization
WHO/HAI	World Health Organization/Health Action International
WPRO	World Health Organization Regional Office for the Western Pacific

MESSAGE FROM SENIOR DIRECTOR OF THE PHARMACEUTICAL SERVICES

The Malaysian National Medicines Policy (MNMP) or Dasar Ubat Nasional (DUNas) serves as a guide for action to drive our nation's pharmaceutical sector to greater heights, in tandem with the Ministry of Health's efforts towards ensuring sustainable and equitable access to healthcare.

Therefore, it is crucial that the right policy, right strategies and right formula are seamlessly incorporated into a foundation of change towards better health and pharmaceutical care for the nation. The core and supportive components of the MNMP defines and prioritizes the medium and long term goals for the pharmaceutical sector. Hence, the Pharmaceutical Services Division has remained committed to ensuring that relevant policies and strategies of the MNMP are in place.

This report documents the performances and achievements of the pharmaceutical sector within the first term of the MNMP (2007-2011). It is heartening to note that the planned strategies and activities have translated into significant outcomes and brought about the transformation in the pharmaceutical sector that we see today.

Undoubtedly, DUNas has paved the way for ensuring the quality, availability and affordability of safe and efficacious medicines as well as setting the platform for human resource development, research & development and international cooperation in relevant fields. DUNas has been instrumental in bringing together all major stakeholders and serving as a compass to drive transformation in pharmaceutical sector towards better health.

I hope that this first term performance report of DUNas will enable us to identify issues and challenges that need to be addressed in the second term (2013-2017). We recognise the contributions, enthusiasm and commitment by various stakeholders in the implementation of DUNas over the years and we hope for your continual support in the coming years.

Thank you.

DATO' EISAH BINTI A. RAHMAN
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EXECUTIVE SUMMARY

This is the First Term Performance Report for initiatives implemented under the Malaysian National Medicines Policy (MNMP) or *Dasar Ubat Nasional* (DUNas) for 2007 until 2011. The policy was first approved by Cabinet in 2006 and the Master Plan of Action outlining the strategies, activities and performance indicators was subsequently produced. This report builds on that five-year action plan and documents the achievements of the pharmaceutical sector and results of the initiatives that support the fundamental building blocks of DUNas.

The four core components of DUNas include *Quality, Safety and Efficacy of Drugs; Drug Availability; Drug Affordability;* and *Quality Use of Drugs,* and four supporting components: *Human Resource Development; Research and Development; Technical Cooperation;* and *Management of DUNas*. This laid the groundwork for pharmacy services, which assume multifold roles as policy makers, drug regulators, enforcers of the law, healthcare providers, logistics managers as well as pharmaceutical industrialists to mould a systematic, viable and a sustainable pharmaceutical industry.

This report demonstrates that considerable progress has been made in promoting equitable access to essential medicines and improving quality use of medicines to improve health outcomes of the people. Coordination by lead agency Pharmaceutical Services Division (PSD), Ministry of Health (MOH) ensures formal mechanisms were in place to allow national facilitation and further integration of activities across the country with various stakeholders. Monitoring of these mechanisms within the core components of the policy is paramount to evaluate the impact and outcome of translated activities.

The framework to regulate quality, safety and efficacy of drugs has been in place for more than 20 years. We have developed and enforced a series of drug legislations and quality control that regulates the registration, import, export, manufacture, distribution, prescribing, dispensing, sale, use, advertising and licensing of drugs as well as notification of cosmetics in this country. However, there are several gaps in terms of tackling problems of counterfeit, adulterated and unregistered medicines within the current legislation. Thus it is hoped that the consolidated New Pharmacy Bill which is waiting to be tabled in Parliament soon will facilitate the transformation needed to strengthen enforcement.

The quality, safety and efficacy of drugs produced in Malaysia are further ensured through several efforts regionally and internationally. Apart from the designation of our drug regulatory agency as a WHO Collaborating Centre for Regulatory Control of Pharmaceuticals, Malaysia was also accepted as the 26th member of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) in 2002 and became a provisional member of Organisation for Economic Cooperation Development (OECD) for the Conduct of Laboratory Inspections and Study Audits since 2008 and obtained full adherence to OECD Good Laboratory Practice in 2012.

The safety aspect of drugs marketed for use is also monitored through an effective Post Marketing Surveillance program which includes Adverse Drug Reactions (ADR) and Adverse Event Following Immunisation (AEFI) reports. Furthermore, under The National Key Economic Area (NKEA) initiatives, it also emphasized on improving and promoting high quality generic products. This includes the enforcement of bioequivalence (BE) studies for new registration application and accreditation of BE Centres based on Good Clinical Practice (GCP) and Good Laboratory Practice (GLP).

The MOH has formulated a MOH Drug Formulary, which at the end of 2011 comprises of 1,530 items for use by all health institutions in the Ministry. From this list, 288 items are listed in the National Essential Drugs List (NEDL). A few criteria have been used for selection of drugs to be listed which include pharmacoeconomic evaluation. In this era of cost-conscious healthcare delivery, pharmacoeconomic research has evolved as a significant and important field in providing evidence-based practice. The generic listing of essential drugs by itself will certainly not be sufficient if efforts are not made to use it appropriately. In this context, educational programs for both the prescribers and the consumers will have to be drawn up to ensure the maximum and appropriate use of the medicines.

Availability of medicines from procurement to distribution and supply to end users is facilitated through various innovative channels. The MOH has in place efficient drug procurement and distribution system. Nonetheless, the need for improving access to medicines in line with technology and innovation is pertinent as the call for transforming the health system delivery is clearly gaining momentum with extensive ICT capacity building being integrated onto the public sector. The introduction of Pharmacy Information System (PhIS) and Clinic Information System (CPS) aim to transform the medicine supply management system in Malaysia. Additionally, this system allows analysis of medication utilisation which will further enhance patient care. Patients at public health institutions can conveniently access to medicines through Integrated Medicine Dispensing System (IMDS), Drive-Through Pharmacy, SMS-and-Take, appointment card system and Delivery of Medicines through the Postal Service (Ubat Melalui Pos 1 Malaysia - UMP1M). These value-added services have reduced the attendance and waiting time of patients. Emphasis is also taken on domestic medicines production and export under the NKEA EPP3 to encourage national self-sufficiency in pharmaceutical supplies and reduces import expenditure.

Generally, medicine prices in most ASEAN countries are not controlled by any mechanism and continue to be determined by market forces and competition. Government procurement policies act as a form of price control to help contain drug expenditure in the public health sector. Procurement of multi-source products by generic names through competitive tender system is already being practiced in the public sector which also tends to force down prices for both local and multinational companies.

However, PSD is looking into ways towards a transparent and fair medicines price structure in order to balance the need and interest between the consumers and the pharmaceutical industries. A medicine price database comprising of national, international and reference medicine pricing is to be developed to secure a reasonable pricing of medicines in pharmaceutical industries, especially in public institutions. Concerted efforts have been implemented in terms of medicine price information sharing such as of standard labeling of medicine price on medication envelopes supplied at public facilities as well as the Recommended Retail Price (RRP) for some drugs made accessible at the PSD official website. Prescribing and dispensing of generic medicines has also been encouraged among healthcare providers.

DUNas encompasses, among many other things, Quality Use of Medicines (QUM) principles, which is strengthened through education and training of healthcare providers through continuous professional developments. MOH has also demonstrated its commitment to education about medicines through initiatives such as the “Know Your Medicines” Program. Education to promote compliance and ensure good treatment outcomes is carried out annually through exhibitions, seminars, workshops and forums. General public or consumers are constantly being provided with medicines knowledge through campaigns, self-empowerment and even incorporation into school educational system.

From the latest preliminary National Study on the Use of Medicines by Malaysian Consumers for 2012, there was an increase of 12% in the responds on the proper use of medicines from our Malaysian consumers (2008 – 44.4%; 2012 – 56.5%). Nevertheless, there is still need for an effective educational intervention targeting consumers in order to empower them with pertinent information on medicines use. The module for public education with community leaders was developed as the “Know Your Medicines Ambassadors” to engage active community participation in healthcare for the effective dissemination of information on quality use of medicines.

The expansion and improvement in clinical pharmacy activities in hospitals have enhanced the role of pharmacists in the multidisciplinary healthcare team in delivering care to patients. Clinical pharmacy services such as patient counselling, Medication Therapy Adherence Clinics (MTAC), specialised ward pharmacy, drug information, therapeutic drug monitoring, parenteral nutrition, oncology pharmacy and nuclear pharmacy services have been implemented over the years. To keep up with demand for specialised services,

pharmacists were also sent for attachment trainings in areas of pharmacy specialisation such as psychiatry, emergency pharmacy, paediatrics, respiratory, critical care, haematology and infectious disease. Post-graduate programs, accreditation and credentialing processes are in place as a way to develop a career pathway for pharmacists in their chosen specialised fields.

Not solely focusing on the public sector, accreditation of community pharmacies against benchmarking standards has already been initiated through collaboration between MOH, Malaysian Pharmaceutical Society (MPS) and Malaysian Society for Quality in Health to ensure that they consistently deliver a high standard of care in the private sector. PSD in collaboration with MPS has also embarked on a geo-mapping project to study the Community-Pharmacy-to-General-Practitioner-Clinic mix in the country. This information is important in our future planning to ensure that access to care and the needs of the public, particularly in the rural areas is sufficient.

Collaboration across agencies and linkage with international bodies are essential to drive the pharmaceutical sector towards success. Inter-agency cooperation is initiated to curb counterfeit drugs and precursors control. Besides working hand in hand with other ministries and private organisations, Malaysia has been active in ASEAN harmonisation efforts, and pharmaceutical studies and testing schemes organised by international organisations to improve standards and quality of medicines.

Our current health system presents many potential areas for further development and improvement. Thus the gaps in certain areas need to be addressed. Pharmacoeconomic studies evaluate the effectiveness of any implemented health strategies, especially in a resource-finite economic environment. Studies on the quality use of drugs can contribute towards quality of care and at the end of the day, promotes cost-effective therapy. With the inclusion of community participation and the empowerment in the delivery of healthcare, such studies, when put into practice, can positively impact healthcare service provision, leading to an improved economic situation.

The uptake and coordination of these activities within a supportive and complete ecosystem that ensures they are sustainable, complementary, synergistic with the new term policy is the next major challenge.

1. INTRODUCTION

The formulation of the Malaysian National Medicines Policy (MNMP or DUNas, *Dasar Ubat Nasional*) was initiated in 2000. It was developed through a systematic and consultative process and assisted by WHO consultancy and funding. The policy was approved by the Cabinet on 11th October 2006. DUNas defines and states the priority on the medium and long-term goals that the Government has set for the pharmaceutical sector and it provides the framework to organise and improve the pharmaceutical sector. The objectives of DUNas are to promote equitable access to, and rational use of, safe, effective and affordable essential drugs of good quality to improve health outcomes of the people. A practical and attainable plan of action for five years was produced to ensure coordinated implementation by all stakeholders.

A review of the policy has to be carried out every five years. The mid-term review of the policy was done in 2009. The initial plan of action was reviewed during the mid-term review to identify gaps in its implementation during the first two and a half years of the planned period. The Malaysian National Medicines Policy Full Term Review workshop was held on 15th – 17th October 2012. The objectives of the workshop were to review on the achievements, shortfalls and relevance of the present strategies which were implemented from 2007 until 2011 and to propose new components and strategies for the next five years. The workshop involved all stakeholders from various professional bodies, relevant industry consumer associations, other government agencies and ministries to provide inputs and consensus towards the formulation of the policy. The review was facilitated by a consultant from the University of South Australia sponsored by WHO.

2. IMPLEMENTATION AND MONITORING OF DUNas

Pharmaceutical Services Division (PSD), Ministry of Health (MOH) is the lead agency which coordinates the monitoring and implementation of DUNas activities. Different levels of committees, i.e., the DUNas Steering Committee, DUNas Implementation Committee and five DUNas Technical Committees have been established to achieve the objectives of DUNas.

The DUNas Steering Committee acts as advisory committee to evaluate the performance and provides direction for DUNas to move forward. The DUNas Implementation Committee's responsibility is to coordinate, oversee and monitor the process and progress of its implementation. The committee also monitors and analyses indicators, provides a report to the Steering Committee and plans the formation of working committees and task forces.

The Technical Committees that were established are as follows:

- Technical Committee for Quality, Safety & Efficacy of Drugs
- Technical Committee for Drug Availability
- Technical Committee for Drug Affordability
- Technical Committee for Quality Use of Drugs
- Technical Committee for Human Resources Development, Research & Development and Technical Cooperation

The Technical Committees are responsible for all aspects of the implementation process. They plan and identify activities that will be implemented according to priorities, determine indicators that will be monitored, obtain data and prepare the Practical Manual for indicators that have been identified.

Task forces were also established to carry out specific activities within the technical committees. For example, the Malaysian Guidelines for the Management of Drug Donations Working Committee was formed under the Drug Availability Technical Committee to develop guidelines for drug supply in emergency situations and drug donations.

DUNas Secretariat liaises with all stakeholders and working committees to ensure the implementation of the activities are carried out according to identified strategies. The involvement, feedback and cooperation from all stakeholders are the key factors which ensure that the stated objectives are met. The Secretariat compiles a wide range of data for indicators and policy reports which are crucial for evaluating the successful implementation and progress of DUNas. There are 105 WHO indicators, which comprises 24 background indicators, 48 structural indicators, 26 process indicators and 7 outcome indicators.

The chart below shows all the committees established for the successful implementation of DUNas.

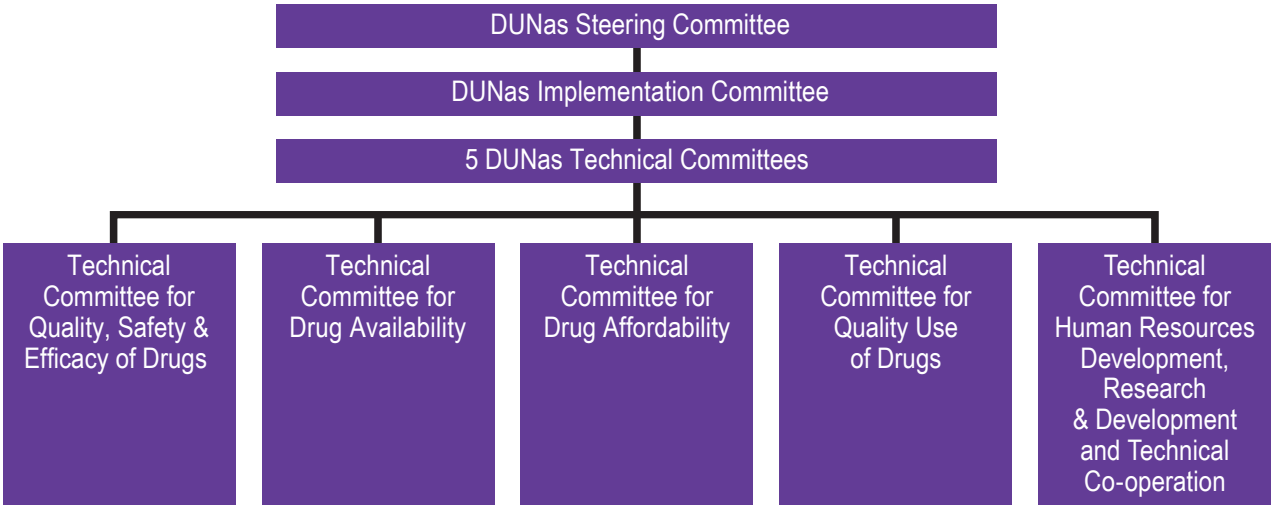


Figure 1: DUNas Committee

3. ACHIEVEMENTS

DUNas consists of four main components: *Quality, Safety and Efficacy of Drugs*; *Drug Availability*; *Drug Affordability*; and *Quality Use of Drugs*, and four supporting components: *Human Resource Development*; *Research and Development*; *Technical Cooperation*; and *Management of DUNas*. The achievements during the five-year period from 2007 to 2011 are attributed to the enthusiastic involvement and strong support from all stakeholders.

3.1 Quality, Safety and Efficacy of Drugs

This component aims to ensure that drugs marketed for patient care are safe, effective and of high quality so as to meet the health needs of the nation.

3.1.1 Legislation and Regulations

Malaysia has a comprehensive set of laws governing medicines and practices that supports the implementation of DUNas. They are as listed below:

- Registration of Pharmacists Act 1951 and regulations
- Poisons Act 1952 and regulations
- Sales of Drugs Act 1952 and regulations
- Medicines (Advertisement and Sales) Act 1956 and regulations
- Dangerous Drugs Act 1952 and regulations

All the Acts and Regulations govern drug development, production, importation, supply, marketing, sale and management (prescribing, dispensing and disposal). Current legislations are reviewed from time to time and updated to ensure its relevance. Amendments to current legislations are proposed to overcome legal impediment and lacuna in the existing laws.

Table 1: Number of Law Revisions and Government Gazettes (2007 – 2011)

	2007	2008	2009	2010	2011
Number of Law Revisions	- (No Data)	5	5	13	3
Number of Government Gazettes	2	6	6	5	9

Source: *PSD, MOH*

3.1.2 Roles of National Pharmaceutical Control Bureau & Drug Control Authority

National Pharmaceutical Control Bureau (NPCB) is a government agency that regulates pharmaceutical, natural (traditional) and cosmetic products in Malaysia. Drug Control Authority (DCA) through NPCB ensures the quality, efficacy and safety of pharmaceutical products as well as the quality and safety of natural (traditional) products and cosmetics marketed in the country. DCA is the executive body set up under the Control of Drugs and Cosmetics Regulations (CDCR) 1984 and as such its responsibility, role and mandate are defined by law. DCA provides the general principles of safety, quality and efficacy that form the basis for the evaluation and eventual registration of products.

In view of its technical expertise and training capabilities, Malaysia was recognised by WHO as a Collaborating Centre for the Regulatory Control of Pharmaceuticals on 10 May 1996.

Malaysia also successfully gained accession as the 26th member of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) on 1st January 2002. The PIC/S comprises of two international instruments between countries and pharmaceutical inspection authorities, which provide together an active and constructive co-operation in the field of GMP.

Malaysia was a Provisional Member to the Organisation for Economic Cooperation and Development (OECD) Mutual Acceptance Data (MAD) System for the Conduct of Laboratory Inspections and Study Audits since 2008 and has been inspected by the OECD Good Laboratory Practice (GLP) Working Group in the **Mutual Joint Visit** on 14 - 19 November 2011. This gives credence to the standards of Good Manufacturing Practice (GMP) and GLP adhered to by domestic manufacturers of pharmaceuticals.

3.1.3 Drug Registration

The registration process for pharmaceuticals and other related products in Malaysia is well established. The registration processes are comprehensive and include the requirement for product re-registration every 5 years. On-going initiatives to facilitate and upgrade the registration process include:

(a) QUEST

All registration applications were submitted via the online system known as QUEST2 that was launched in 2002 and this system has since been upgraded to QUEST3 in 2010. This upgraded online submission system includes applications for New Chemical Entities (NCE) and biotechnology products that were previously processed through manual submissions.

(b) Fast-track Evaluation for Life-saving Products and Essential Medicines

Approval for fast-track evaluation or priority review will be granted by the Director of NPCB for certain products including life-saving products (anticancer, antiretroviral), products for the treatment of rare diseases and products for emergency use.

The application for registration will be processed within ninety (90) working days provided the application is complete and the documents comply with all requirements.

(c) Drug Registration Guidance Document (DRGD)

Drug Registration Guidance Document (DRGD) is regularly updated to ensure relevance to the current regulatory framework. DRGD is the reference guide for the registration process and includes updated information on quality control, inspection and licensing, as well as post-registration activities of medicinal products, health supplements and traditional products.

(d) Active Pharmaceutical Ingredient (API)

The regulatory control of Active Pharmaceutical Ingredient (API) as part of the requirements in the product registration application has been implemented in phases according to the timeline established by NPCB. The implementation started with voluntary submission of API information and/or data for NCE on 1st April 2011, to be followed by mandatory implementation on 1st January 2012.

The technical requirements on API have to be submitted together with the registration application to facilitate the simultaneous assessment with the dossier for the registration of the finished product.

(e) Bioequivalence (BE) Studies

DCA reviewed the registration of generic products at its 92nd meeting in 1999 to include Bioequivalence (BE) studies requirements for certain categories of oral, immediate-release products. This is in line with the MOH objectives of ensuring quality, safety and efficacy of pharmaceutical products that are marketed. Bioavailability (BA) testing of drug products in humans provides the most appropriate method available for determining BE. Notification of BE studies conducted in local or foreign BE centres for registered or to-be-registered products will be made effective from 1st January 2012.

The implementation of requirements for BE studies for all generic “immediate-release, oral, solid dosage form” products is an extension to the previous nine lists and is applicable only to products containing Scheduled Poisons. Implementation for new registration will be started on 1st January 2012 and for existing products, it will be implemented on 1st January 2013 upon submission for renewal.

(f) Ready-to-dispense Packs

The decision to enforce ready-to-dispense pack used "as is" in dispensing outlets effective from 1st September 2008 was made at the 21st DCA meeting on 31st January 2008. Exemption of ready-to-dispense pack for certain creams/ointments used in hospitals and skin specialist clinics was granted since December 2010.

Ready-to-dispense pack is convenient and improves the quality of dispensed medicines. It will increase efficiency in dispensing and improve safety by reducing the risk and possibility of errors. It will also result in the reduction of medicines wastage and promote better use of resources.

(g) Consumer Medication Information Leaflets (*Risalah Maklumat Ubat Pengguna* - RiMUP)

"Guidelines for Submission of Consumer Medication Information Leaflets" was issued in 2011. Effective from 1st April 2011, registration holders must submit RiMUP in two languages (Malay and English) along with other documents for the product registration process. The implementation of RiMUP started with two different groups of drugs (antihypertensives and antidiabetics) and will be extended in stages to other identified drugs used for chronic diseases. However, in 2011, only 228 (27.3%) out of the 836 products were supplied with RiMUP. Further action is therefore necessary to ensure that RiMUP is provided for each product with RiMUP requirement.

3.1.4 Licensing

(a) Licensing of Manufacturers, Importers and Wholesalers

Only licensed manufacturers, importers and wholesalers shall handle registered medicinal products at licensed premises. The manufacture of registered medicines must comply with the requirements of GMP, whereas for import and wholesale activities with Good Storage Practice (GSP), which was later replaced with Good Distribution Practice (GDP) in 2011 and other additional requirements as stipulated by the law. The issuance of the Manufacturer's Licence, Import Licence and Wholesaler's Licence is in accordance with Regulation 12 of CDCR 1984.

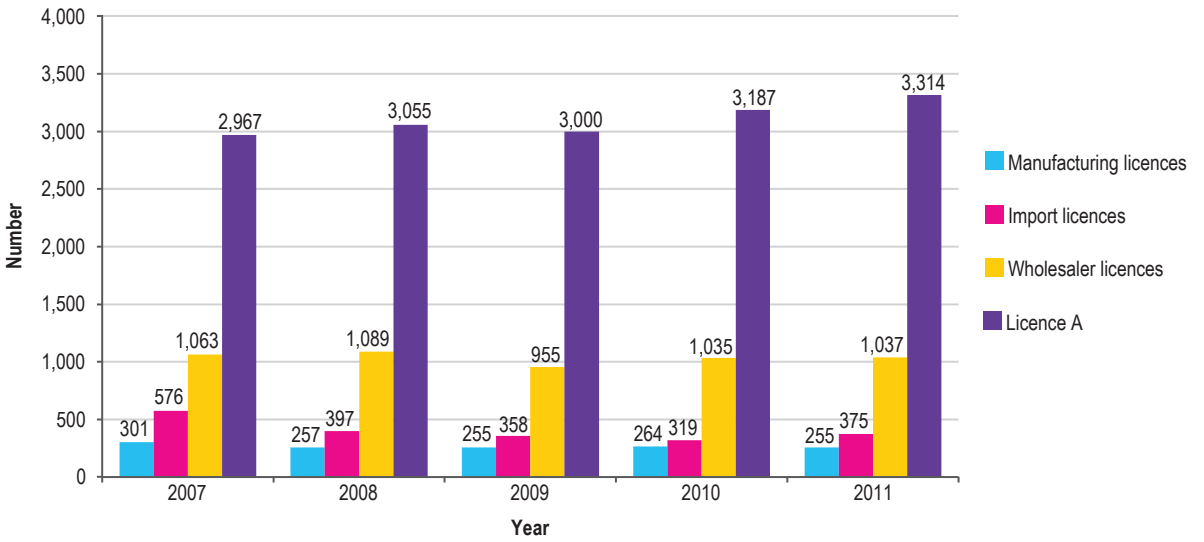
(b) Licensing of Pharmacy Premises

Retail sale of controlled medicines must be carried out in licensed premises by licensed pharmacists. The issuance of licences for pharmacy premises are in accordance with the Poisons Act 1952.

Only licensed manufacturers, importers and wholesalers can handle registered pharmaceutical products and these activities must be conducted in licensed premises in accordance with the requirements of GMP, GSP, GDP and other additional requirements as stipulated by the law. The issuance of Manufacturing Licence, Import Licence and Wholesaler Licence is in accordance with Regulation 12 of CDCR 1984 (Revised 2006).

Sale of poisons must be carried out by licensed pharmacists (Licence A). The issuance of poison licences for pharmacist is in accordance with Section 26 of Poisons Act 1952 and these are issued by the respective Pharmacy State Enforcement Branches.

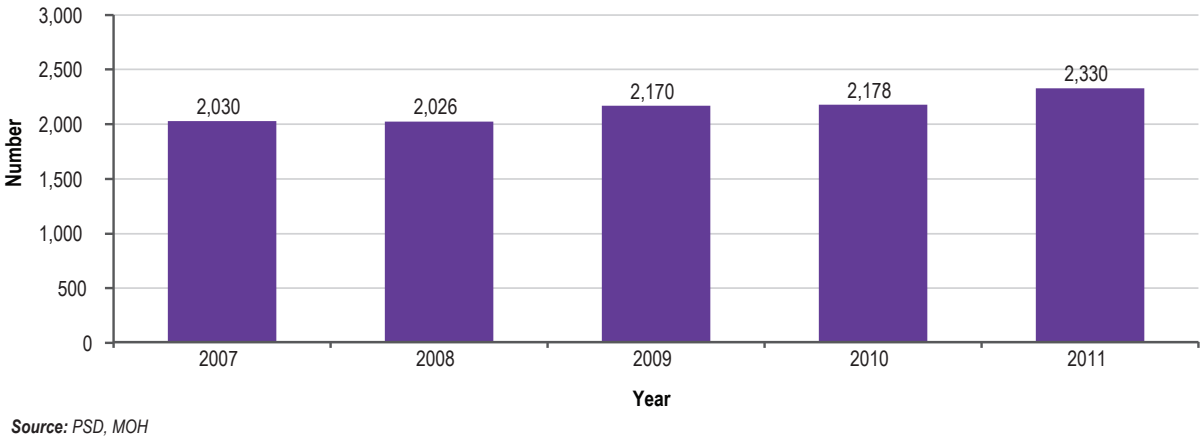
The number of Manufacturer's Licence, Import Licence and Wholesaler's Licence as well as Licence A issued in 2007 until 2011 is as shown in Figure 2. Issuance of manufacturing, import and wholesaler licences as well as Licence A show a stable trend from 2007 until 2011.



Source: *NPCB & PSD, MOH*

Figure 2: Number of Manufacturing, Import and Wholesaler Licences and Licence A Issued (2007 – 2011)

There are 2,330 pharmacy premises in 2011 as compared to 2,178 premises in 2010 (Figure 3). The increasing number of pharmacy premises is more concentrated in the industrial state such as Selangor and Penang. The increase in the number of pharmacy premises is a healthy development. The public will have more choice and more convenient services nearest to them. The increase in the number of pharmacy premises are also in line with the desire to ensure the chain of health services to the people is not broken.



Source: *PSD, MOH*

Figure 3: Number of Pharmacy Premises (2007 – 2011)

3.1.5 Inspection

Pharmacy enforcement officers and GMP/GDP auditors are responsible for inspection of all premises involved in manufacturing, importing and wholesaling activities of medicines.

All activities within the drug manufacturing and supply chain have to comply with the relevant Acts and Regulations, current GMP and GDP principles and any other necessary requirements set by the regulatory authority. Inspections are also extended to drug quality control laboratories to ensure compliance with current GLP.

NPCB has also been appointed by the Malaysian Government as the national Compliance Monitoring Authority (CMA) for monitoring compliance to OECD Principles of GLP. Following the appointment, the NPCB GLP Compliance Programme (CP) was established. The CP is currently a voluntary programme for Test Facilities conducting non-clinical safety studies for the purpose of registering and/or licensing involving pharmaceutical products, cosmetics products, veterinary drugs and food additives.

As the CMA, NPCB performs GLP inspections on Test Facilities which conduct non-clinical safety studies. The inspection is to ensure that such facilities are in compliance with the requirements of OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring.

In addition to GMP, GDP and GLP inspection, there is also GCP inspection. The main purpose of GCP inspection is to ensure protection of the rights, safety and well-being of study subjects for all drug-related clinical trials conducted in Malaysia as well as to assure the integrity of scientific testing and study conduct comply with applicable regulatory requirements, ethical standards, Malaysian Guidelines for Good Clinical Practice and Declaration of Helsinki. GCP inspection includes the inspection on clinical trial sites, sponsors and/or contract research organisations (CRO), BE centres and independent ethics committee/institutional review boards. All GCP inspections are based on the Guidelines for Good Clinical Practice Inspection in Malaysia that was issued in October 2010.

In line with the guidelines, a directive on the requirements of BE studies for *all generic products "immediate release, oral, solid dosage form" which contains poison as active ingredient according to the poison schedule* and *requirements of BE centre accreditation* was issued under the CDCR 1984. Accreditation of local and overseas BE centres are carried out by conducting inspections based on the GCP principles for the clinical part, GLP principles for the bio-analytical part and international guidelines for the method validation part. BE inspections on the foreign BE centres will only commence after the establishment of a Trust Fund which is expected in 2012.

The number of GMP, GSP/GDP, GLP and GCP inspections in 2007 until 2011 is as shown in Table 2. The percentage of manufacturers, importers and wholesalers complying with the requirements is found to be more than 80% as shown in Table 3.

Table 2: Number of GMP, GSP/GDP, GLP and GCP Inspections (2007 – 2011)

	2007	2008	2009	2010	2011
Number of GMP inspections	321	306	246	244	341
Number of GSP inspections	559	453	644	747	-
Number of GDP inspections	-	-	-	-	756
Number of GLP inspections	-	-	1[Ga]	3	9
Number of GCP inspections	-	-	-	1	4[Gb]

Source: *NPCB & PSD, MOH*

****Ga → Gap Analysis Visit:*** *The purpose is to determine the strength, area of expertise and to assess the readiness of the Test Facility towards GLP compliance.*

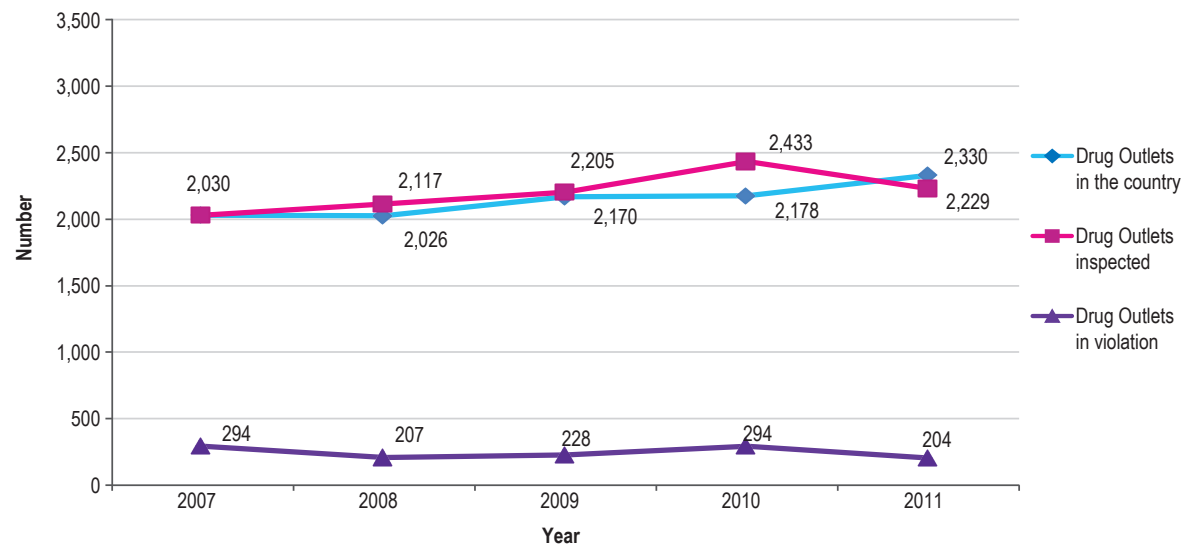
****Gb → Gap Analysis:*** *Visit to assist the local BE centres in identifying their weakness in getting accredited.*

Table 3: Number of Manufacturers/Importers/Wholesalers that Meet the GMP & GDP Requirements, out of Total Number of Manufacturers/Importers/Wholesalers Inspected (2011)

	Number	Percentage
Manufacturers	340/341	99.7%
Importers	19/22	86.4%
Wholesalers	35/39	89.7%

Source: *NPCB, MOH*

Inspections are carried out in all or almost all drug outlets every year. Drug outlets refer to retail, retail and wholesale, and wholesale pharmacies. The number of drug outlets in the country has been increasing steadily over the years from 2,030 in 2007 to 2,330 in 2011. Around 10% to 15% of drug outlets inspected are generally found to be non-compliant. Sanctions and administrative measures will be implemented to these drug outlets (Figure 4).



Source: *PSD, MOH*
Drug outlets **=** *Retail pharmacy + retail & wholesale pharmacy + wholesale pharmacy*

Figure 4: Number of Drug Outlets (2007 – 2011)

3.1.6 Medicines Advertisement and Promotion

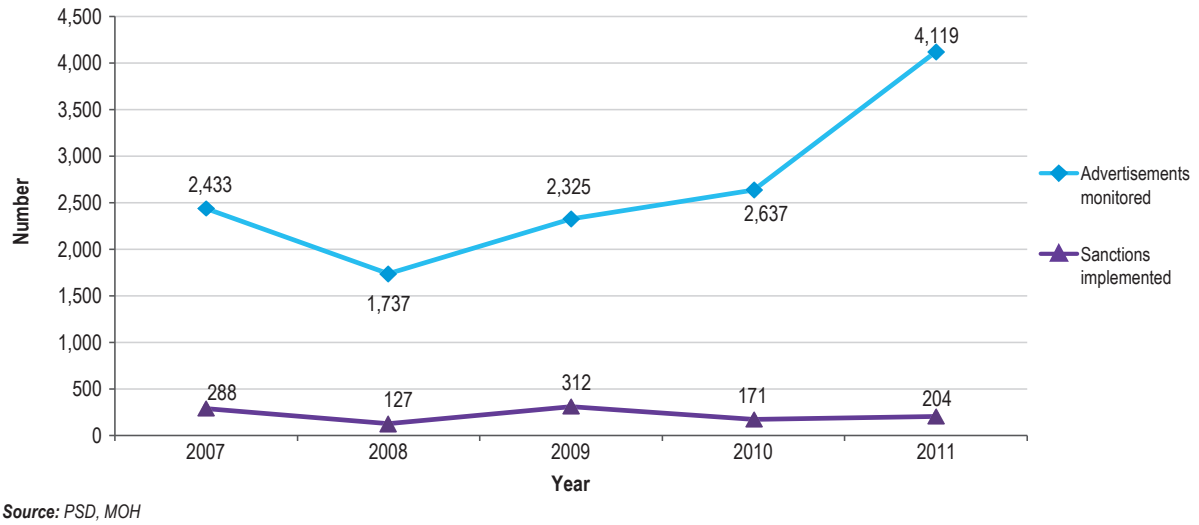
MOH regulates all advertisements and promotion of medicines, including traditional medicines. The regulations used are in line with the WHO ethical criteria for medicinal promotion. Advertisements pertaining to medicines, appliances, remedies and healthcare services are governed through Medicines (Advertisement and Sale) Act 1956.

In September 2010, the liberalisation of advertisement for the healthcare sector has been made possible following MOH's effort in promoting Malaysia as a health tourism destination. As a result, healthcare

establishments can now publish information on their services and facilities as well as healthcare packages offered upon obtaining approval from Medicines Advertisement Board (MAB). The responsible dissemination of healthcare advertisements through the mass media will benefit the public by empowering them to make rational decisions about their choice of healthcare.

MAB has issued two guidelines, the "Advertising Guidelines for Healthcare Facilities and Services" (last updated on 1st November 2011) and the "Advertising Guidelines for Medical Products" (to be updated in 2012), to assist advertisers in producing advertisement formats suitable for publication to the general public. These guidelines are constantly reviewed and revised to keep up with the changing healthcare scenario and current needs of all stakeholders in the healthcare industry.

The monitoring programme involves screening all advertisements published in the mass media, including both printed and electronic media such as newspapers, magazines, radio and television. Other advertising media such as the Internet, promotional kits, pamphlets, posters and buntings are also monitored. Monitoring also depends on complaints received from the public, advertisers, companies and some non-governmental organisations. The number of advertisements monitored has been increasing sharply from 2008 with a rise of 137% in 2011. However, sanctions implemented on all advertisements found to be in violation remain stable over the years. This reflects that the advertisers conform to the required guidelines (Figure 5).



Source: *PSD, MOH*

Figure 5: Number of Advertisements Monitored and Sanctions Implemented (2007 – 2011)

3.1.7 Intellectual Property Rights

The Directive on Data Exclusivity (DE) came into force on 1st March 2011 and is applicable to new drug products containing a NCE and the second indication of a registered drug product. The Directive is to protect the undisclosed, unpublished and non-public domain pharmaceutical test data. The DE is granted by the Senior Director of Pharmaceutical Services, MOH. For NCE, application for registration and DE should be submitted within 18 months from the date of first registration in the country of origin. The DE will be given for a period of five years calculated from the date the product is registered or received marketing approval and granted DE in the country of origin. For a second indication of a registered product, the application is to be made within 12 months from approval of second

indication and the duration of DE granted is three years. Compulsory Licensing and essential products required during national emergency are excluded from DE and it is also not applicable to Biologics/Biotechnology products.

3.1.8 Counterfeit Drugs

A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.

Products registered with DCA have two main features: the registration number and genuine hologram sticker. The authenticity of the hologram sticker can be checked with the Meditag hologram decoder available at retail pharmacies. The use of hologram stickers is one of the efforts to combat counterfeit products.

Raids are carried out to curb the distribution, manufacturing and possession of unregistered, adulterated and counterfeit products. Among the products seized during such raids include sex stimulants, psychotropics, poison-contaminated, both registered and unregistered, unnotified cosmetics as well as counterfeits.

The number of counterfeit products seized has risen slightly over the years and these products include poison, over-the-counter, traditional and cosmetic products (Table 4).

Table 4: Number of Counterfeit Products Seized (2007 – 2011)

Category	2007	2008	2009	2010	2011
Counterfeit	323 (5%)	239 (2%)	234 (2%)	362 (3%)	344 (2%)
Sex Stimulant	617 (9%)	670 (7%)	607 (6%)	1,077 (9%)	1,435 (8%)
Psychotropic	217 (3%)	159 (2%)	138 (1%)	215 (2%)	605 (4%)
Adulterated	1,216 (17%)	1,075 (11%)	1,124 (11%)	1,694 (14%)	2,538 (15%)
Unregistered	4,686 (66%)	7,489 (78%)	8,375 (80%)	8,586 (72%)	12,252 (71%)
Total	7,059	9,632	10,478	11,934	17,174

Source: *PSD, MOH*

MOH shares information on counterfeit products domestically and internationally through the Bay of Bengal Initiative for Multi Sectoral Technical and Economic Cooperation (BIMST-EC), ASEAN harmonisation, Single Point of Contact (SPOC) for counterfeit medicines, Post-marketing Surveillance Alert System (PMAS) and the Rapid Alert System (RAS).

3.1.9 Quality Control (QC)

Quality Control (QC) is imperative to ensure the quality, safety and efficacy of a product. It is an integral part of the systematic Malaysian regulatory system under the purview of NPCB. QC involves various processes including sample testing as well as the evaluation of protocol analysis and analytical method validation data for registration of pharmaceutical products.

Sample testing is conducted for:

i. Registration of traditional products
ii. Pharmaceutical, traditional and cosmetic products in the market
iii. Adulterated products

The number of protocol analysis and analytical method validation data evaluated as well as samples received and tests conducted for 2010 – 2011 is as shown in Table 5 and Table 6 below:

Table 5: Number of Protocol Analysis and Analytical Method Validation Data Evaluated (2010 – 2011)

Year	Number of protocol analysis and analytical method validation data evaluated
2010	1,250
2011	1,988

Source: *NPCB, MOH*

Table 6: Number of Samples Received and Tests Conducted (2010 – 2011)

Year	Number of samples received	Number of tests performed
2010	3,722	4,371
2011	2,959	3,104

Source: *NPCB, MOH*

Aside from this, NPCB has also obtained MS ISO 17025:2005 accreditations for the Centre for Quality Control under the Malaysian Laboratory Accreditation Scheme in 2010. The accredited tests include:

i. Microbial Contamination Test for traditional products
ii. Heavy Metal testing (arsenic, lead, cadmium & mercury) for traditional products
iii. Disintegration Test for traditional products
iv. Uniformity of weight for traditional products

3.1.10 Post-Marketing Surveillance

An effective post-marketing surveillance system is vital to ensure drug quality, safety and efficacy. This includes product sampling, laboratory testing, handling of product complaints and product safety profile through Adverse Drug Reactions (ADR) as well as Adverse Event Following Immunisation (AEFI) reports. The total number of ADR and AEFI reports has increased from 3,068 reports in 2007 to 9,385 reports in 2011 (Figure 6). This increment is mainly attributed to the active surveillance of Human Papilloma Virus (HPV) vaccine through MOH HPV vaccination programme, continuous promotional activities and educational sessions for healthcare professionals conducted in the MOH facilities as well as seminars sponsored by professional associations. In 2011, the Key Performance Indicator (KPI) for number of ADR reports, which is about 200 reports per million population has been achieved with 9,385 reports for a total population of 28,964,300 making it 324 reports per million population.

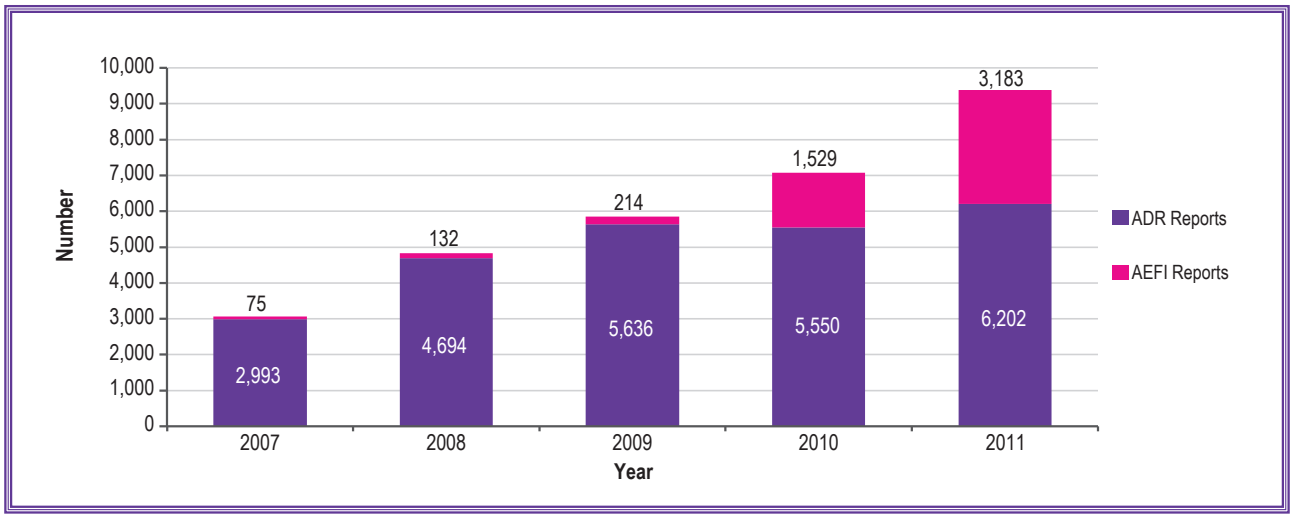
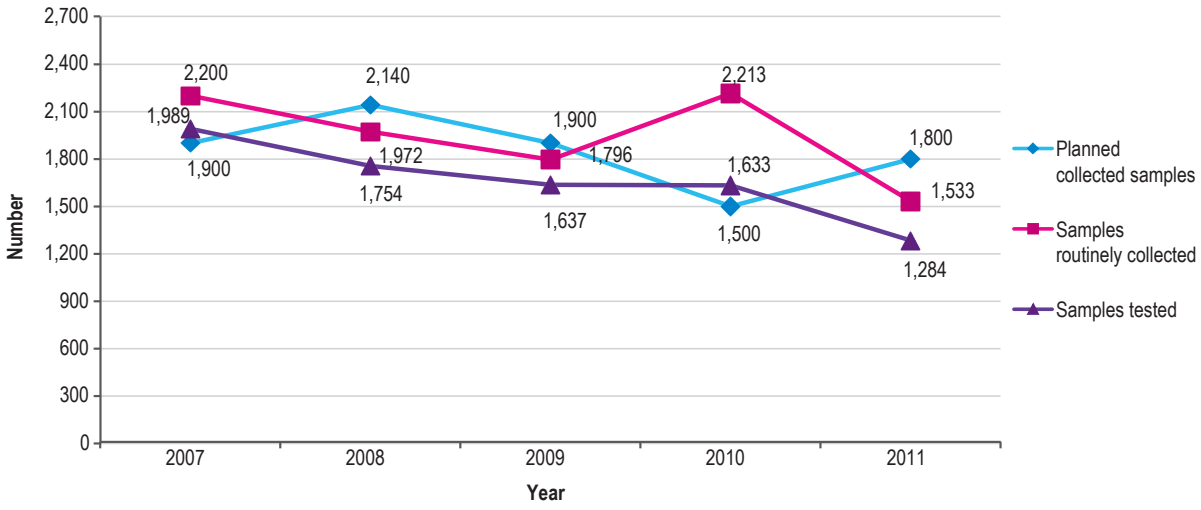


Figure 6: Number of ADR & AEFI Reports Received (2007 – 2011)

The collection of samples for testing is an important means of monitoring the quality of drugs and ensures that drugs provided to the patients are in compliance with the stipulated standards. The number of products routinely collected and tested is as shown in Figure 7. Aside from testing, labels and package inserts are also routinely reviewed to verify labelling compliance. Punitive actions such as warnings and product recalls will be taken for products which do not comply with the specifications and the relevant requirements.

Post-marketing surveillance also involves risk minimisation and risk communication activities, Consumer Medication Information Leaflets (RiMUP), MADRAC bulletins and Drug Safety News newsletter (REAKSI). Risk communication is also carried out through media statements and "Dear Healthcare Professional Communication" (DHPC) letters.



Source: *NPCB, MOH*

Figure 7: Number of Planned Collected Samples, Samples Routinely Collected and Samples Tested (2007 – 2011)

3.2 Drug Availability

This component of the policy aims to ensure that there will be equitable, adequate and continuous availability of safe, effective and quality essential medicines for the entire population.

3.2.1 Selection of Medicines

The MOH Drug Formulary is the official formulary for all medicines and pharmaceutical preparations approved for use in MOH institutions/hospitals/clinics. It serves as a guide for professionals/drug committees in the selection of pharmacotherapy and development of local formulary at the institution, hospital or clinic levels.

The MOH Drug Formulary is consistently updated according to the circulars issued after each MOH Drug List Review Panel Meeting. Basic information of the updated comprehensive formulary is available for public viewing at the PSD official website. At the end of 2011, there were 1,530 preparations in the formulary.

MOH has also developed a National Essential Drugs List (NEDL) out of the MOH Drug Formulary, which comprises medicines required to treat a majority of conditions found prevalent in the county in a cost-effective and efficient manner. These medicines are deemed basic, indispensable and necessary for the

healthcare of the majority of the population and must be made readily available at all times, in adequate amounts and in the proper dosage forms to all segments of the society.

The NEDL 2nd Edition containing a list of 288 items was published in 2008 and widely circulated to all stakeholders and uploaded into the PSD official website.

Pharmacoeconomic evaluation is one of the criteria to be used for the selection of medicines in 2012.

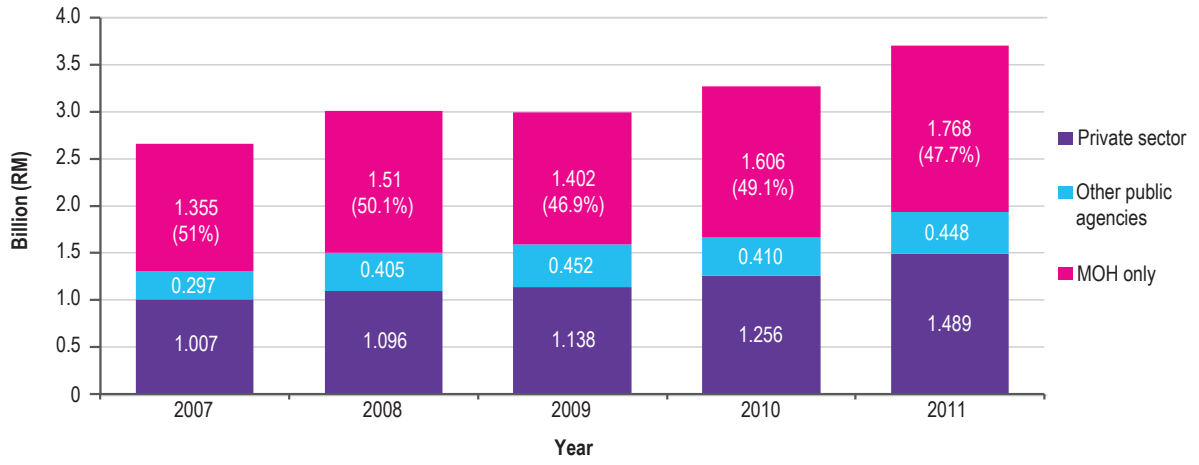
3.2.2 Supply of Medicines

3.2.2.1 Procurement

The total medicines expenditure in Malaysia was RM2.659 billion in 2007 whereby about 63% was contributed by the public sector. There is an annual increase in total medicines expenditure from 2007 and it has reached RM3.705 billion in 2011. MOH contributes about 50% of the total medicines expenditure every year (Figure 8).

MOH procured medicines based on the MOH Drug Formulary whereby all procurement processes are governed by Treasury Instructions. The directives have included the requirement for the selection of local manufactured products in procurement. Procurement in the private sector procurement is governed by their own institutional policies.

The percentage of value of drug purchased through competitive tender out of the value of drug purchased by MOH was found to be reduced to 13.9% in 2011 (Figure 9).



Source: *PSD, MOH & other public agencies*

Figure 8: Total Public and Private Medicines Expenditure (MYR) (2007 – 2011)

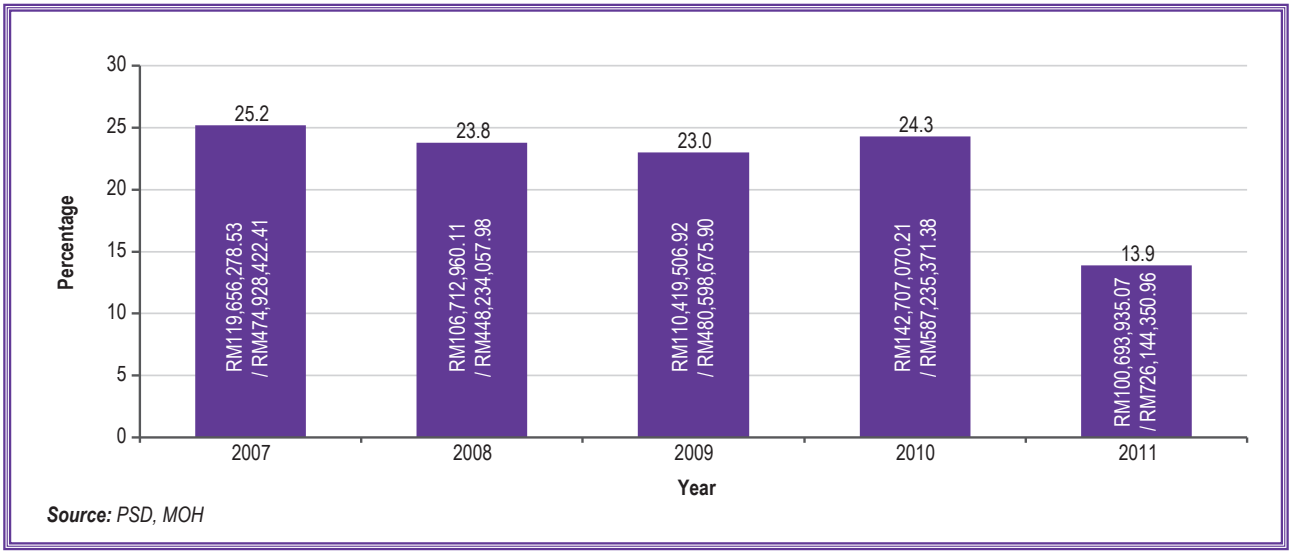


Figure 9: Value of Medicines Purchased through Competitive Tender, out of Value of Medicines Purchased (by MOH) (2007 – 2011)

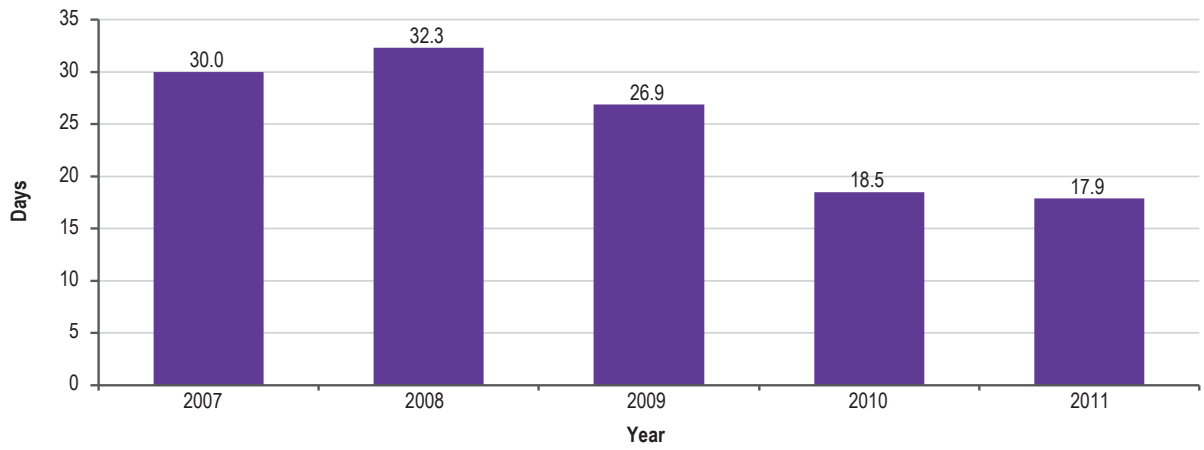
3.2.2.2 Distribution

The supply chain of medicines in public and private sectors are required to meet necessary GDP requirements in terms of supply, storage, inventory control and quality assurance of facilities.

An effective distribution network has been established to ensure prompt delivery and adequate supply of medicines to MOH facilities that involves door-to-door delivery directly from suppliers to the pharmacy stores of the facilities and through regional or state stores.

In 2011, a new concession agreement was signed for the supply of pharmaceuticals to MOH facilities that dictated a further improvement of the performance of the Concessionaire. Pharmaceuticals covered in the agreement must be delivered directly to pharmacy stores in health and dental clinics in Peninsular Malaysia within 7 days and within 10 days for clinics located in remote areas of Labuan, Sabah and Sarawak. Penalties are imposed for failure to fulfill these conditions.

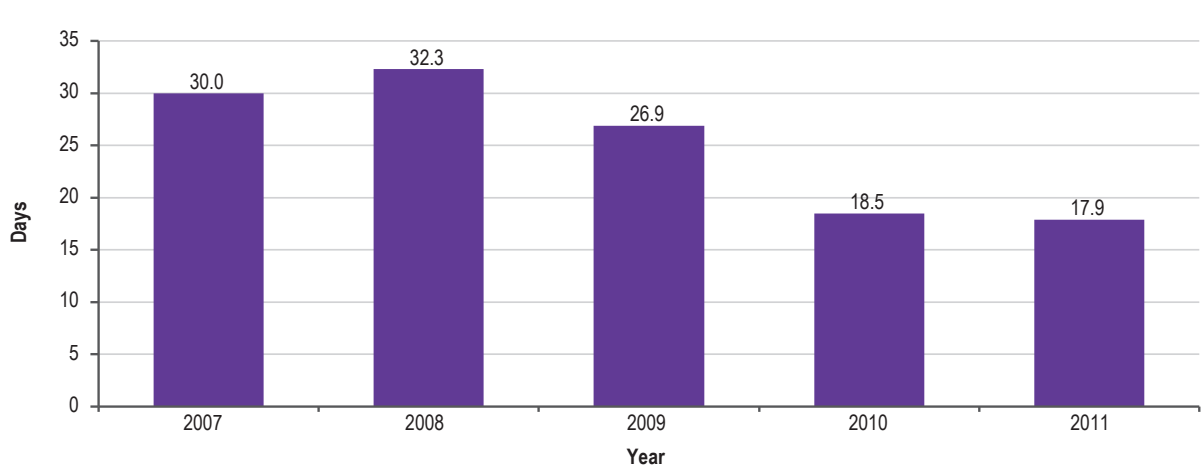
The supply time of medicines is vital in ensuring continuous availability of medicines. The average time taken between order and delivery from central store to remote facilities has shown a decreasing trend over the years, indicating an improvement in the medicine distribution process (Figure 10).



Source: *PSD, MOH*

Figure 10: Average Time Between Order and Delivery from Central Store to Remote Facilities (Days) (2007 – 2011)

Prevention of medicine shortages is managed by setting a requirement of a buffer stock (3 months for NEDL and 2 months for non-NEDL products). This ensures that adequate quantities of essential medicines are supplied and stored at healthcare facilities and thus, minimising stockout situations (number of days when medicine shortages occurred). The average stockout duration decreased from 2008 to 2011, indicating an improvement in drug availability (Figure 11).



Source: *PSD, MOH*

Figure 11: Average Stockout Duration for a Basket of Drugs in the Central and/or Regional Stores (Days) (2007 – 2011)

3.2.2.3 Innovative Ways of Medicines Supply

PSD has made use of innovative and creative methods such as the Integrated Medicine Dispensing System, Drive-Through Pharmacy, SMS-and-Take and the appointment card system to further improve the medicine delivery system, which enable patients to collect medications for their repeat prescriptions at their own convenience. In a collaborative effort with *Pos Malaysia Berhad*, patients can also request for repeat medications to be posted to their homes or other locations.

These value-added services contribute to the reduction in attendance of patients and waiting time to receive medications at these health facilities. These services are currently available in most MOH facilities (Table 7) while the Integrated Medicine Dispensing System is offered by all MOH facilities with at least one pharmacy staff.

Table 7: Number of Facilities Offering Value-Added Services for Patients on Long Term Therapy

Value Added Services	No. of Hospitals	No. of Health Clinics
Appointment System		
Appointment Card	86	257
Telephone & Take	67	121
SMS & Take	102	111
Pharmacy Home Delivery with *Pos Laju*	44	19
Other Systems*	28	44

Source: *PSD, MOH*
** Drive-Through Pharmacy, Fax & Take, E-mail & Take*

3.2.3 Domestic Medicines Production

Domestic medicines production is a vital aspect of the National Key Economic Area (NKEA). The Third Entry Point Project (EPP3), Pursuing Malaysian Pharmaceuticals Export Opportunities, can become the driving force to transform Malaysia into a major player in the export of pharmaceuticals. Although RM422 billion of prescription and pharmaceutical drug patents are about to expire in the next 10 years, Malaysia remains a net importer of generic products.[1] Under EPP3, local pharmaceutical producers are given aid to upgrade their production while multinational companies are encouraged to localise their production.

In July 2011, the Economic Council approved the Pharmaceutical Off-Take Agreement-Government Procurement for New Local Manufactured Pharmaceuticals. The scheme allows the Government to procure locally manufactured products from qualified manufacturers for a set period of time. The manufacturers are required to register their products in another country before the contract to supply is extended for another set period of time. This will be a very important incentive for new pharmaceutical plants to expand or invest in producing new locally manufactured products.

These efforts also increase national self-sufficiency in pharmaceutical supplies and reduce excessive dependence on imports. The percentage of locally manufactured NEDL items has increased slightly from 63.5% in 2010 to 64.2% in 2011 (Figure 12).

[1] *Economic Transformation Programme; A Roadmap for Malaysia, Chapter 16: Creating Wealth Through Excellence in Healthcare*

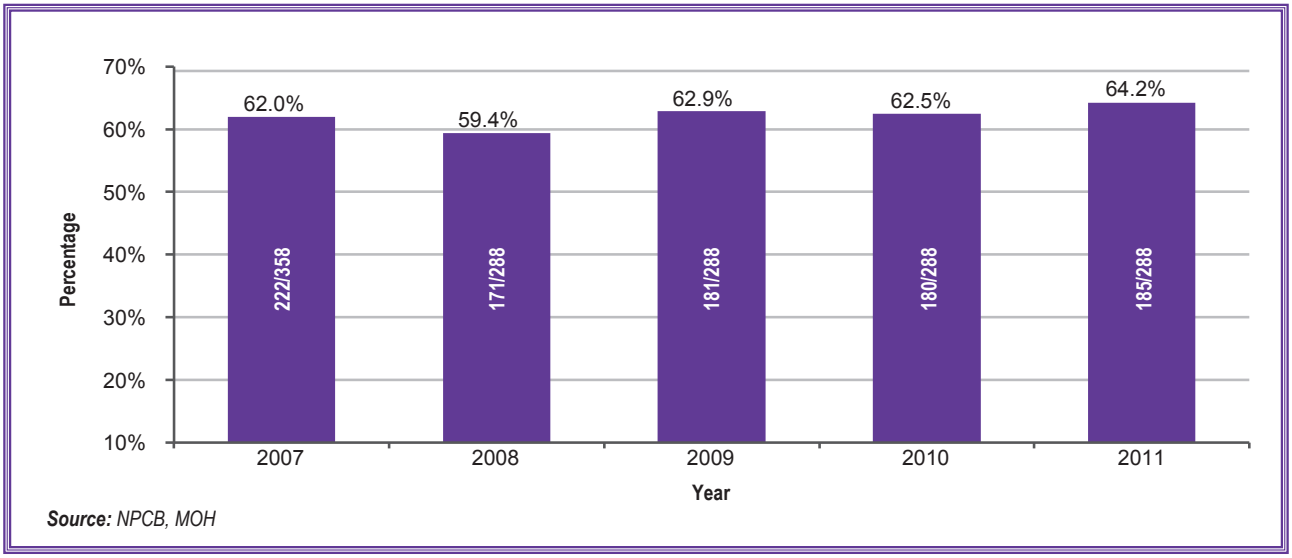


Figure 12: Number of Locally Manufactured Medicines Sold in the Country from the National Essential Drugs List (NEDL), out of Total Number of Drugs from NEDL (2007 – 2011)

3.3 Drug Affordability

This component aims at ensuring continuous access and financial sustainability of essential medicines at prices affordable to all.

3.3.1 Prices of Medicines

The medicine price database has been established through price monitoring activities such as voluntary reporting by pharmaceutical companies and surveys done since 2007 in both the public and private sector. Approximately 50% (47.88%) of products registered in Malaysia are contained in the medicine price database. Wholesale, retail and recommended retail prices are reported in the database.

Based on the Medicine Price Monitoring Survey in 2011 for the WHO/HAI core list, the median wholesale price in government hospitals, private hospital and retail pharmacies are 1.87, 6.66 and 2.92 times the median international reference price (MPR) respectively. The median percentage availability of medicines in public sector is 70.37% and 44.44% in the private sector. The median wholesale mark-up in the private sector, retail pharmacies and private hospitals are 39.46%, 40.86% and 33.27% respectively. The MPR of wholesale price for generic medicines in private sector is 4 times of that in the public sector.

Medicine prices in Malaysia have been reported to be among the highest in Asia and in the region. Thus, a comprehensive online medicine price database consisting of national and international medicine prices as well as the International Reference Pricing Management Sciences for Health (MSH) guide is currently in preparation and expected to be ready by 2015. This comparative price information will be used as a tool for reference in order to secure the best price for value in the public medicine procurement process.

3.3.2 Medicine Pricing Policy

Medicine prices in the private sector still remain under the free price system and prices are subjected to market forces. On the other hand, there is indirect control over the prices of medicines in the public sector through government procurement policies, procedures and regulations.

Development of a rational pricing structure that is also fair, reasonable and stable is still on-going with the assistance from WHO/WPRO consultants

and engagement of relevant stakeholders in the pharmaceuticals industry, medical and health care professionals, other relevant government agencies and the consumer groups. The proposed pricing structure will also take into consideration the provision of other legislation such as the Anti-Competition Act 2010, Price Control and Anti-Profiteering Act 2011 and other trade agreements.

3.3.3 Medicine Price Information and Sharing

The National Essential Drug Price list (recommended retail price) is available for public viewing at the PSD official website (*www.pharmacy.gov.my*) whereas the following information is disseminated internally:

- Public wholesale price
- National Essential Drug Price list (public)
- National Essential Drug Price list (private)
- Private wholesale price (controlled drug)
- Private wholesale price (OTC)

Due to escalating MOH medicine expenditure every year, MOH has implemented a standard labelling of medicine price on medication envelopes supplied in public outpatient pharmacies towards the end of 2011. This aims to provide patients with medicine pricing information and raise their awareness of the cost of medications subsidised by the government so that they will be more responsible when taking their medications to improve their health outcomes and reduce wastage.

Starting from 2009, Recommended Retail Prices (RRP) for some drugs are accessible at the PSD official website for consumers to make informed choices.

3.3.4 Generic Medicines Policy

Registration of generic medicines is allowed by DCA to facilitate early access to affordable generic medicines prior to patent expiry. Currently, there is no limit to the number of generic medicines that can be registered. To ensure the quality of locally-manufactured generic medicines, all generic medicines are required to undergo BE studies from January 2012. The implementation of BE studies is hoped to inspire public confidence with the quality of generic medicines and thus, leading to the increase of their use.

In MOH health facilities, the use of generic medicines has been promoted in activities such as procurement, prescribing and dispensing. In procurement, the use of generic names for multisource products will promote fair competitions and increase the chances in selecting generic medicines.

Table 8: Value of Medicines Procured through Tender by MOH (2007 – 2011)

Year		2007	2008	2009	2010	2011
Value in million (RM)	Innovator	478 (46.9%)	454 (44.6%)	527 (48.5%)	655 (53.3%)	762 (52.6%)
	Generic	542 (53.1%)	564 (55.4%)	559 (51.5%)	575 (46.7%)	688 (47.4%)

Source: *PSD, MOH*

MOH has enforced the use of generic names when prescribing medicines. In 2011, 53.5% of medicines in MOH hospitals and health clinics have been prescribed in generic names compared to 49.4% in 2008. Prescribing in generic names is fully practiced in 2 hospitals with an IT system, Putrajaya Hospital and *Universiti Kebangsaan Malaysia* Medical Centre. MOH will undertake an ICT project in pharmacy information system in all hospitals and health clinics by 2015 where medicines are expected to be fully prescribed in generic names.

Dispensed medicines are labelled with generic names to increase patients' awareness and acceptance of generic medicines. However, more effort is still needed to increase generic names prescribing in the public sector while steps to promote the use of generic medicines in private sector need to be taken in the near future.

3.3.5 Medicine Financing

Malaysian health system is still dichotomous where comprehensive healthcare is offered both by a government-led public sector and private sector. MOH remains the main provider and financier of healthcare in the country. Health services (inclusive of medicines) in the public sector are provided at minimal charges or free and financed from the government's general revenues while services provided in the private sector are paid by patients out-of-pocket or with private health insurance.

Discussion on health transformation towards Universal Health Coverage (UHC) is underway. As medicines is a fundamental part of UHC, many forms of capacity building through country visits, workshops and conferences have been organized so that we can set up our own medicines benefit and reimbursement policies that will benefit the general public.

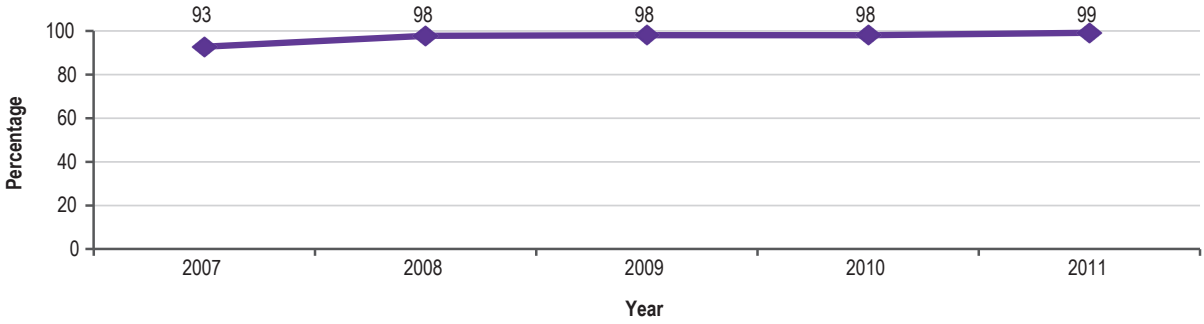
3.4 Quality Use of Drugs

This component aims to contribute towards the provision of quality care and cost-effective therapy.

3.4.1 Education and Training – Healthcare Providers

Education and training for healthcare providers was identified as one of the priority issues to be addressed in the quality use of medicines. Continuing Professional Development (CPD) is a structured process of learning that had been accepted by many professional groups as an excellent means of maintaining the professional competence of the practitioners.

Therefore, each pharmacist is responsible for the systematic maintenance, development and broadening of their knowledge, skill and attitude to ensure that they remain competent as a healthcare professional throughout their careers. In the Pharmacy Programme, CPD achievement has been set at a minimum of 40 points and from 2007 to 2011, over ninety percent of pharmacists have consistently achieved this standard.



Source: *PSD, MOH*

Figure 13: CPD Achievement for Pharmacy Programme (2007 – 2011)

3.4.2 Education and Training - General Public

Besides educating the healthcare providers, public education and awareness on the quality use of medicines is also very important. In 2011, 1040 talks, exhibitions and dialogues were organised as part of consumer education on counterfeits, adulterated and unregistered drugs.

The Quality Use of Medicine-Consumer (QUM-C) programme is a strategy to educate consumers on the rational use of medicines. This programme aims to increase their knowledge and skills so that they are able to make informed decisions. Consumers are also encouraged to play a more proactive role on management of their medications and be responsible for their own health. Many activities have been actively carried out nationwide so that the impact of this programme can reach a wider population. These activities include seminars, exhibitions and radio talks (Figure 14).

Figure 14: Quality Use of Medicine - Consumers Activities (2007 – 2011)

"A National Survey on the Use of Medications by Malaysian Consumers" is a project carried out to evaluate the extent of public awareness and knowledge in the country about quality use of medicines. Two surveys were conducted in 2008 and 2012 in collaboration with the School of Pharmaceutical Sciences, Universiti Sains Malaysia. In 2008, it was found that only 44.4% Malaysian understood the proper use of medicines. A post-intervention study conducted in 2012 revealed that the percentage has increased to 56.6%.

(i) "Know Your Medicine" Campaign

The "Know Your Medicine" campaign is a project initially organised by MOH with the Consumers Association of Malaysia (FOMCA). The campaign, which was officially launched on 29 June 2007, is a promotional initiative to increase consumers' awareness on rational use of medicines and their right to information. This campaign has now been extended to all pharmacy facilities in hospitals, health clinics and Pharmacy State Enforcement Branches to ensure that the message gets across to the target groups. In conjunction with the launch of the campaign, an official portal was established (*www.knowyourmedicine.gov.my*). The portal aims to facilitate the dissemination of medicines information to the public.

(ii) Community Empowerment: *Know Your Medicines Ambassadors*

"*Know Your Medicines Ambassadors*" is the new approach towards the empowerment of the community. Introduced in 2011, it aims to encourage active community participation in healthcare. Elected representatives in the community known as "*Know Your Medicine Ambassadors*" will work in collaboration with pharmacists in carrying out peer educational and behavioural change activities for the effective dissemination of information on quality use of medicines to the community.

(iii) 24-hour National Pharmacy Call Centre (NPCC)

The National Pharmacy Call Centre (NPCC), which is located in Kuala Lumpur Hospital, was established to improve accessibility to accurate, unbiased and relevant information on medicines for all healthcare providers, patients and the general public. Responses to enquiries are provided through the phone. The service is provided 24 hours a day, 7 days a week, including public holidays and weekends. In 2011, a toll free line (1800-88-6722) was introduced to increase the public's accessibility to NPCC.

(iv) Basic Curriculum in the Educational System

Subjects on quality use of medicines have been introduced into both curricular and co-curricular activities in primary schools. In 2011, lessons relating to "Know Your Medicines" have been incorporated into Standard 1 textbooks and also introduced in the Young Doctors' Club. The Young Doctors' Club is a school-based health promotion programme conducted in collaboration between the Health Promotion Division, MOH and the School Department, the Ministry of Education. The programme is aimed at establishing healthy habits among primary school students by providing them with basic knowledge about health.

3.4.3 Pharmacists' Role in Improving Quality Use of Medicines

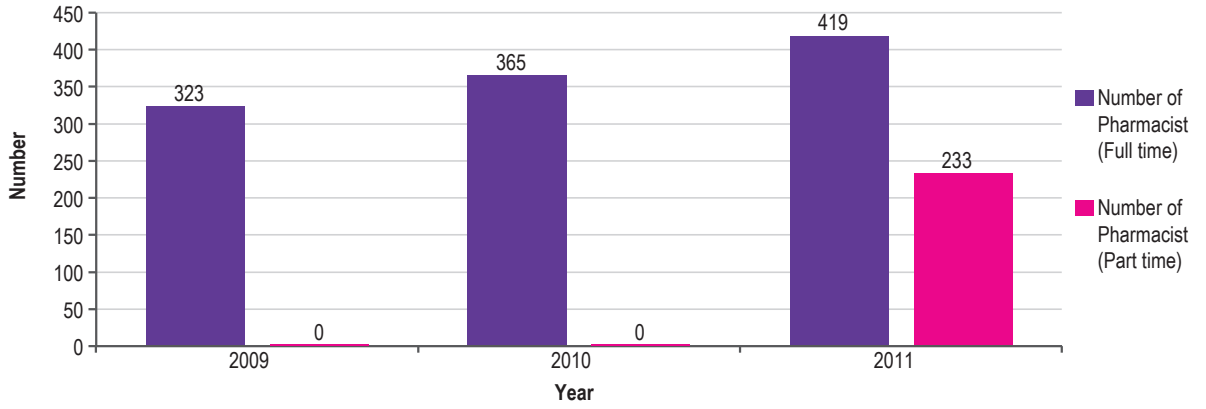
Pharmacists play a vital role in the healthcare system in providing medication management services and promoting quality use of medicines, which may be undertaken independently and also as part of the healthcare team. Their diverse responsibilities include dispensing medications, monitoring patients' progress through pharmaceutical care approach to optimising the benefits of medication therapy.

(i) Multidisciplinary Team (MDT)

An MDT is composed of members from different healthcare professions with specialised skills and expertise where members complement knowledge and skill to deliver the best definite outcomes that improves the patient's quality of life. Clinical Pharmacists working in hospitals are active members of this multidisciplinary medical team where they participate in ward rounds and contribute to bedside therapeutic discussions.

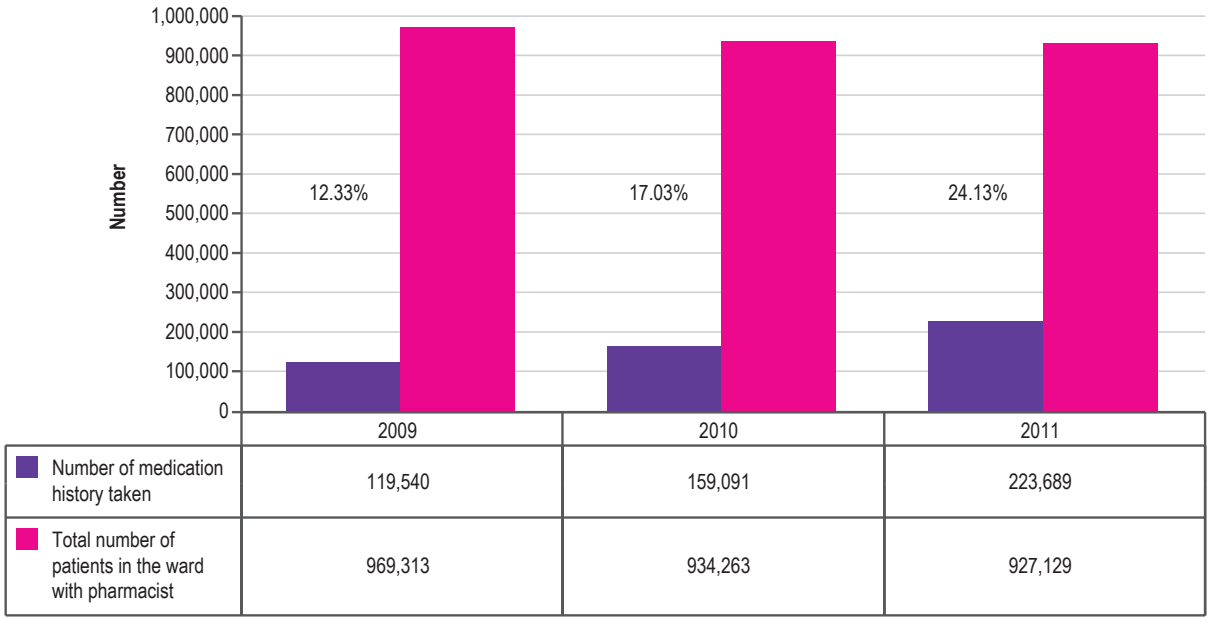
Pharmacists play a diversity of roles in the MDT, which include taking medication history, performing medication reconciliation, reviewing current and discharge medication, monitoring case progression, counselling patients at the bedside and/or upon discharge, monitoring and reporting adverse drug reactions as well as detecting and overcoming drug-related problems. By taking direct responsibility for their individual patient's medication-related need, pharmacists can make a unique contribution to the outcome of the pharmacotherapy and to their patient's quality of life.

By 2011, there were a total of 419 pharmacists working full time in the wards in MOH hospitals, mainly in the disciplines of general medicine, critical care, paediatrics and nephrology (Figure 15).



Source: *PSD, MOH*

Figure 15: Posting of Ward Pharmacists (2009 – 2011)



	2009	2010	2011
Number of medication history taken	119,540	159,091	223,689
Total number of patients in the ward with pharmacist	969,313	934,263	927,129

Source: *PSD, MOH*

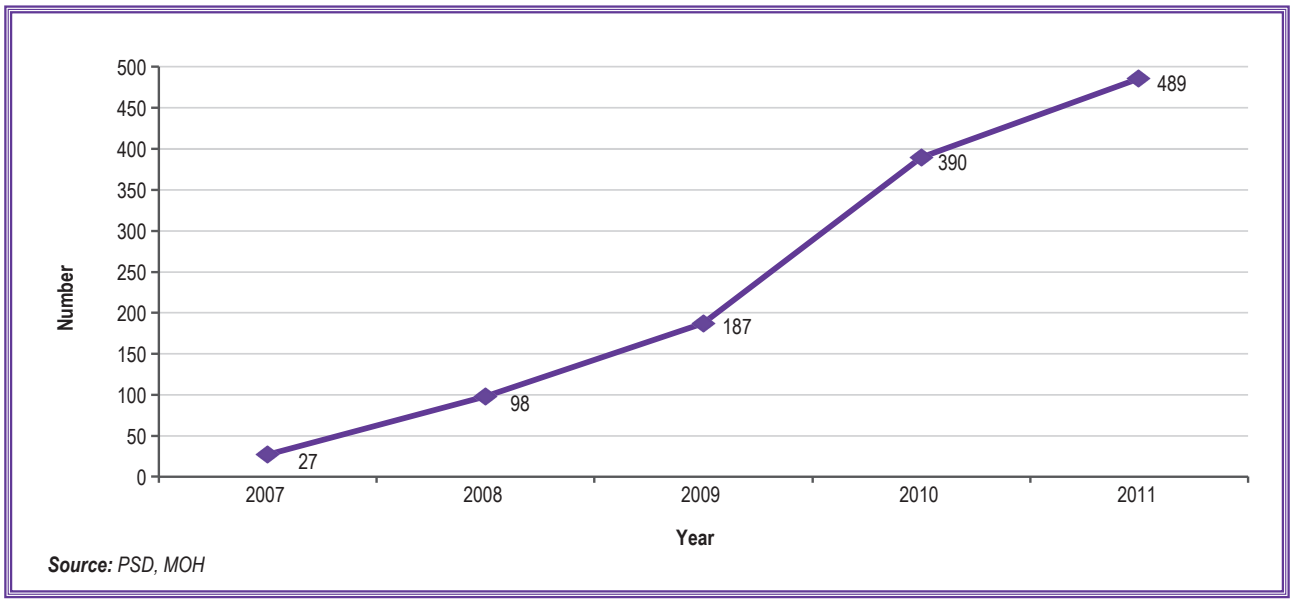
Figure 16: Percentage of Medication History Taken by Pharmacists in the Wards with Ward Pharmacy Service in MOH Hospitals (2009 – 2011)

(ii) Medication Therapy Adherence Clinic (MTAC)

MTAC was introduced in 2004 as a component of clinical pharmacy in ambulatory care. It is an adherence clinic led by pharmacists in collaboration with the physicians and other healthcare providers. The objective of MTAC is to improve patients' knowledge on disease and medication taking and thus, enhancing their adherence to the prescribed medication regimen and leading to improved clinical outcomes and achievement of treatment goals.

MTAC pharmacists carry out the monitoring of medication therapy and provide information and motivation to patients to improve their understanding of their treatment so that they have a positive perception of their health outcome.

By 2011, there were 489 facilities in MOH offering five types of MTAC such as diabetes, warfarin, respiratory, retroviral disease and nephrology (Figure 17). All MTAC services are carried out by trained pharmacists using the protocols approved by PSD. MTAC services are also available in university hospitals.



Source: *PSD, MOH*

Figure 17: Number of MTACs Established in MOH Facilities (2007 – 2011)

3.5 Human Resources Development

This component aims to ensure sufficient experts, professionals and trained personnel in the pharmaceutical sector.

3.5.1 Accreditation of Training Centres

In the period of 2007 – 2011, there has been continuous development of the training of healthcare professionals to meet the country's healthcare needs. Training programmes are required to be accredited to ensure that the standards of professionals trained are maintained. Currently, a total of five (5) public higher learning institutions and twelve (12) private higher learning institutions are approved to begin undergraduate pharmacy programme (Table 9). Of these, 10 have received full recognition from the Pharmacy Board Malaysia.

Table 9: Number of Public and Private Higher Learning Institutions offering Accredited Pharmacy Programmes (2007 – 2011)

Year	2007	2008	2009	2010	2011
Public universities	5	5	5	5	5
Private institutions	8	8	10	11	12
Total	**13**	**13**	**15**	**16**	**17**

Source: *PSD, MOH*

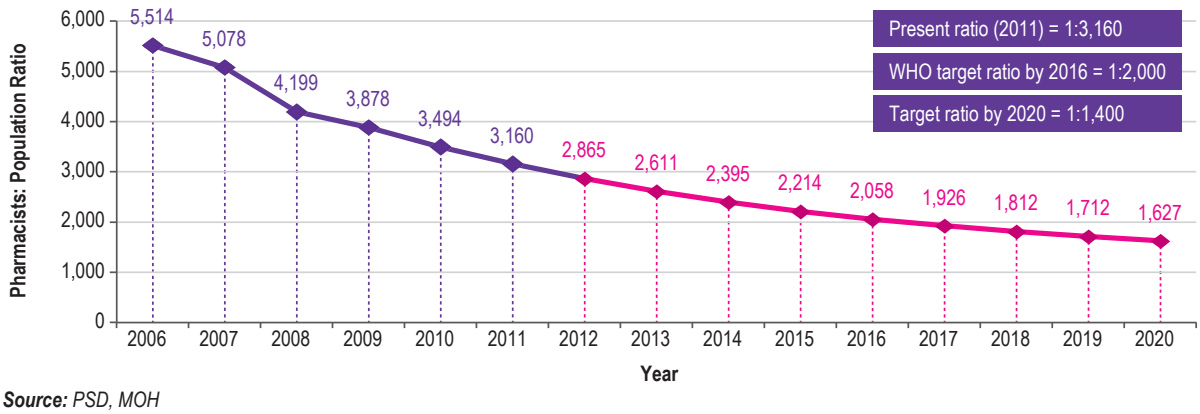
3.5.2 Number of Healthcare Providers

In 2011, the total number of doctors in the country is 36,607 and the total number of pharmacists is 9,005 (Table 10). The aim is to increase the ratio of pharmacists to doctors from the current 1:5 to 1:3. The ratio of pharmacists to population has improved from 1:4,533 in 2007 to 1:3,282 in 2011 in line towards achieving the target of 1:1,200 in 2020 (Figure 18).

Table 10: Total Doctors and Pharmacists and Ratio of Profession: Population (2007 – 2011)

Year	2007	2008	2009	2010	2011
Total doctors	23,738	25,102	30,536	32,979	36,607
Doctor:Population	1:1,145	1:1,105	1:927	1:859	1:791
Total pharmacists	**5,335**	**6,594**	**7,298**	**8,278**	**9,005**
Pharmacist:Population	**1:5,078**	**1:4,199**	**1:3,878**	**1:3,494**	**1:3,160**

Source: *Health Facts and PSD, MOH*



Source: *PSD, MOH*

Figure 18: Projection of Registered Pharmacists to Population Ratio (2006 – 2020)

3.5.3 Compulsory Service for Pharmacists

In September 2004, MOH proposed a three-year compulsory service for pharmacists in the public sector, which included placements in public hospitals, health clinics, regulatory control, enforcement and pharmacy management. As a result of that, compulsory service for new pharmacy graduates/registered pharmacists started in 2005. The main objective of the compulsory service was to ease the shortage of pharmacists in the public sector. However, it has caused a strain on the private sector, affecting the pharmaceutical industry, community pharmacies, private health institutions and institutions for higher learning.

To strike a balance and ensuring that both public and private sectors can grow in tandem, the government has reduced the period of compulsory service to one year in September 2011 as well as allowing new pharmacy graduates to be attached to accredited private facilities such as hospitals, community pharmacies, pharmaceutical industries and academic institutions.

3.5.4 Education and Training

The pharmacy education programme has undergone several intensive revisions since the early days. It is an innovative curriculum that is in line with current trends in pharmaceutical education and the nation's need for its pharmaceutical services. The multidisciplinary and integrated approach found in most curriculum have produced pharmacy graduates who are skilled, professional, ethical, and can function as leaders and medicine specialists.

Many pharmacists also hold postgraduates degree (masters and PhD) in many specialised areas of pharmacy.

Table 11: Number of Pharmacists with Master/PhD in MOH* (2007-2011)

	2007	2008	2009	2010	2011
Master	52	34	52	53	53
PhD	1	1	2	4	5

Source: *PSD, MOH*

**Pharmacists awarded Hadiah Latihan Persekutuan (HLP) or granted study leave [Cuti Belajar Bergaji Penuh (CBBP)/Cuti Tanpa Gaji (CTG)]*

With rapid advancements in medicine and pharmaceutical care, it is imperative that pharmacists keep themselves abreast with new developments that would provide better care and treatment outcomes for their patients. Realising the need for capacity building, MOH has been sending pharmacists for attachment trainings both locally and overseas. Local training focused mainly on the various MTAC programmes, ward pharmacy and technical aspects such as parenteral nutrition, clinical pharmacokinetic services and cytotoxic drug reconstitution.

Pharmacists running the MTAC programmes are trained with a standardised training module endorsed by PSD. They undergo a two-week attachment training at a certified training centre under a qualified preceptor.

To ensure the quality of training, training centres and preceptors undergo a stringent qualification process. Until 2011, 108 pharmacists have been trained in the field of MTAC (diabetes, respiratory, nephrology, respiratory and retroviral disease). Some examples of the trainings done for ward pharmacy included the areas of critical care, nephrology, paediatrics and others.

To keep up with global development in pharmacy practice, 16 pharmacists were sent overseas for attachment training from 2009 to 2011. The main focus of these attachment trainings were in the areas of pharmacy specialization such as oncology, psychiatry, emergency pharmacy, paediatrics, respiratory, critical care, haematology, infectious disease and nuclear pharmacy.

3.5.5 Community Pharmacy Benchmarking Guideline

The Community Pharmacy Benchmarking Guideline Review Committee was established in 2009 to review the guideline first published in 2005. The purpose of establishing the guideline is to set a benchmark for the standards and practices in the community pharmacy that reflects the pharmacy profession in general.

This guideline provides an overview of the requirements that community pharmacies are expected to fulfill in terms of infrastructure, equipment, personnel and practices. Standard operating procedures and optional professional services available in community pharmacies are also highlighted in the guideline. The updated guideline was published in 2011.

3.5.6 Malaysia Healthcare Provider's Mapping Service

PSD has collaborated with the Malaysian Pharmaceutical Society (MPS) in the development of a geo-mapping system that shows the location of community pharmacies and related healthcare providers in Malaysia. The system was developed to facilitate public access to these facilities and provide necessary data for the purpose of restructuring the public health system.

It was successfully completed in November 2010 and is available online. The total number of facilities in the geo-mapping system is 12,930 (Table 12).

Table 12: Types of Healthcare Providers in the Malaysia Healthcare Providers' Mapping Service (2011)

Healthcare Providers	Number of Facilities
Government Hospital	135
Government Health Clinic	2,815
1Malaysia Clinic	99
Private Hospital	277
Private Medical Clinic	6,157
Private Dental Clinic	1,593
Community Pharmacy	1,854
Total	**12,930**

Source: *PSD, MOH*

3.6 Research and Development

The Research and Development component of the policy aims to improve medicines utilisation and management and to encourage drug research and development.

3.6.1 Research Activities and Projects

Research activities have been conducted in various areas such as pharmacoeconomics, drugs utilisation and pharmaceutical care. In 2011, about 178 pharmacists had been certified with Good Clinical Practice (GCP), five pharmacists had qualified with a Master in Medical Statistics degree and a number of them had participated in drug utilisation research.

3.6.1.1 Clinical Trials

NPCB is involved as a secretariat to the National Committee for Clinical Research (NCCR), which is chaired by the Director General of Health Malaysia.

This committee is responsible to:

i. Establish policies and plan clinical trial activities in Malaysia
ii. Utilise all experts available in MOH, academic institutions and pharmaceutical industries through "smart partnership" concepts in enhancing clinical research
iii. Identify available infrastructures and take necessary steps in improving them
iv. Organise training programmes such as Good Clinical Practice (GCP), Good Laboratory Practice (GLP), Biostatistics and other training related to human development
v. Take proactive action at all times in enhancing clinical research in Malaysia in tandem with the development in developed nations

In 2011, NPCB had evaluated a total of 85 new applications to conduct clinical trials on pharmaceutical, biological, biotechnology, vaccines, herbal, health supplements products and others in Malaysia (*NPCB, 2011*). A total of 318 clinical trials were conducted in Malaysia from 2007 to 2011 (*National Medical Research Register*).

3.6.1.2 National Studies

i. ***Drug Utilisation Study (DUS) in the Treatment of Diabetes Mellitus in the Ministry of Health Facilities***

The Drug Utilisation Study (DUS) in the Treatment of Diabetes Mellitus is a national multicentre research project involving 94 healthcare facilities (hospitals and health clinics) in MOH. This research started in 2009 and is due for completion in 2012.

The three main objectives of this study are:

a. To determine the utilisation pattern and cost of medications in the treatment of diabetes mellitus (DM)
b. To assess the adherence of DM patients towards medications; and
c. To determine the direct and indirect costs of diabetic treatment for DM patients in the MOH facilities.

Data collection for this research project was carried out in two phases using a retrospective approach (DUS Phase 1) and a prospective approach (DUS Phase 2). A total of 2,509 Type 2 diabetes mellitus patients participated in the study.

ii. National Medicines Use Survey (NMUS)

The National Medicines Use Survey (NMUS) was initiated in 2005 and is a joint venture project between PSD and Clinical Research Centre, MOH (CRC). This survey is an ongoing project and aims to study the utilisation of medicines in the country with the following objectives:

a. To know the types and amount of medicines supplied in Malaysia to measure the utilisation and expenditure levels of medicines in the country
b. To know the types and amount of medicines prescribed and/or dispensed in Malaysia to gauge the quality of prescription and dispensing practices in the country
c. To know the types and amount of medicines consumed by consumers in Malaysia to identify the pattern of use of medicines for evaluation of rational use
d. To stimulate and facilitate researches on use of medicines

As a result of the implementation of NMUS, the Malaysian Statistics on Medicines (MSOM) for 2004 to 2008 have been published. The reports are accessible through the PSD official website and CRC website (*www.crc.gov.my*). These reports are useful in providing preliminary data on medicines used in the country, which can be used for comparison on medicine usage pattern with developed countries and also as a tool for better decision making in the allocation of healthcare resources for the Malaysian population. This is in line with the objectives of the DUNas that is to increase the quality of medicine usage towards a more cost-effective treatment.

3.6.2 National Pharmacy R&D Conference

PSD have been organising the National Pharmacy R&D Conference every two years since 2002. The main objectives in organising this conference are:

a. To give pharmacists the opportunity to present their research findings
b. To encourage the involvement of pharmacist in research activities; and
c. To enable participants to interact and share ideas on related topics

In 2010 and 2012, the 6th and 7th National Pharmacy R&D Conference had received a total of 103 and 101 participations for both oral and poster presentation from all pharmacists in public and private health facilities respectively.

3.7 Technical Cooperation

3.7.1 ASEAN Harmonisation

NPCB has been actively playing its role in the regional harmonisation efforts of ASEAN through the ASEAN Consultative Committee on Standards and Quality Pharmaceutical Product Working Group (ACCSQ PPWG), Traditional Medicines and Health Supplements Product Working Group (TMHS PWG) as well as the ASEAN Cosmetic Committee (ACC). In the ACCSQ PPWG, NPCB is heavily involved in discussions related to BE inspections.

3.7.2 Good Laboratory Practice (GLP)

NPCB, as a national CMA for GLP, is involved in technical cooperation with other international GLP CMAs through the Working Group on GLP and the Working Group of National Coordinators of the Test Guidelines Programme. NPCB also has technical cooperation with STANDARDS MALAYSIA, i.e., the other national CMA in Malaysia.

3.7.3 Quality Control (QC)

In view of its functions related to Quality Control, NPCB is involved in technical cooperation with other agencies, which include among others:

i. Continuous involvement in collaborative studies and the proficiency testing scheme organised by ASEAN, WHO, European Directorate for the Quality of Medicines (EDQM) and other regulatory agencies to strengthen ability and competence in the analytical field
ii. Provide training for local pharmaceutical industry and WHO fellows
iii. Collaborates with the Centre for Compliance and Licensing, NPCB in auditing manufacturers of pharmaceutical, traditional and cosmetic products to ensure compliance of their QC lab to prescribed regulations and guidelines
iv. Establish pharmaceutical reference standards for local pharmaceutical industry or institution usage

3.7.4 Enforcement Activities

PSD is the lead agency for the National Task Force for precursors control. This task force has been formed to strengthen the inter-agency cooperation and information exchange on issues related to the control of precursor chemicals that can be used in drugs manufacturing. Task force members consist of senior officers from the National Anti-Drug Agency (NADA), the Royal Malaysian Police (RMP), Royal Malaysian Customs (RMC) and Chemistry Department Malaysia (CDM).

A task force to combat counterfeits has also been formed and the Ministry of Domestic Trade, Co-Operatives and Consumerism is the lead agency for this special task force. This special task force consists of members from various government and private agencies including PSD, who also plays an important role in combating counterfeit medicines. Inter-agency discussion and sharing of information on issues related to counterfeit products are held twice a year.

4. GAPS AND CHALLENGES

4.1 Product Registration

A major challenge related to product registration is to ensure compliance to the client's charter with respect to the application processing timeline. The evaluation process is affected by various factors which include, among others, the incomplete submission of the dossiers. Measures taken to overcome these problems include upgrading of the online system as well as increasing and improving the level of understanding among applicants in terms of requirements by dialogues, workshops and training sessions.

4.2 Good Distribution Practice (GDP)

In 2011, NPCB issued a total of 375 Import Licenses and 1,037 Wholesaler's Licenses throughout Malaysia. All the licensees are required to comply with the requirement of GDP (previously known as Good Storage Practice). As a centralised authority agency, NPCB has been working very closely with State Enforcement Officers to ensure that all license holders who deal with the import or wholesale of registered products adhere to the requirements of the GDP guidelines.

State Enforcement Officers are responsible for GDP inspections on all importer and wholesaler premises outside the Klang Valley. However, for GDP inspections in Kuala Lumpur and Selangor, the State Enforcement Officers will carry out GDP inspections on all importer or wholesaler premises dealing with registered products containing poisons only.

There are identified differences in the practice of GDP inspections between NPCB and the State Enforcement Officers. In order to minimise these gaps, NPCB will continue to strengthen cooperation with the State Enforcement Officers.

4.3 Good Laboratory Practice (GLP) Inspection

In 2011, a Mutual Joint Visit (MJV) was conducted on both national CMAs; the NPCB and STANDARD MALAYSIA by the OECD GLP Working Group Inspection Team, which comprised of three OECD inspectors from the United Kingdom (UK), Switzerland and Japan. The major challenge faced by NPCB as a national CMA is to maintain Malaysia's membership as a non-member country fully adherent to the OECD Mutual Acceptance of Data (MAD) in the Assessment of Chemicals and ensuring non-clinical Test Facilities in Malaysia comply and maintain the OECD Principles of GLP.

4.4 Good Clinical Practice (GCP) and Bioequivalence (BE) Inspections

Current trends show an increasing number of clinical trials conducted in Malaysia. This indicates that NPCB will face an increasing number of clinical trial sites, sponsor and Contact Research Organization (CRO) to be inspected. Therefore, efforts to continuously train and improve GCP inspection knowledge and skills among inspectors are important, which is in line with the advancements of the computerised system and technology in the performance of clinical trials. Increasing demand for Phase I trials in Malaysia encouraged the establishment of the Phase I unit in Malaysia where specific skills and knowledge for the inspection can be attained via attachment training with other more experienced regulatory authorities such as European Medicines Agency (EMEA), US Food and Drug Administration and Australian Therapeutic Goods Administration among others.

The directive that was issued under the Control of Drugs and Cosmetics Regulations 1984 on the accreditation for local BE centres in compliance to GCP and GLP will be fully enforced in 2012. Thus, local BE centres identified during the Gaps Analysis need to take up the challenge to further improve their system and practice in terms of compliance to GCP principles, GLP principles and also relevant guidelines before the full inspection in 2012. The Trust Fund for Overseas Bioequivalence (BE) Centre Inspection also needs to be established to facilitate the process of inspections on foreign BE centres, which is projected to commence in 2013.

4.5 Quality Control

New challenges are continuously developing in the field of quality control due to the advancement of new technologies and discoveries in today's constantly

evolving world. Such challenges give rise to the need to further strengthen competency and knowledge in various related aspects such as:

i. Research and development of testing methodologies
   - requires knowledge, skills and extensive technical expertise

ii. Detection of adulterants and their analogues
   - requires knowledge, skills and expertise in isolation, extraction and purification
   - understanding structural elucidation and capability to interpret analytical data (Tandem Mass Spectrometry, MS/MS and Nuclear Magnetic Resonance, NMR)
   - detection of marker compound to verify plant species in natural medicinal products

4.6 Liberalisation of Provisionally Registered Pharmacists (PRP) Training

The liberalisation of the training for the Provisionally Registered Pharmacists (PRP) is set to commence by November 2012 where these pharmacists are able to practise and be trained in any accredited private facilities such as hospitals, community pharmacies, pharmaceutical industries and academic institutions.

4.7 Specialisation in Pharmacy Practice

PSD has decided to use certification from the Board of Pharmacy Specialties (BPS) to recognise specialty areas of pharmacy in Malaysia and thus, initiated discussion with the American College of Clinical Pharmacy in mid of 2011. This resulted in a collaborative effort to organise a Pharmacotherapy Review Program for Advanced Clinical Pharmacy in 2012. This programme aims to help candidates with their preparation for the BPS examination scheduled for the same year.

4.8 Integrity and Good Governance

Malaysia has participated in the Good Governance for Medicines (GGM) programme since 2004 and is currently in Phase III, which is Implementation of the National GGM Programme. GGM has been successfully incorporated into the current procurement process by setting up various committees such as the Specification Committee, Technical Evaluation Committee and Price Evaluation Committee.

Implementation of Integrity Pact as one of the initiatives of National Key Result Area (NKRA) (Corruption on 16 December 2010) has further improve integrity and transparency in public procurement. All the committee members are required to sign a pact or agreement not to be involved in corruption during the administration of a contract.

The level of implementation of good governance for medicines can be shown by the constant enhancement of administrative procedures throughout the medicines management system. For example, disclosure of medicines contracts awarded and implementation of the conflict of interest policy for various committee members are practised.

The two GGM related guidelines published are "Guidelines for Pharmacy Members in Dealing with Pharmaceutical Company Representatives and Suppliers" as well as "Guidelines On Giving and Receiving Gifts For Civil Servants" under the Pharmacy Programme, Ministry of Health Malaysia.

4.9 Increase the Use of Generic Medicines

PSD has started promoting the use of generic medicines among prescribers by addressing their concerns with the quality, safety and efficacy of the generic products. Generic prescribing in government facilities started since 1999. Efforts for the Generic Medicines Policy need to be intensified to achieve higher usage of generic medicines throughout the country.

4.10 Guidelines on the Procurement of Orphan Medicines

A working committee was established in 2011 to look into the process of preparing the "Guidelines on the Procurement of Orphan Medicines." Involvement of the private sector is very important in the process of developing the guidelines. Hence, members from various pharmacy organisations such as Malaysian Organisation of Pharmaceutical Industries (MOPI), Pharmaceutical Association of Malaysia (PhAMA) and Malaysian Association of Pharmaceutical Suppliers (MAPS) were appointed as members of the working committee.

The guideline will serve as a useful reference to all key players involved to ensure the continuous availability of orphan medicines to the public. Orphan Medicines refer to medicines that are not currently available in the market but are still required and essential for treatment as well as medicines used in emergency cases. Contents of the guidelines will include product registration process with the Drug Control Authority (DCA), listing process in MOH Medicines Formulary and medicines procurement process. The draft of the guideline is expected to be ready by the end of 2013.

4.11 Malaysian Guidelines for the Management of Drug Donations

The Malaysian Guidelines for the Management of Drug Donations Working Committee was established in 2010 to produce a guideline that can serve as a basis for national utilisation in dealing with drug donations. The framework of these guidelines is adapted from the WHO Guidelines for Drug Donations (Revised 1999).

The initial draft was successfully prepared in 2011 and is currently being scrutinized and updated before obtaining approval from the higher level of the ministry.

4.12 Development of Standard Treatment Guidelines (STG)

Standard Treatment Guidelines (STG) are essential in ensuring that standards of best practice are applied in the provision of quality, safe and cost-effectiveness use of medicines at all levels of healthcare. Currently, there is a list Clinical Practice Guidelines (CPG) produced by multi-disciplinary and multi-organisational development groups for a variety of medical disciplines. These guidelines are used as references for clinical practices based on the best available evidence at the time of development. However, such guidelines need to be strengthened with the incorporation of pharmacoeconomic evaluations.

5. FUTURE DIRECTION

Under the 10th Malaysian Plan, health transformation has been identified as one of the main agenda alongside the Government Transformation Programme (GTP) and Economic Transformation Programme (ETP) in our nation's quest to achieve developed status by 2020. In the planning and development of this health transformation blueprint, PSD has identified several key areas in pharmaceutical services to be strengthened in preparation for the proposed health reform.

PSD remains committed to the original pharmaceutical policy objectives in wanting to keep medicine costs affordable, encourage appropriate use and improve equitable access. To ensure that good medicines are available and accessible in a system that uses resources efficiently, building blocks such as legislations, formulary, medicine pricing, ICT, infrastructure and capacity building, and logistics system were determined for transformation to address current issues and challenges faced by primary and secondary health facilities, community pharmacies and pharmaceutical industry.

Firstly, a new Pharmacy Bill has been formulated to consolidate all the existing laws, regulations and guidelines that predated the country's independence. Current laws were found to be outdated and thus lacking in facing current challenges. Lacunae in the current legislations have been a major concern for PSD in tackling problems such as counterfeit, adulterated and unregistered medicines. The new Malaysia Pharmacy Act is a transformation of the pharmacy legislation through its consolidation, harmonisation and liberalization and will replace the Registration of Pharmacists Act 1951, Poisons Act 1952, Sale of Drugs Act 1952 and Medicines (Advertisement and Sale) Act 1956.

The new Pharmacy Bill will provide for the integration of enforcement activities through the establishment of a Competent Authority to deal with bureaucracy. It will also support our country's obligation to ratify the laws in consistence with international conventions regarding psychotropics and precursors. It also will offer better protection to the public's interest, safety and health with deterrent penalties for offences related to counterfeit medicinal products, adulteration, psychotropic distribution and precursor diversion.

Secondly, the establishment of a financing mechanism for pharmaceuticals through the formulation of a national medicines formulary, reimbursement list and pharmaceutical benefits package would be instrumental in regulating prescribing practices and medicine use, and forecasting realistic pharmaceutical budgets. For this to work, a price monitoring system and drug tariff has to be set up to control medicines sales practices and prevent unregulated markups on medicine pricing. Information on the markups of medicine prices along the supply chain needs to be obtained to enable a comparison of price structures with other countries.

One of the challenges currently faced is the acquisition of a complete internal and external price data. Internal price consists of manufacturer/ex-factory price, laden price, wholesaler price and retail price with the markups. There is no existing law or act that binds the pharmaceutical key players to comply with the provision of price information and price declaration to the government and thus, causing the accuracy of price information obtained through voluntary reporting questionable. External reference is needed so that the Malaysian market can be compared with other ASEAN countries and middle-income countries to ensure that the RRP is affordable. Both the internal and external price information will assist MOH in performing data analysis and creating a transparent and fair medicine price structure.

Thirdly, alternative ways of supplying medicines to the public are being explored to ease the congestion in government facilities. In 2011, a proposal was made to outsource the supply of medication for outpatients in public hospitals and health clinics. A cost-benefit analysis is planned for to compare the two proposed implementation concepts of partial and full outsourcing.

With the planned public-private integration of the health system, the importance of ICT development cannot be overlooked. Following the concession agreement of the privatisation of the Government Medical Store

(*Makmal Ubat dan Stor)*, MOH signed in March 2011, the Pharmacy Information System (PhIS) and Clinic Information System (CPS) were developed to transform the medicine supply management system in Malaysia. These systems will facilitate online prescribing and enable monitoring and analysis of medicine utilisation. Development of the system started from 2011 and will go on until 2013. A total of six hospitals, one district health office and nine clinics were chosen to be pilot sites where the system is expected to be implemented in 2013 before it is rolled out for a nationwide implementation in all MOH health facilities by 2015.

Besides PhIS and CPS, there is also the Integrated Substance Control Management System or SPIKES (*Sistem Pengurusan Integrasi Kawalan Efektif Substan*), a web-based system *(www.spikes.gov.my)* that regulates the movement and use of illicit substance in the country. It originated under the Crime Lab National Key Result Areas (NKRA) initiative of the GTP to reduce the incidence of street crimes commonly associated with drug abuse. PSD is the lead agency for this initiative and has an important role in collaborating with the other drug enforcement agencies in the country such as the National Anti-Drug Agency (NADA), the Royal Malaysian Police (RMP), Royal Malaysian Customs (RMC) and Chemistry Department Malaysia (CDM).

The system is designed with the objective of ensuring legitimate substance use for medical treatment and industrial purposes. Substances that are controlled in SPIKES are narcotics, psychotropics and precursor chemicals. SPIKES can create an effective and systematic substance control system with the cooperation of the various drug enforcement agencies. This is consistent with the control authorised by the International Narcotics Control Board (INCB).

Besides ICT development, capacity building also focuses on professional development and career pathway advancement because the value of such competency in providing quality pharmaceutical care is important throughout the healthcare continuum. Credentialing and Privileging (C&P) is a new project developed in 2010 by the PSD to establish and recognise pharmacists and pharmacy assistants with specialised skills in certain areas. To date, PSD and NPCB have identified courses that can be credentialed and modules for Pharmacotherapy, MTAC and GMP are being prepared.

In conclusion, PSD remains driven towards improving the quality of pharmaceutical services towards health transformation with commitment from the government and all stakeholders within the identified key areas.

6. CONCLUSIONS

DUNas has fulfilled its objectives for the first term of its implementation since 2006. The policy has showed tremendous growth, achievements and significant impact to the pharmaceutical sector of the nation. Nevertheless, there are gaps which need to be addressed to create a more wholesome and sustainable policy for the benefit of all stakeholders. The future paves more challenges as the second term of the policy (2013 – 2017) has emerged.

APPENDICES

i. BACKGROUND ON ECONOMIC, HEALTH STATUS AND PHARMACEUTICAL CONTEXT

Background indicators provide information on the demographic, economic, health status and pharmaceutical contexts in which drug policy is implemented. The information can be used to help identify major problems in health status, in the health system and in the drug sector. The indicators provide basic data that a policy-maker responsible for the drug sector should know and have available.

BACKGROUND INFORMATION	2006	2007	2008	2009	2010	2011
Total population	26,640,200	27,173,600	27,728,700	28,081,500	28,588,600	28,964,300
Average annual growth of the population (%)	1.96	2.00	2.00	1.80	1.80	1.30
Percentage of the total population living in urban areas (%)	63.2	63.4	63.5	63.3	63.4	NA
Life expectancy (years) (Male)	71.5	71.5	71.6	71.6	71.9	NA
Life expectancy (years) (Female)	76.3	76.4	76.4	76.5	77	NA
GNP per capita (MYR)	19,739	23,114	25,784	24,055	26,355	28,725
Average annual rate of inflation (%)	3.6	2.0	5.4	0.6	1.7	NA
Infant mortality rate (per 1,000 live births)	6.2	6.2	6.2	6.9	6.8	NA
Maternal mortality rate (per 100,000 live births)	30	29	28.9	27	27.3	NA
Total number of prescribers (Doctors only)	24,877	23,738	25,102	30,536	32,979	36,607
Total public health budget (refer to total MOH's budget – million - MYR)	8,660	11,200	12,901	13,716	15,348	16,870
Total public drug expenditure (million - MYR) (refer to expenditures from all public sectors)	1,511	1,652	1,915	1,855	2,016	2,216
Total value of drug imports (CIF) (million - MYR)	2,700	2,900	4,313	4,373	3,753	4,171

BACKGROUND INFORMATION	2006	2007	2008	2009	2010	2011
Total number of pharmacists (registered)	5,442	5,335	6,594	7,298	8,278	9,005
Total number of pharmacy technicians or other aides/assistants (pharmacy assistants - MOH only)	2,589	2,633	2,818	2,958	3,202	3,414
Total number of drug manufacturing units in the country Poison & OTC only (excluding traditional products)	85	60	69	74	67	71
Total number of wholesalers in the country (poison wholesaler) Poison & OTC only (excluding traditional products)	426	455	479	481	517	533
Total number of pharmacies and drug outlets in the public sector (including health facilities and hospitals that dispense drugs)	941	942	939	946	1,000	1,066
Total number of pharmacies and drug outlets in the private sector (retail pharmacy + retail & w/sale pharmacy) - licensed only	1,876	1,847	1,895	2,030	2,066	2,163
Total number of private pharmacies and drug outlets in the three major urban areas (Penang, Selangor ,WP KL – private pharmacies only)	851	861	866	940	985	1,058
Total number of registered drugs (in dosage forms and strengths)	27,673	22,354	22,424	23,278	23,741	23,580
Total number of drugs on the national essential drugs list (in INN)	358	358	288	288	288	288

Note: *NA – Not Available*

ii. PHARMACEUTICAL SYSTEM CAPACITY INFORMATION - STRUCTURAL INDICATORS

Structural indicators provide qualitative information on the basic structures that are considered necessary for implementing a national drug policy; checking whether the basic structures/systems/mechanisms under each key component exist in the country.

STRUCTURAL INDICATORS	YES (√) or NO (x)
Is there an official national drug policy document updated in the past 10 years?	√
Is there drug legislation updated in the past 10 years?	√
Have regulations based on the drug legislation been issued?	√
Is there a drug regulatory authority whose mandate includes registration and inspection?	√
Is there a licensing system to regulate the sale of drugs (wholesalers, pharmacists, retailers)?	√
Are pharmacists legally entitled to substitute generic drugs for brand name products?	√ (Public) x (Private)
Are there legal provisions for penal sanction?	√
Is there a checklist for carrying out inspections in different types of pharmaceutical establishments?	√
Are there any institutions within or outside the country where quality control is carried out?	√
Is the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce used systematically?	√
Are there controls on drug promotion based on regulations and consistent with the WHO Ethical Criteria for Medicinal Drug Promotion?	√
Is there a national essential drugs list (EDL)/formulary using INN officially adopted and distributed countrywide?	√
Is there an official drug committee whose duties include updating the national essential drug list (EDL)?	√
Has the national essential drugs list (EDL)/formulary been updated and distributed countrywide in the past five years?	√
Are there formal procedures for registering drugs?	√
Is there a drug registration committee?	√
Is drug registrations renewal required at least every five years?	√

STRUCTURAL INDICATORS	YES (√) or NO (x)
Is the public drug budget spent per year more than 20% of the ministry of health operating budget spent per year for the last three years? Year — % of public drug budget spent out of the MOH operating budget 2009 — 22.97 2010 — 18.88 2011 — 18.06	√ (2009) x (2010) x (2011)
Is the public drug budget spent per capita per year more than US$1.00 per year for the last three years? Year — Public drug spent per capita (RM) — (US$) 2009 — 63.53 — 20.32 2010 — 66.51 — 21.27 2011 — 69.54 — 22.24	√
Is the public drug budget spent for national hospitals less than 40% of the total public drug budget spent for the last three years? (National hospitals = State hospitals + HKL)	√
Has the public drug budget spent per capita increased in the last three years?	√
Are there any financing systems in addition to the public drug budget that contribute to the provision of drugs in the public sector?	x
Are drugs usually procured in the public sector through competitive tender?	√
Is there a system for monitoring supplier performance?	√
Is most of the tendering done under international non-proprietary name (INN)?	√
Is procurement in the public sector limited to drugs on the national essential drugs list (EDL)?	x
Is the average lead time (from order to receipt at central level) less than eight months?	√
Is procurement based on a reliable quantification of drugs needs?	√
Are good storage practices observed in the central procurement/distribution unit and/or major regional warehouses?	√
Are the stocks for a basket of drugs within their expiry dates in the central procurement/distribution unit and/or major regional warehouses?	√
Have all incoming products being physically inspected for the last three deliveries in the central procurement/distribution unit and/or in major regional warehouses?	√
Are only drugs which are on the national essential drugs list (EDL) in stock in the central procurement/ distribution unit and/or in major regional warehouses?	x
Are drug prices regulated in the private sector?	x

STRUCTURAL INDICATORS	YES (√) or NO (x)
Is there at least one major incentive for the private sector to sell essential drugs at low cost?	x
Is there a system for monitoring drug prices?	√
Are essential drugs under INN or generic name sold in private drug outlets?	√
Is there a national publication (formulary/bulletin/manual, etc.), revised within the past five years, providing objective information on drug use?	√
Is there a national therapeutic guide with standardized treatments?	√
Is the concept of essential drugs part of the curricula in the basic training of health personnel?	x
Is there an official continuing education system on rational use of drugs for prescribers and dispensers?	√
Is there a drug information unit/centre?	√
Does the drug information unit/centre (or another independent body) provide regular information on drugs to prescribers and dispensers?	√
Are there therapeutic committees in the major hospitals?	√
Are there public education campaigns on drug use?	√
Is drug education included in the primary/secondary school curricula?	√

iii. DUNas COMMITTEES AND MEMBERS

1. Steering Committee

Chairman
Director-General of Health, MOH

Alternate Chairman
Senior Director of Pharmaceutical Services, MOH

Members

- Dr. Salmah binti Bahri, *Pharmaceutical Services Division, MOH*
- Dr. Nour Hanah binti Othman, *Pharmaceutical Services Division, MOH*
- En. Selvaraja Seerangam, *National Pharmaceutical Control Bureau, MOH*
- Pn. Siti Aida binti Abdullah, *National Pharmaceutical Control Bureau, MOH*
- Dr. Ramli bin Abd Ghani, *Traditional & Complementary Medicine Division, MOH*
- En. Jaafar bin Lassa, *Traditional & Complementary Medicine Division, MOH*
- To' Puan Dr. Safurah binti Jaafar, *Family Health Development Division, MOH*
- Dr. Kamaliah binti Mohamad Noh, *Family Health Development Division, MOH*
- Dr. Nooraini binti Baba, *Medical Practise Division, MOH*
- Dr. Ahmad Razid bin Salleh, *Medical Practise Division, MOH*
- Dato' Dr. Azmi bin Shapie, *Medical Development Division, MOH*
- Dr. Anita Delilah binti Salahuddin, *Medical Development Division, MOH*
- En. Hazally bin Jali, *Procurement and Privatisation Division, MOH*
- En. Hisyam Yong bin Abdullah, *Procurement and Privatisation Division, MOH*
- En. Choy Lup Bong, *Policy and International Relations Division, MOH*
- En. Unny Sankar a/l Ravi Sankar, *Policy and International Relations Division, MOH*
- Tuan Mohamad Fazin bin Mahmud, *Legal Advisor Office, MOH*
- Pn. Wong Mee Ling, *Legal Advisor Office, MOH*
- Dr. Chua Hong Teck, *Economic Planning Unit, Prime Minister's Department*
- Pn. Sudha Sivadas, *Economic Planning Unit, Prime Minister's Department*
- En. Wan Mohd. Yusof bin W.Taib, *Ministry of Domestic Trade, Co-Operatives and Consumerism*
- Pn. Widayati binti Samutu, *Ministry of Domestic Trade, Co-Operatives and Consumerism*
- Dato' Tuan Haji Yusof bin Yahya, *Corporate Planning Division*
- En. Nasaruddin bin Abdul Muttalib, *Corporate Planning Division*
- Pn. Gan Mui Huei, *Ministry Of International Trade and Industry*
- En. Mohammad Izuddin bin Idris, *Ministry Of International Trade and Industry*
- Dr. Mohamed Azmi bin Ahmad Hassali, *Universiti Sains Malaysia*
- Dr. Asrul Akmal bin Shafie, *Universiti Sains Malaysia*

- Prof Madya Dr. Mohamed Ibrahim bin Noordin, *University of Malaya*
- Datin Dr. Junaidahbinti Amir, *University of Malaya*
- Prof P.T. Thomas, *National University of Malaysia*
- Dr. Mohd Makmor Bakry, *National University of Malaysia*
- Datuk Nancy Ho, *Malaysian Pharmaceutical Society*
- Pn. Yip Sook Ying, *Malaysian Pharmaceutical Society*
- Dr. Haji Farouk bin Abdullah, *Malaysian Medical Association*
- Dr. Sivanaesan Letchumanan, *Malaysian Medical Association*
- Dr. Ng Swee Choon, *Academy of Medicine of Malaysia*
- Dato' Dr. Khoo Kah Lin, *Academy of Medicine of Malaysia*
- En. Y.S Tong, *Malaysian Organisation of Pharmaceutical Industries*
- Pn. Ng Su Yee, *Malaysian Organisation of Pharmaceutical Industries*
- En. Keh Song Hock, *Pharmaceutical Association of Malaysia*
- Pn. Tan Booi Charn, *Pharmaceutical Association of Malaysia*
- En. Sam Wong Chin Kah, *Federation of Malaysian Consumers Associations*
- Pn. Mohana Priya Veerabarathi, *Federation of Malaysian Consumers Associations*

2. Implementation Committee

Chairperson

Dato' Eisah binti A. Rahman
Senior Director of Pharmaceutical Services, MOH

Members

- En. Mohd Hatta bin Ahmad, *Pharmaceutical Services Division, MOH*
- Dr. Salmah binti Bahari, *Pharmaceutical Services Division, MOH*
- Dr. Nour Hanah binti Othman, *Pharmaceutical Services Division, MOH*
- En. Tan Kee Leong, *Pharmaceutical Services Division, MOH*
- Pn. Abida Haq binti Syed M. Haq, *Pharmaceutical Services Division, MOH*
- Pn. Anis binti Talib, *Pharmaceutical Services Division, MOH*
- Pn. Faridah binti Abdul Malek, *Pharmaceutical Services Division, MOH*
- Pn. Faridah Hanin binti Ismail, *Pharmaceutical Services Division, MOH*
- En. Tan Ann Ling, *National Pharmaceutical Control Bureau, MOH*
- Pn. Siti Aida binti Abdullah, *National Pharmaceutical Control Bureau, MOH*
- Pn. Rosnaini binti Kamaruddin, *State Deputy Director of Health (Pharmacy)*
- Pn. Rosidah binti Md. Din, *State Deputy Director of Health (Pharmacy)*
- Pn. Zawiyah binti Mat Johor, *State Deputy Director of Health (Pharmacy)*
- Cik Wee Suat Bee, *State Deputy Director of Health (Pharmacy)*

3. Technical Committee for Quality, Safety & Efficacy

Chairperson

Pn. Siti Aida binti Abdullah
National Pharmaceutical Control Bureau, MOH

Members

- Dr. Kamaruzaman bin Salleh, *National Pharmaceutical Control Bureau, MOH*
- Dr. Noraida binti Mohamad Zainoor, *National Pharmaceutical Control Bureau, MOH*
- Pn. Mazuwin binti Zainal Abidin, *National Pharmaceutical Control Bureau, MOH*
- Pn. Nurhayati binti Othman, *National Pharmaceutical Control Bureau, MOH*
- Cik Nor Hafizah binti Mohd. Potri, *National Pharmaceutical Control Bureau, MOH*
- En. Mohd Zulkifli bin Abdul Latif, *Pharmaceutical Services Division, MOH*
- Cik Latifah binti Hj Idris, *Pharmaceutical Services Division, MOH*
- En. Adnan bin Salimin, *Wilayah Persekutuan Kuala Lumpur & Putrajaya*

Health Department

- En. Lam Kai Kun, *Malaysian Pharmaceutical Society*
- Pn. Sabrina binti Haron, *Malaysian Organisation of Pharmaceutical Industries*
- Pn. Sumitha Ganasegaram, *Pharmaceutical Association of Malaysia*
- Pn. J.S. Sunitha Dewi, *Pharmaceutical Association of Malaysia*
- En. Sam Wong, *Federation of Malaysian Consumers Associations*
- Pn. Zarrah Banu Hulwani binti Abdul Rahim, *Direct Selling Association of Malaysia*

4. Technical Committee for Drug Availability

Chairperson

Pn. Anis binti Talib
Pharmaceutical Services Division, MOH

Members

- Pn. Zainab binti Md Yusuf, *Pharmaceutical Services Division, MOH*
- Pn. Azuwana binti Supian, *Pharmaceutical Services Division, MOH*
- Cik Farahwahida binti Mohd Kasim, *Pharmaceutical Services Division, MOH*
- Pn. Arpah binti Abas, *National Pharmaceutical Control Bureau, MOH*
- Dr. Ashari bin Yunus, *Medical Development Division, MOH*
- Cik Aileen Chong, *Malaysian Pharmaceutical Society*
- En. Jimmy Piong Teck Onn, *Malaysian Organisation of Pharmaceutical Industries*
- En. Hisyam Yong Abdullah, *Procurement & Privatization Division, MOH*
- Pn. Tan Booi Charn, *Pharmaceutical Association of Malaysia*

- Dr. Wan Nurdiana Zaireen binti Wan Zainal Abidin, *Malaysia Medical Relief Society (MERCY Malaysia)*
- En. Mohd Hadi bin Mohd Zin, *Traditional & Complementary Medicine Division, MOH*

5. Technical Committee for Drug Affordability

Chairperson

Pn. Anis binti Talib
Pharmaceutical Services Division, MOH

Members

- Pn. Fatimah binti Abdul Rahim, *Pharmaceutical Services Division, MOH*
- Pn. Saimah binti Mat Noor, *Pharmaceutical Services Division, MOH*
- Pn. Norliah binti Ardee, *Tengku Ampuan Rahimah Hospital*
- Pn. Rosilawati binti Ahmad, *National Pharmaceutical Control Bureau, MOH*
- Pn. Zaiton binti Shato, *Pejabat Kesihatan Daerah Petaling*
- Pn. Ng Su Yee, *Malaysian Organisation of Pharmaceutical Industries*
- En. Rohan Talalla, *Pharmaceutical Association of Malaysia*
- Dr. Ng Siew Choon, *Federation of Private Medical Practitioners' Associations Malaysia*
- Pn. Wan Hwei Yen, *Malaysian Pharmaceutical Society*
- Pn. Lum Sau Mei, *General Insurance Association of Malaysia*
- Dr. T. Jayabalan, *The Consumers Association of Penang*
- Dr. Kok Chin Leong, *Association of Private Hospitals of Malaysia*
- Dr. Choe Tong Seng, *Malaysian Association of Pharmaceutical Suppliers*

6. Technical Committee for Quality Use of Drugs

Chairperson

Pn. Abida Haq binti Syed M. Haq
Pharmaceutical Services Division, MOH

Members

- En. Azman bin Yahya, *Pharmaceutical Services Division, MOH*
- En. Mazlan bin Ismail, *Pharmaceutical Services Division, MOH*
- Pn. Che Pun binti Bujang, *Pharmaceutical Services Division, MOH*
- Pn. Faridah Hanin binti Ismail, *Pharmaceutical Services Division, MOH*
- Pn. Fuziah binti Abd. Rashid, *Pharmaceutical Services Division, MOH*
- Pn. Noraini binti Mohamad, *Pharmaceutical Services Division, MOH*
- Cik Sameerah binti Shaikh Abd. Rahman, *National Pharmaceutical Control Bureau, MOH*
- Pn. Nur Azibahwati binti Aziz, *Kuala Lumpur Hospital*
- Kol. Dr. A. Halim bin Hj. Basari, *Ministry of Defence*

- Pn. Yip Sook Ying, *Malaysian Pharmaceutical Society*
- Dr. Krishna Kumaran, *Malaysian Medical Association*
- Dr. Mohamed Azmi bin Ahmad Hassali, *Universiti Sains Malaysia*
- Assoc. Prof. Dr. Chua Siew Siang, *University of Malaya*
- Dr. Samsuddeen bin Abd. Aziz, *Ministry of Education*

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