THE REPUBLIC OF THE UNION OF MYANMAR

Ministry of Health and Sports

NATIONAL MEDICINES POLICY

Strategy and Implementation Plan

(2018-2021)

June 2019

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Contents

Abbreviations

ADR	adverse drug reaction
ASEAN	Association of Southeast Asian Nations
ASP	Antibiotic Stewardship Programme
cGMP	current Good Manufacturing Practice
CMSD	Central Medical Store Department
DFA	Department of Food and Drug Administration
DFDA	Department of Food and Drug Administration
DMS	Department of Medical Services
DPH	Department of Public Health
eLMIS	Electronic Logistics Management Information System
EML	Essential Medicines List
FDA	Food and Drug Administration
GDP	Good Distribution Practice
GMP	Good Manufacturing Practice
GPP	Good Pharmacy Practice
GSP	Good Storage Practice
GVP	Good Pharmacovigilance Practice
HRH	Human Resource for Health
ICSR	Individual Case Safety Report
IRIMS	Integrated Regulatory Information Management System
M&E	monitoring and evaluation
MoHS	Ministry of Health and Sports
MTC	Medicines and Therapeutic Committee
NEML	National Essential Medicines List
NGO	nongovernmental organization
NHA	National Health Accounts
NHP	National Health Plan

NIMU	National Health Plan Implementation Monitoring Unit
NMP	National Medicine Policy
NMS	National Medicine Strategy
OTC	over-the-counter (drugs)
PHC	primary health care
PICS	Pharmaceutical Inspection Cooperation Scheme
PTC	Pharmacy or Medicine Therapeutic Committee
R&D	research and development
RAS	rapid communication
RIMS	Regulatory Information Management System
RUM	rational use of medicine
SARA	service availability and readiness assessment
SDG	Sustainable Development Goal
STG	Standard Treatment Guidelines
TPE	total pharmaceutical expenditure
TWG	Technical Working Group
UHC	Universal Health Coverage
URTI	upper respiratory tract infection
WHO	World Health Organization
WMS	warehouse management system

I. Introduction

The Strategy and Implementation Plan 2018–2021 of the National Medicine Policy (NMP) serves as a guide for implementing the policy as part of the National Health Plan 2017–2021 supporting the goal of the Universal Health Coverage Policy for the population of the Republic of the Union of Myanmar. The strategic plan is developed through a consultative process by the three Technical Working Groups – (i) on access and supply chain management; (ii) on safety, quality and regulations; and (iii) on rational use of medicines – to address the priority issues and challenges based on the current situation of the health sector.

II. Medicine situation

The Government of Myanmar has implemented an NMP for decades. Despite significant progress, there are challenges in access and availability, quality and rational use of medicines. The findings from the Medicine for Healthcare Delivery Situation Analysis (1) and National Service Availability and Readiness Assessment (2) served as the basis for identifying priority issues and remedial interventions needed for the strategic plan to support the implementation of the National Health Plan (2017–2021).

(1) **Supply, availability and affordability of medicines**

- **Medicine selection**

  Myanmar has followed an essential medicines policy for many years and the current National Essential Medicines List (NEML) is the 2016 version with 486 medicines. Though NEML should serve as a basis for procurement and use of medicines at public health facilities, there is a need to improve compliance. The average percentage of non-EML medicines was 29% at public referral hospitals, 20% at public township hospitals and 14.25% at public primary health centres. Obviously, there is a need to better advocate the use of essential medicines at hospital facilities with emphasis on types and levels of services delivered.

- **Medicine procurement**

  Before 2013, the procurement and distribution of medicines in Myanmar was done centrally by the Central Medical Store Department (CMSD), with a later transition to decentralized procurement at hospitals with 200 beds and those managed by regional/state health authorities. The CMSD still undertakes the central procurement and distribution to health facilities; however, the coordination mechanism is not defined. Local purchase of medicines accounted for over 50% of the total consumption. Quantification methods differ for the central procurement and local purchase. There is a need to synchronize the procurement system of the national and regional/state health authorities. Weak governance, lack of trained personnel, inefficient information

and financial management have been identified as areas for improvement in the procurement system. A systematic consumption and expenditure analysis of medicines will help to identify any inefficiencies in procurement and supply management.

- **Medicine availability**

  The average availability of essential medicines (2014) was 80% at public referral hospitals, 75% at public township hospitals and 59% at public primary health centres; with stock-outs of 24%, 19% and 18%, respectively. This requires a mechanism for routine monitoring of availability of medicines and their efficient replenishment at health facilities.

- **Medicine prices**

  The Government of Myanmar requires that prices of medicines should be comparable with those in the neighbouring countries. An assessment (2) showed that the unit prices from local purchase were double as compared to the unit price of the central procurement; which may be due to different economies of scale or inefficient procurement practices at these levels. A systematic survey of price of medicines at the public and private sector facilities will enable monitoring of prices of medicines under local purchase as well as at the national level. A centralized collective price negotiation mechanism along with a price framework agreement with suppliers can potentially avoid large price variations between local purchases.

(2) **Quality and regulatory system for medicines**

The DFDA under the MoHS is the mandated government agency responsible for regulations and quality assurance of medicines. It was set up in 1995 under the Department of Health, but since 2011 it has been reorganized and became a department under the MoHS. The DFDA is responsible for regulating food, medicines and medical devices as well as registration and licensing of medicines, inspection of medicine outlets and manufacturers, quality surveillance, safety surveillance (pharmacovigilance) and controlling promotional materials of medicines.

Current situation: There are 17 000 registered pharmaceutical products regulated by the DFDA and 12 000 traditional medicines regulated by the Department of Traditional Medicines. There are 170 wholesalers, over 10 000 retailers of medicines while 8 manufacturing sites are in place. About 1000 medicinal samples are tested annually by the National Drug Quality Testing Laboratory with a failure rate of 3–5%. The limited number of human resource (n=392) in the DFDA (2014) remains one of the impediments in implementing the regulatory functions. A functional and robust system of safety surveillance (pharmacovigilance) needs to be established. Obviously, there is a need for human resource strengthening of the DFDA for more stringent regulatory decisions.

Developments: There have been significant developments in recent years in medicine regulation and quality assurance In Myanmar, reflecting the commitment of the government in collaboration with the partners. These, among others, include the following:

- The development of an Integrated Regulatory Information Management System (IRIMS). This system will enable rapid exchange of information and coordination across all medicine regulatory functions including registration, company licensing, quality testing, inspection of manufacturers, distributors and outlets and post-marketing quality as well as safety surveillance. Training for using the system is under way in 2018.
- A national coordination mechanism between the DFDA, police, customs and the Ministry of Trade was agreed and developed (2017) to combat substandard and falsified medicinal products.
- A comprehensive assessment of the DFDA was undertaken in 2017, using the WHO benchmarking tool for the evaluation of national regulatory authority, whereby the department agreed to follow the recommendations.
- A review of medicines approved for marketing in Myanmar was undertaken by the Department of Pharmacology of the University of Barcelona (2018), which will serve as a basis for designing a protocol for monitoring adverse drug reactions (ADRs) – this has not been established in Myanmar.
- Online medicine registration has been developed and operationalized (2018) and the regulatory staff trained for using the system.
- All these developments should be systematically continued in the coming years.

(3) **Rational use of medicines**

- Rational use of medicines is vital for high quality health care and outcomes. The assessment in 2014 (2) indicated the issues of polypharmacy, overuse of antibiotics and multivitamins because monitoring of medicine utilization was not regularized. Use of antibiotics in upper respiratory tract infection (URTI) (3) is the highest in Myanmar (80%) as compared to other ASEAN countries. Promotion of rational use intervention package among health providers should become an integral part of the health-care delivery system. Pharmacy or Medicine Therapeutic Committees (PTCs) mandated for monitoring and promoting rational use of medicines do not always exist at referral hospitals. Similarly, public education and advocacy to influence demand side is not systematically undertaken. The concept of the NMP, essential medicines and rational use of medicines are not yet systematically introduced in the curricula of health professionals. The need for a drug information centre and introduction of the above-mentioned concepts into pre-service and in-service

training of health-care providers calls for collaboration with professional associations and academic institutions.

(4) **Pharmaceutical workforce**

- Lack of trained human resource in medicine supply management, regulatory and quality surveillance system is evident especially at the regional/state health authority and township levels. Mobilization of pharmacy graduates to the regional and township levels is also problematic due to their lack of interest. A systemic survey for human resource requirements needs to be done at these levels, in line with the Myanmar Health Workforce Strategic Plan.

(5) **Medicine policy coordination**

- The collaboration and coordination between relevant stakeholders from within and outside the MoHS, at the national and subnational levels, as well as the public and private sectors has been emphasized by political leaders, which needs to be strengthened. An interdepartmental or intersectoral policy discussion forum at the central as well as the subnational levels will help in resolving priority issues related to pharmaceuticals and immediate remedial action can be taken. There is also a need to monitor the progress of policy implementation, which is currently not yet in place.

III. Strategies

- To improve accessibility, availability and affordability of essential medicines for the population of Myanmar, through strengthening the procurement and supply management system at all levels
- To improve safety, efficacy and quality of all medicines and to combat substandard and falsified medicines through strengthening regulation of medicines and quality assurance system at all levels
- To improve rational use of medicines at all levels
- To strengthen human resource in medicine management in all departments of the health sector
- To strengthen collaboration, communication, coordination and evaluation of implementation of the NMP at the national and subnational levels.

III.1. Strategy 1: *To improve accessibility, availability and affordability of essential medicines for the population of Myanmar, through strengthening the procurement and supply management system at all levels*

Issues and challenges

- Ineffective implementation and use of essential medicines – an obvious need to consistently advocate the use of essential medicines among health managers and prescribers. There is also a need to analyse utilization of medicines to identify inefficiencies
- Unavailability and stock-outs of essential medicines – need for regular monitoring of availability, procurement, supply and replenishment of essential medicines, particularly in rural areas
- Inefficient supply chain information management – need to develop an electronic logistics management information system (eLMIS) and warehouse management system (WMS)
- High variation in procurement prices – need for a medicine price survey, a mechanism for centralized collective medicine price negotiation, regular monitoring of procurement prices
- Lack of trained human resource in procurement and supply management – need for institutionalized pre- and on-job continuous professional education
- Lack of organizational structure for pharmaceutical management in health facilities – need for central and satellite pharmacies at big hospitals for efficient supply management of medicines
- Weak organizational structure for pharmaceutical management at the central, regional and township health offices for primary health-care facilities – need to institutionalize procurement and supply management units at the central, regional/state and township levels.

Recommended actions

- To implement the essential medicine policy according to the service provision level
- To undertake an advocacy campaign on essential medicines and generics for health managers and health service providers
- To undertake a financial analysis of medicine utilization at the national and regional/state health authority hospitals to address inefficiencies
- To regularly quantify before making an annual procurement plan and a systematic bottom up need plan inclusive of township health facilities
- To define a mechanism for prequalification of suppliers

- To undertake a medicine price survey and compare with international reference prices
- To undertake a regular monitoring of procurement prices at regional health authorities and hospitals and share the information
- To monitor the utilization of essential medicines at health facilities and develop a replenishing mechanism to prevent stock-outs
- To undertake a capacity building programme on procurement and supply management for staff at the regional/state, township and hospitals levels.
- To institutionalize pre- and on-job continuous professional education in health and education institutions
- To develop a framework for eLMIS and WMS as part of the management information system of the MoHS and roll out trainings on their application
- To create central and satellite pharmacies in national/big hospitals
- To institutionalize procurement and supply management units at the central, regional/state and township levels
- To develop social health insurance and reimbursement mechanisms.

III.2. Strategy 2: *To improve safety, efficacy and quality of all medicines and to combat substandard and falsified medicines through strengthening regulation and quality assurance system of medicines at all levels*

Issues and challenges

- The National Drug Law, enacted in 1992 – needs to be updated
- Unlicensed/non-accredited medical outlets – need to be regulated as licensing medicine outlets
- Organization and function of the Drug Inspectorate need to be strengthened through appropriate legislation
- Use of un-registered medicinal products – need for efficient market surveillance including sampling, analytical protocols and penalties
- Shortage of human resource at the DFDA – needs attention of the MoHS
- Awareness campaign for health practitioners and the general public regarding the importance of use of registered medicinal products
- High burden of applications on the DFDA for registration – needs strengthening of the mechanism for registration of applications
- Lack of an ADR monitoring and safety surveillance system – need for a pharmacovigilance system to detect any serious adverse reactions at an

early stage for public safety as well as advocacy on ADRs monitoring among practitioners and the public

- Low capacity of quality control testing at the central and regional levels – need to improve quality control laboratories in terms of technology, technical capacity and resource availability
- Quality and legality of priority medicines especially at the borders – need for rapid communication (RAS) and coordinated border surveillance between allied agencies dealing with substandard, unregistered and falsified medicinal products
- Limited capacity of state/regional Food and Drug Supervisory Committees – need for strengthening the committee for enforcing regulations.

Recommended actions

- To undertake human resource needs assessment at the central and regional/state levels for regulatory functions and advocate with the MoHS for more pharmacists to meet the regulatory work requirements at the central and peripheral levels
- To revise and upgrade the National Drug Law with inclusion of the missing clause on authorizing drug inspectors through the official gazette to inspect all premises licensed for the manufacture, import, warehousing and sale of medicines
- To develop a mechanism for mandatory licensure and accreditation of pharmacies
- To recruit and authorize health inspectors for post-marketing surveillance, pharmacy sampling and processing requests for quality testing in laboratories
- To expand the network of quality control laboratories and strengthening their technology, technical capacity and resource availability
- To devise rules for and strengthening the existing IRIMS to handle the burden of applications, for new product supporting many cross-functional processes such as manufacturing, authoring R&D documents and clinical trial submissions
- To advocate medical practitioners on the importance of prescribing only registered products. Special permission may be granted for importing unregistered medicinal products in dire need
- To advocate hospitals, manufacturing units and importers on importance of reporting ADRs
- To establish a national pharmacovigilance unit

- To strengthen RAS by continuous collaboration with the customs and allied departments for monitoring the quality and legality of medicinal products at the borders
- To strengthen the roles, functions and capacities of the state/regional Food and Drug Supervisory Committees
- To train the regulatory staff for registration using existing IRIMS, inspection, post-marketing surveillance and analytical testing for quality assurance.

III.3. Strategy 3: *To improve rational use of medicines at all levels*

Issues and challenges

- Irrational prescribing – strengthening and expanding WHO problem-based pharmacotherapy teaching (Guide to Good Prescribing) to medical schools; Advocacy for compliance with STGs in line with the Essential Health Services Packages; need for an essential medicine formulary for independent and unbiased information on medicines
- Self-medication – need for enforcing a "No prescription = No drug" policy to promote the role of the pharmacist in community pharmacy; categorization of outlets for dispensing medicine and authorization for dispensing medicine on the basis of type of the registered qualified person in respective pharmacies
- Non-adherence with prescription – need for promotion of patient counselling and feedback mechanisms at health facilities and community pharmacies; use of technology to promote adherence to treatment and mitigation of resistance; mandatory bilingual labelling and inserts; medicine information booklet on essential medicines to be used by pharmacists at the time of dispensing
- Absence of technical coordination and supervision on rational use of medicine – need to devise PTC at all levels, especially at big hospitals, for framing policies and procedures for selection, procurement, dispensing, labelling, availability, administration and control of medicines throughout the hospital
- Monitoring for inefficient information management and irrational use – need to develop an electronic prescription recording and dispensing tool; and implementation of monitoring tools with indicators for utilization of medicines and compliance by health-care providers in line with the Essential Health Services at health facilities
- Antimicrobial resistance – need for advocating and educating as per the Antibiotics Stewardship Programme (ASP) for both public and health professionals

Recommended actions

- To develop and implement an essential medicine formulary

- To define regulations for prescription-based categorical dispensing at the pharmacies
- To devise and promote use of technology for better adherence to treatment and mitigation of resistance
- To develop and implement a comprehensive rational use intervention package for health workers. The package should be shared in national consultative meetings with all stakeholders in the country
- To develop and implement STGs for Essential Health Services at health facilities
- To establish PTC at all levels especially at big hospitals with clear tasks to promote rational, safe, effective as well as efficient use of essential medicines and to monitor adverse reactions
- To strengthen and expand the use of WHO problem-based pharmacotherapy teaching, namely Guide To Good Prescribing to medical schools
- To develop and implement monitoring tools and indicators for utilization of medicines at health facilities
- To undertake public education on rational use of medicine in the communities
- To make licensure of all health-care personnel mandatory and ensure necessary competence with regard to diagnosing, prescribing and dispensing
- To devise and implement regulations for prevention of perverse prescribing financial incentives
- To implement the Antibiotic Stewardship Programme (ASP).

III.4. Strategy 4: *To strengthen human resource in medicine management in all departments of the health sector*

Issues and challenges

- Lack of clarity in organizational structure, departmental scope, job roles, responsibilities and coordination mechanism – need for a well-defined organizational structure with clear linkages and coordination mechanism within the MoHS for various functions related to medicine management; workforce analysis and planning; defined scope with intradepartmental hierarchical structure; position-specific job description with clear lines of reporting and delegation of authority
- Lack of availability and retention of skilled human resource – need to advocate with the MoHS to fill positions in respective departments at all levels; structured onboarding strategies and processes for retention of employees; performance appraisal: performance assessment, evaluation, reward and motivation to prevent rapid turn over of professionals

- Continuous pre-job and on-job training and development – need to introduce the key issues of the NMP, essential medicines and rational use of medicines into the pre-service training curricula of health professionals for better adaptation to innovation and technology.

Recommended actions

- To clearly define the organizational, hierarchical structure and scope of work for all departments and individual positions; to define managerial functions of planning, organizing, staffing, directing, controlling and decision-making
- To undertake needs assessment of human resource for respective functions at all levels of the health system
- To generate and recruit need-based positions according to defined skill-mix and organizational structure
- To develop and institutionalize pre- and on-job training; to develop a continuous pharmacy education curriculum and mechanisms on essential medicine management especially supply chain, regulatory affairs and rational use of medicine for all health professionals including licensed practitioners of traditional medicine
- To develop and institutionalize performance management and appraisal mechanisms of human resource at all levels.

III.5. Strategy 5: *To strengthen collaboration, communication, coordination and evaluation of NMP implementation at the national and subnational levels*

Issues and challenges

- Lack of a clearly defined collaborative platform for implementation of the NMP – need for constitution of an authoritative technical group for policy implementation
- Ineffective communication and coordination among stakeholders – need for exchange of information and pooled data for better monitoring on a regular basis
- Lack of defined indicators for policy monitoring – need for periodic monitoring and assessment of implementation of the NMP using relevant indicators on accessibility and availability, quality and on rational use. Gaps to be reviewed jointly, remedial action to be defined and taken.

Recommended actions

- To define roles for collaborative partners at the supervisory, middle management and senior management levels for implementation of the NMP

- To define relevant indicators for monitoring the progress in implementation of the NMP for accessibility, availability, quality and utilization of essential medicines; pooled data for exchange of information among all stakeholders for better decision-making
- To undertake a survey on baseline assessment for implementation of the NMP
- To create a mechanism for regular coordination meetings at the national, regional and township levels to address any barriers to implementation of the NMP where remedial action should be decided.

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Myanmar National Medicine Policy Implementation Plan 2018–2021				2018		2019		2020		2021	
NMP Strategic Objective	Strategy	Programme Component/Technical Activity	Responsibility	1	2	1	2	1	2	1	2
To improve accessibility, availability and affordability of essential medicines for the population of Myanmar	Strengthening of the supply chain system	**Selection**									
		Development and institutionalization of a governance mechanism (selection board and operational procedures) for selection of medicines at the central, regional and township levels	DMS/DPH	✓	✓	✓					
		Revision and categorization of the current NEML according to service delivery levels	DMS/DPH		✓	✓	✓				
		Update STGs and protocols according to service delivery levels	DMS/DPH		✓	✓	✓				
		Implementation and advocacy of NEML, STGs and protocols at the national and peripheral levels	DMS/DPH			✓	✓	✓	✓	✓	✓
		Procurement									
		Development and adoption of procurement guidelines (needs and supply planning; prequalification, purchase, quality assurance, payment and performance management) for the central, regional, state, township and hospital levels	PSD/DPH/DMS		✓	✓	✓				
		Conduct a national and state/regional "Purchase price disparity" survey for medicines	PSD/DMS/ DPH/related departments			✓	✓				
		Development and field-testing of a procurement price monitoring mechanism	DMS			✓	✓	✓			
		Development and implementation of a forecasting and supply planning mechanism at the central, regional, township and hospital levels	PSD/DMS/ DPH/related departments		✓	✓	✓				

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NMP Strategic Objective	**Strategy**	**Programme Component/Technical Activity**	**Responsibility**	**1**	**2**	**1**	**2**	**1**	**2**	**1**	**2**
To improve accessibility, availability and affordability of essential medicines for the population of Myanmar	Strengthening of the supply chain system	Design and roll out of a framework for contracting, quality assurance and vendor performance management mechanism for purchase and delivery of medicines at the central, state/regional and township levels	PSD/DPH/DMS			✓	✓	✓	✓	✓	✓
		Warehousing and distribution									
		Strengthening of medicine storage and distribution in hospitals through the establishment of a central and satellite pharmacy system	PSD/DPH/DMS		✓	✓	✓	✓	✓	✓	✓
		Strengthening of medicine storage and distribution at the central, state/regional and township levels	PSD/DPH/DMS		✓	✓	✓	✓	✓	✓	✓
		Development and pilot-testing of an integrated logistics information management system at the central, regional and township levels	PSD/DPH/DMS		✓	✓	✓	✓	✓	✓	✓

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NMP Strategic Objective	**Strategy**	**Programme Component/Technical Activity**	**Responsibility**	**1**	**2**	**1**	**2**	**1**	**2**	**1**	**2**
To improve safety, efficacy and quality of all medicines; and to combat substandard and falsified medicines through strengthening regulation of medicines and quality assurance systems	Strengthening the registration system for medicines	Review and update regulations and operational procedures on medicine registration to ensure availability of safe, effective and quality assured medicines in Myanmar	DFDA		✓	✓	✓				
		Conduct an assessment of the registartion department of the DFDA to identify gaps for improving its organizational structure and skill-mix; human availability and capcity; performance management and improvement mechanisms	DFDA		✓	✓	✓				
		Advocate with the MoHS to increase the number of positions in the registration department of the DFDA to meet the existing and future needs	DFDA		✓	✓	✓				
		Develop and roll out a pre- and on-job professional development mechanism for registration of medicines	DFDA			✓	✓	✓			
		Develop and roll out an integrated registration management information system to improve efficiency for registration/renewal of medicines	DFDA			✓	✓	✓	✓		
	Strengthening the quality control system	Improve and expand the network of quality control laboratories in terms of technology, technical capacity and resource availability to meet the quality control testing requirements at the central and regional levels for all essential medicines	DFDA		✓	✓	✓	✓	✓	✓	✓
		Advocate with the MoHS to increase the number of positions at quality control laboratories at the central and regional levels	DFDA		✓	✓	✓	✓	✓	✓	✓
		Review and update regulations, operational procedures and governing mechanism of the quality control department of the DFDA	DFDA			✓	✓	✓	✓		

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NMP Strategic Objective	**Strategy**	**Programme Component/Technical Activity**	**Responsibility**	**1**	**2**	**1**	**2**	**1**	**2**	**1**	**2**
To improve safety, efficacy and quality of all medicines; and to combat substandard and falsified medicines through strengthening regulation of medicines and quality assurance systems	Strengthening the pharmacovigilance system	Review and update the pharmacovigilance framework, regulations, operational procedures in the country	DFDA/DPH/DMS			✓	✓	✓	✓		
		Design and roll out an advocacy campaign on pharmacovigilance for health-care service providers, pharmaceutical manufacturers and importers	DFDA/DPH/DMS					✓	✓	✓	✓
		Design and roll out a roadmap to strenghten the pharmacovigilance information management system at the central, regional and hospital levels	DFDA/DPH/DMS			✓	✓	✓	✓	✓	✓
		Advocate with the MoHS to improve the availability and capacity of human resource for pharmacovigilance activities at the central, regional and hospital levels	DFDA/DPH/DMS			✓	✓	✓	✓	✓	✓
	Strengthening of market surveilance and quality assurance systems	Review, update and roll out a framework for regulations and operational procedures on market surveillance and quality assurance; advertisements, promotional materials and activities concerning medicines	DFDA			✓	✓	✓			
		Develop and roll out a mandatory licensure and accreditation system for all medicine outlets	DFDA					✓	✓		
		Advocate with the MoHS to address the human resource needs of the Drug Inspectorate at the central, state/regional and township levels	DFDA			✓	✓	✓	✓	✓	✓

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NMP Strategic Objective	**Strategy**	**Programme Component/Technical Activity**	**Responsibility**	**1**	**2**	**1**	**2**	**1**	**2**	**1**	**2**
To improve safety, efficacy and quality of all medicines; and to combat substandard and falsified medicines through strengthening regulation of medicines and quality assurance systems	Strengthening of market surveilance and quality assurance systems	Design and conduct trainings on market surveillance and quality assurance of medicnes at the central, regional and township levels	DFDA			✓	✓	✓	✓	✓	✓
		Design and roll out advocacy campaigns; enforcement of regulations to discourage and mitigate the use of unregistered medicines by health practitioners, i.e. clinicians, pharmacists, paramedics and sellers of traditional medicine	DFDA			✓	✓	✓	✓	✓	✓
		In collaboration with the customs and other relevant departments, establish surveillance, quality assurance and communication (rapid alert system) to mitigate the entry of illegal, falsified and substandard medicines at the borders	DFDA			✓	✓	✓	✓	✓	✓
To improve rational use of medicines	Promoting good clinical practices	Organize a national consultative workshop to discuss a comprehensive package of rational use interventions; essential health service packages in line with STGs; clearly define roles and responsibilities of different stakeholders	DMS/DPH			✓	✓				
		Draft and enforce regulations for prevention of perverse prescribing financial incentives	DMS/DPH/DFDA					✓			
		Strengthening and expanding the WHO problem-based pharmacotherapy training on "Guide to Good Prescribing"	DMS/DPH/DFDA					✓			
		Organize a national training workshop on "Guide to good prescribing" involving teachers of medical schools	DMS/DPH/DFDA						✓		
		Develop a formulary of essential medicines by updating the Myanmar Medicines Formulary for use at health facilities	DMS/DPH/DFDA			✓	✓	✓	✓		

Myanmar National Medicine Policy Implementation Plan 2018–2021				2018		2019		2020		2021	
NMP Strategic Objective	Strategy	Programme Component/Technical Activity	Responsibility	1	2	1	2	1	2	1	2
To improve rational use of medicines	Promoting good dispensing practices	Develop and enforce regulations on: (i) prescription-based dispensing ("No prescription = No medicines") except over-the-counter medicines; (ii) qualified person-based pharmacy ("No pharmacist = No pharmacy")	DFDA/DMS/DPH			✓	✓	✓	✓		
		Review, development and implementation of guidelines on good dispensing and pharmacy practices	DFDA/DMS/DPH			✓	✓				
		Develop an electronic prescription recording and dispensing tool and use of technology at health facilities and community pharmacies to promote counselling, feedback, treatment adherence of patients as well as mitigation of antimicrobial resistance	DFDA/DMS/DPH			✓	✓	✓	✓	✓	✓
		Promotion of the role of the pharmacist in community pharmacy	DFDA/DMS/DPH			✓	✓	✓	✓	✓	✓
		Develop and use an essential medicine information booklet for patients to be used by pharmacists	DFDA/DMS/DPH		✓	✓	✓				

Myanmar National Medicine Policy Implementation Plan 2018–2021				2018		2019		2020		2021	
NMP Strategic Objective	**Strategy**	**Programme Component/Technical Activity**	**Responsibility**	**1**	**2**	**1**	**2**	**1**	**2**	**1**	**2**
To improve rational use of medicines	Stewardship of rational use	Review, design and institutionalize rules, guidelines and operational procedures to establish pharmacy and therapeutic committees (PTCs) at the central and state/regional health departments; and secondary and tertiary hospitals at all levels of the health system	DMS/DPH		✓	✓	✓	✓			
		Establish PTCs and develop their capacity regarding the rules, guidelines and operational procedures at all levels	DMS/DPH		✓	✓	✓	✓			
		Define and roll out indicators to monitor availability and utilization of essential medicines and their compliance with STGs	DMS/DPH			✓	✓				
		Design and roll out a campaign to promote rational use of antibiotics and mitigate antimicrobial resistance	DMS/DPH			✓	✓	✓	✓	✓	✓
		Draft rules and advocate for bilingual labelling and leaflets to promote adherence	DFDA			✓	✓				
		Establish a drug information centre to improve access to unbiased information on medicines	DFDA			✓	✓	✓			
		Develop and disseminate electronic advocacy messages pertaining to the NMP, essential medicines, rational use and promotion of generic use in prescribing and dispensing	DFDA			✓	✓	✓	✓	✓	✓

Myanmar National Medicine Policy Implementation Plan 2018–2021				2018		2019		2020		2021	
NMP Strategic Objective	Strategy	Programme Component/Technical Activity	Responsibility	1	2	1	2	1	2	1	2
To strengthen human resource on medicine management in all departments of the health sector	Human resource organization	Review and design the organizational structure of all departments related to medicine management with clear scope and functions	DFA/DFDA/PSD/ DMS/DPH	✓	✓	✓	✓				
		Design clear hierarchy, roles and responsibilities of different posts within various departments related to medicine management	DFA/DFDA/PSD/ DMS/DPH	✓	✓	✓	✓				
		Conduct needs assessment to identify the gaps in terms of availability and capacity of human resource in various departments of medicine management	DFA/DFDA/PSD/ DMS/DPH			✓	✓				
		Advocate with the MoHS for additional staff on the basis of defined needs and skill-mix	DFA/DFDA/PSD/ DMS/DPH			✓	✓	✓	✓	✓	✓
	Human resource development	Review, develop and institutionalize the university curriculum for graduate and postgraduate students of pharmacy and other health-related disciplines to respond to the needs of the public and private sectors in medicine management	PSD/DFDA/DPH/ DMS		✓	✓	✓	✓			
		Develop a pre- and on-Job training curriculum and training methodolgies at various levels of the health system to respond to the professional development needs in medicine management			✓	✓	✓	✓	✓		
		Develop and roll out a training plan to improve the capacity and efficiency of human resource at all departments related to medicines at all levels					✓	✓	✓		

Myanmar National Medicine Policy Implementation Plan 2018–2021				2018		2019		2020		2021	
NMP Strategic Objective	Strategy	Programme Component/Technical Activity	Responsibility	1	2	1	2	1	2	1	2
		Develop and institutionalize a professional registration and certification mechanism for pharmacists, pharmacy technicians and dispensers				✓	✓	✓	✓		
	Performance management	Design and roll out a performance management and appraisal mehcanism for pharmacists, pharmacy technicians and dispensers at all levels of the health system	DFA/DFDA/PSD/ DMS/DPH			✓	✓	✓	✓		
To strengthen collaboration and coordination at all levels	Collaboration and coordination	Define roles for collaborative partners at the supervisory, middle management and senior management levels for implementation of the NMP	DMS, DPH	✓	✓	✓	✓	✓	✓	✓	✓
		Define monitoring indicators on accessibility, quality and utilization of essential medicnes for analysing the progress of implementation of the NMP	DMS, NIMU, DPH			✓	✓	✓	✓		
		Establish pooled data for exchange of information among all stakeholders and better decision-making	DMS, DPH			✓	✓	✓	✓	✓	✓
		Organize regular coordination meetings at the national, regional and township levels to address any barriers to implementation of the NMP where remedial action should be decided	DMS, DPH	✓	✓	✓	✓	✓	✓	✓	✓

Monitoring and Evaluation Plan for the National Medicine Strategy 2018–2021

Myanmar

I. Introduction

The Monitoring and Evaluation (M&E) plan of the National Medicine Strategy (NMS) 2018–2021 would serve all relevant stakeholders to assess the progress in implementation of the NMS. It includes core indicators for monitoring, review and evaluation of each of the five strategies[1] (Parts 1 and 2), and monitoring of progress/actions for achieving the targets in each of the strategies (Part 3).

Part 1 lists the proposed core indicators for each strategy. There are five core indicators proposed for each strategy. The selection of the core indicators is based on their crucial importance in the successful strategy implementation, and some of them should be monitored and reviewed for the National Health Plan and Sustainable Development Goals.

Part 2 shows the **template for core indicators for monitoring, review and evaluation**, with baseline for each indicator with year and data source, achievement in 2018 and targets for the years 2019 / 2020 / 2021 including data sources. This will also show reporting frequency, responsible agency for data collection and a reporting channel.

Part 3 is designed to monitor progress/detailed activities for achieving the targets (according to the NMS Implementation Plan), with selection of the appropriate Monitoring Code (1–5) by planning year and responsible agency. The starting date and the date of completion of the activity are indicated, which will help in the routine monitoring process. If required, making a comment to guide future action, or identifying constraints on achieving the target or implementing the activity can be indicated in the monitoring tool. The comments/evaluation section provides space to record any important factors that are constraining the actions, which require additional actions (such as negotiation or expertise) or need to be aligned with another activity.

As per the Implementation Plan of the NMS, there are 11 activities to implement Strategy 1; 18 activities to implement Strategy 2; 17 activities to implement Strategy 3; 8 to implement Strategy 4; and 4 activities to implement Strategy 5.

It is anticipated that this M&E plan will be used and periodically updated by the concerned central level agencies and at NMS coordination meetings.

1 **Strategy 1:** TO IMPROVE ACCESSIBILITY, AVAILABILITY, AFFORDABILITY AND PROCUREMENT AND SUPPLY MANAGEMENT OF ESSENTIAL MEDICINES
Strategy 2: TO IMPROVE QUALITY, SAFETY AND EFFICACY OF MEDICINES; MEDICINE REGULATION; AND THE QUALITY ASSURANCE SYSTEM
Strategy 3: TO IMPROVE RATIONAL USE OF MEDICINES AT ALL LEVELS
Strategy 4: TO STRENGTHEN HUMAN RESOURCE ON MEDICINE MANAGEMENT IN ALL DEPARTMENTS OF THE HEALTH SECTOR
Strategy 5: TO STRENGTHEN COLLABORATION, COMMUNICATION, COORDINATION AND EVALUATION OF NMP IMPLEMENTATION AT THE NATIONAL AND SUBNATIONAL LEVELS

II. Coordination mechanism and involvement of key agencies and stakeholders

The implementation of the NMS will be overseen and monitored by an NMS Coordination Committee led by the concerned departments of the MoHS, with involvement of subnational health structure representatives (regions/states and selected townships), the private sector, medical associations and major development partners. The involvement of the Division of Health Information in the monitoring process will help in data collection, validation and consistency.

III. Monitoring and reviews of progress and performance

Monitoring of implementation of activities will be conducted by the responsible agencies on a monthly basis, by using the templates of Part 3. The coordination meetings of the NMS will be held quarterly, to review the progress and to make all necessary directions for successful implementation of the activities.

Annual reviews of the progress and performance in NMS implementation will be conducted in conjunction with the Annual Joint Reviews of the health sector. The core indicators of Part 2 monitoring tool can be used in the reviews, and it will be an opportunity to take stock of progress made, to analyse what is working well and what is not, and to assess whether a reprioritization or some modification of directions is necessary.

Midterm review and end-of-strategy evaluation will be more extensive. Midterm review will address all targets and core indicators indicated in this M&E Plan of the NMS. The midterm review should coincide with the annual review (2020). The results can be used to adjust strategic activities. End-of strategy evaluation will be a comprehensive analysis of progress and performance for the entire period of the NMS. This evaluation will build upon the annual and midterm reviews.

Depending on the needs, different issues/priorities may be selected and addressed with varying levels of depth in annual reviews.

IV. Part 1. Core indicators for Monitoring, Review and Evaluation of the National Medicine Strategy 2018–2021

Core indicators for Strategy 1. To improve accessibility, availability, affordability and procurement and supply management of essential medicines

1.1	***Number of townships in which x% of health facilities have at least 80% of essential medicines and commodities kept in optimum stock levels*** *(National Health Plan indicator OP4)* *Definition*: Number of essential medicines considered to be explicitly specified; essential medicines and commodities as per the National Essential Medicines List; optimum stock to be understood as a stock level in between minimum and maximum stocks; minimum stock = minimum quantities (by month of stock) of stock defined for specific health facility; maximum stock = maximum quantities (by month of stock) of stock defined for specific health facility. *Data collection methodology*: Routine quarterly LMIS reports by health facilities and/or regular health facility survey.
1.2	***Proportion of population with access to affordable medicines and vaccines on a sustainable basis*** *(SDG indicator 3.b.1)* *Data collection methodology:* health facility and household surveys Periodicity: every three to five years
1.3	***Median consumer price ratio of selected essential medicines in public and private health facilities*** *Definition*: The ratio between median unit prices (e.g. price per tablet or therapeutic unit) and median international reference prices (*Management Sciences for Health*) for that exact product for the year preceding the survey. *Data collection methodology*: as per the above indicated national survey (under 1.1). *Periodicity*: every three to five years.
1.4	***Public and private per capita expenditure on medicines*** *Definition*: The reference indicator is total pharmaceutical expenditure (TPE). It may be defined as the total consumption of pharmaceuticals, regardless of the means of distribution, the place or condition of consumption or its type (prescription or over-the-counter). Per capita data are obtained from the whole population. As much as possible, this indicator is disaggregated into two components to reflect public and private sector financing. Public financing includes social security, private financing includes out-of-pocket spending, finances related to private insurance, NGOs, and corporations (excluding social security). *Data collection methodology*: Data on medicine expenditure can be obtained from the National Health Accounts (NHA). TPE should be the basis of estimation for this indicator. *Periodicity*: depends on collection of NHA data.
1.5	***Percentage of population covered by health insurance*** *Definition*: Numerator: number of people covered by health insurance. Denominator: total population *Data collection methodology*: Household survey

Core indicators for strategy 2.
To improve quality, safety and efficacy of medicines; medicine regulation; and the quality assurance system

2.1	***National Drug Law revised and enhanced*** The current National Drug Law lacks comprehensiveness and needs to be revised and upgraded. In particular, authorities of the drug inspectors may be clearly elaborated, and a drug inspectorate section should be established.
2.2	***A pharmacovigilance framework reviewed and updated*** This will include its regulations and operational procedures in the country.
2.3	***Pharmacovigilance unit established*** This will include the availability and capacity of human resources for pharmacovigilance activities at the central, regional and hospital levels.
2.4	***Setting up mandatory licensure and accreditation of pharmacies*** Addressing unlicensed and non-accredited medicine outlets
2.5	***ADR monitoring and safety surveillance system established*** For detection of any serious adverse reactions at an early stage for public safety

Core indicators for strategy 3.
To improve rational use of medicines at all levels

3.1	***Essential Medicine Formulary developed and implemented*** There is a need for an essential medicine formulary for independent and unbiased information on medicines.
3.2	***A comprehensive rational medicine use intervention package for health workers developed and implemented*** The package will be finalized and shared with all stakeholders at the consultative meeting.
3.3	***Pharmacy and Therapeutic Committees (PTCs) established at all levels*** It is particularly important for big hospitals to promote the rational, safe, effective and efficient use of essential medicines and to monitor adverse reactions.
3.4	***Mandatory licensure of all healthcare personnel*** This is mainly for ensuring the necessary competence in diagnosing prescribing and dispensing.
3.5	***A drug information centre established*** To improve access to unbiased information on medicines

Core indicators for strategy 4.
To strengthen human resource on medicine management in all departments of the health sector

4.1	***University curriculum for graduate and postgraduate students of pharmacy and other health-related disciplines institutionalized*** This is to respond to the needs of the public and private sectors in medicine management.
4.2	***Pre- and on-job training curriculum and training methodologies at various levels of health system developed*** This indicator relates to the professional development needs in medicine management.
4.3	***Performance management and appraisal mechanism for pharmacists, pharmacy technicians and dispensers designed and rolled out*** This is to monitor and review the quality of the relevant health personnel.
4.4	***Needs assessment of human resources in medicine management conducted*** It is important to identify the gaps in terms of availability and capacity of human resource in various departments of medicine management.
4.5	***The organizational structure of all departments related to medicine management reviewed and designed*** Clear scope and function to be indicated.

Core indicators for strategy 5.
To strengthen collaboration, communication, coordination and evaluation of nmp implementation at the national and subnational levels

5.1	***A mechanism for regular coordination of all stakeholders in medicine management established*** This should be created at the national, regional and township levels to address any barriers to implementation of the NMP.
5.2	***Roles of collaborative partners in implementation of the NMP defined*** These should be defined at the supervisory, middle management and senior management levels.
5.3	***Survey on baseline assessment on implementation of the NMP conducted*** Baseline data for some of the core indicators are needed to be obtained by the surveys.

Part 2. Monitoring, Review and Evaluation of Core Indicators

No.	Core Indicator	Baseline			Achievement 2018	Target			Data source	Reporting frequency	Responsible agency (data collection)	Reporting to
		Data	Year	Source		2019	2020	2021				
Strategy 1. To improve accessibility, availability, affordability and procurement and supply management of essential medicines												
1.1	Number of townships in which x% of health facilities have at least 80% of essential medicines and commodities kept in optimum stock levels (NHP indicator OP4)								LMIS / health facility survey	Quarterly / Annually	DPH - HIS	NMS Coordination Committee; NIMU; Annual Joint Review of the Health Sector
1.2	Proportion of the population with access to affordable medicines and vaccines on a sustainable basis (SDG indicator 3.b.1)								Household surveys; administration data	3–5 years	HIS; Central Statistical Office	NMS Coordination Committee; NIMU; Annual Joint Review of the Health Sector
1.3	Median consumer price ratio of selected essential medicines in public and private health facilities								Health facility survey	3–5 years	HIS	NMS Coordination Committee; NIMU; Annual Joint Review of the Health Sector

No.	Core Indicator	Baseline			Achievement 2018	Target			Data source	Reporting frequency	Responsible agency (data collection)	Reporting to
		Data	Year	Source		2019	2020	2021				
1.4	Public and private per capita expenditure on medicines								National Health Accounts (NHA)	When NHA updates available	Department of Finance; HIS	NMS Coordination Committee; NIMU; Annual Joint Review of the Health Sector
1.5	Percentage of population covered by health insurance								Household survey	2 years	HIS; Ministry of Interior; Central Statistical Office	NMS Coordination Committee; NIMU; Annual Joint Review of the Health Sector
Strategy 2. To improve quality, safety and efficacy of medicines; medicine regulation; and quality assurance system												
2.1	National Drug Law revised and enh anced	Existing Drug Law	valid from …	DFDA	National Drug Law revision and enhancement planned and discussed			December 2021	DFDA	Annually	DFDA	Annual Review of the Health Sector
2.2	Pharmaco-vigilance framework reviewed and updated	The first framework set up		DFDA			December 2020		DFDA/DPH/ DMS	Quarterly	DFDA/ DPH/DMS	NMS Coordination Committee
2.3	Pharmaco-vigilance Unit established.	Unit not set up	2017	DFDA	Establishment of the unit planned	December 2019			DFDA/DPH/ DMS	Quarterly	DFDA/ DPH/DMS	NMS Coordination Committee

No.	Core Indicator	Baseline			Achievement 2018	Target			Data source	Reporting frequency	Responsible agency (data collection)	Reporting to
		Data	Year	Source		2019	2020	2021				
2.4	Setting up a mechanism for mandatory licensure and accreditation of pharmacies	Licensure and accreditation of pharmacies not set up	2017	DFDA	Setting up a mechanism for mandatory licensure and accreditation of pharmacies planned		December 2020		DFDA	Quarterly	DFDA	NMS Coordination Committee
2.5	ADR monitoring and safety surveillance system established	No ADR monitoring system in place	2017	DFDA			December 2020		DFDA	Quarterly	DFDA	NMS Coordination Committee
Strategy 3. To improve rational use of medicines at all levels												
3.1	Essential Medicine Formulary developed and implemented	The Formulary not developed	2017	DMS/ DPH/ DFDA	Development of the Formulary planned		December 2020		DMS/DPH/ DFDA	Quarterly	DMS/DPH/ DFDA	NMS Coordination Committee
3.2	A comprehensive rational medicine use intervention package for health workers developed and implemented	The package not developed	2017	DMS/DPH	National workshop planned for December 2019		June 2020		DMS/DPH	Quarterly	DMS/DPH	NMS Coordination Committee
3.3	Pharmacy and Therapeutic Committees (PTC) established at all levels	PTCs not set up	2017	DMS/DPH	PTCs establishment planned for all levels		June 2020		DMS/DPH	Quarterly	DMS/DPH	NMS Coordination Committee

No.	Core Indicator	Baseline			Achievement 2018	Target			Data source	Reporting frequency	Responsible agency (data collection)	Reporting to
		Data	Year	Source		2019	2020	2021				
3.4	Mandatory licensure of all health-care personnel	Mandatory Licensure for all health-care personnel not fully implemented	2017	DMS				December 2021	DMS	Annually	DMS	Annual Joint Reviews of the Health Sector
3.5	Drug information centre established	Drug information centre not available	2017	DFDA	Drug Information Centre at the DFDA planned		June 2020		DFDA	Quarterly	DFDA	NMS Coordination Committee
Strategy 4. To strengthen human resource on medicine management in all departments of the health sector												
4.1	University curriculum for graduate and postgraduate students of pharmacy and other health-related disciplines institutionalized	The existing curriculum before review	2017	PSD			June 2020		PSD/DFDA/ DPH/DMS	Quarterly	PSD/DFDA/ DPH/DMS	NMS Coordination Committee; Joint Annual Review of the Health Sector
4.2	Pre- and on-job training curriculum and training methodologies at various levels of health system developed	Training methodologies not developed	2017	PSD			December 2020		PSD/DFDA/ DPH/DMS	Quarterly	PSD/DFDA/ DPH/DMS	NMS Coordination Committee; Joint Annual Review of the Health Sector

No.	Core Indicator	Baseline			Achievement 2018	Target			Data source	Reporting frequency	Responsible agency (data collection)	Reporting to
		Data	Year	Source		2019	2020	2021				
4.3	Performance management and appraisal mechanism for pharmacists, pharmacy technicians and dispensers designed and rolled out	No performance management mechanism introduced	2017	DFDA			December 2020		DFA/DFDA/ PSD/DMS/ DPH	Quarterly	DFA/DFDA/ PSD/DMS/ DPH	NMS Coordination Committee; Joint Annual Review of the Health Sector
4.4	Needs assessment of human resources in medicine management conducted	No human resource needs assessment conducted	2017	DMS/PSD	HR needs assessment planned	December 2019			DFA/DFDA/ PSD/DMS/ DPH	Quarterly	DFA/DFDA/ PSD/DMS/ DPH	NMS Coordination Committee; Joint Annual Review of the Health Sector
4.5	Organizational structure of all departments related to medicine management reviewed and designed		2017	DMS		December 2019			DFA/DFDA/ PSD/DMS/ DPH	Quarterly	DFA/DFDA/ PSD/DMS/ DPH	NMS Coordination Committee; Joint Annual Review of the Health Sector

No.	Core Indicator	Baseline			Achievement 2018	Target			Data source	Reporting frequency	Responsible agency (data collection)	Reporting to
		Data	Year	Source		2019	2020	2021				
Strategy 5. To strengthen collaboration, communication, coordination and evaluation of nmp implementation at the national and subnational levels												
5.1	A mechanism for regular coordination of all stakeholders in medicine management established	No mechanism in place	2017	DMS/DPH		June 2019			DMS/DPH	Annually	DMS/DPH	Joint Annual Review of the Health Sector
5.2	Roles of collaborative partners in implementation of the NMP defined					June 2019						Joint Annual Review of the Health Sector
5.3	Survey on baseline assessment on implementation of the NMP/NMS conducted	No survey conducted	2017	DPH	Survey in preparation	February 2019			HIS/DPH/ Ministry of Finance/ Ministry of Planning/ other relevant departments			

Part 3. Monitoring progress/actions

No.	Activity	Planned Start / Completion target	Monitoring Codes (1–5) 1. Not Started, 2. Started (+ month), 3. On Target, 4. Deferred (to year), 5. Achieved					Comments/evaluation
			2018	2019	2020	2021	(2022)	
Strategy 1. To improve accessibility, availability, affordability and procurement and supply management of essential medicines								
1.i	Development and institutionalization of governance mechanism (selection board and operational procedures) for selection of medicines at the central, regional and township levels	January 2018 / June 2019						Responsible: DMS/DPH
1.ii	Revision and categorization of the current NEML according to service delivery levels	July 2018 / December 2019						Responsible: DMS/DPH
1.iii	Development of STGs and protocols according to service delivery levels	July 2018 / December 2019						Responsible: DMS/DPH
1.iv	Implementation and advocacy of NEML, STGs and the protocols at the national and peripheral levels	January 2019 / December 2021						Responsible: DMS/DPH
1.v	Development and adoption of procurement guidelines (demand and supply planning, prequalification, purchase, quality assurance, payment and performance management) for the central, regional/state, township and hospital levels	July 2018 / December 2019						Responsible: PSD/DPH/DMS

No.	Activity	Planned Start / Completion target	Monitoring Codes (1–5) 1. Not Started, 2. Started (+ month), 3. On Target, 4. Deferred (to year), 5. Achieved					Comments/evaluation
			2018	2019	2020	2021	(2022)	
1.vi	National and state/regional "Medicine purchase price disparity" survey	January 2019 / December 2019						Responsible: PSD/DMS/DPH/ related departments
1.vii	Development and field-testing of a procurement price monitoring mechanism	January 2019 / June 2020						Responsible: DMS
1.viii	Development and implementation of forecasting and supply planning mechanism at the central, regional, township and hospital levels	July 2018 / December 2019						Responsible: PSD/DMS/DPH/ related departments
1.ix	Design and roll out of a framework for contracting, quality assurance and vendor performance management mechanism for purchase and delivery of medicines at the central, state/ regional and township levels	January 2019 / December 2021						Responsible: PSD/DPH/DMS
1.x	Establish a central and satellite pharmacy system to strengthen medicine storage and distribution in hospitals	July 2018 / December 2021						Responsible: PSD/DPH/DMS
1.xi	Develop and roll out an integrated logistics information management system at the central, regional and township levels	July 2018 / December 2021						Responsible: PSD/DPH/DMS
strategy 2. To improve quality, safety and efficacy of medicines; medicine regulation; and quality assurance system								
2.i	Review and update regulations and operational procedures on registration of medicines to ensure availability of safe, effective and quality assured medicines in Myanmar	July 2018 / December 2019						Responsible: DFDA

No.	Activity	Planned Start / Completion target	Monitoring Codes (1–5) 1. Not Started, 2. Started (+ month), 3. On Target, 4. Deferred (to year), 5. Achieved					Comments/evaluation
			2018	2019	2020	2021	(2022)	
2.ii	Conduct assessment of the registration department of the DFDA to identify gaps for improving its organizational structure of seven divisions; skill-mix; human resources availability and capacity; performance management and improvement mechanism	July 2018 / December 2019						Responsible: DFDA
2.iii	Advocate with the MoHS to increase the number of positions in the registration department of the DFDA to meet the existing and future needs	July 2018 / December 2019						Responsible: DFDA
2.iv	Develop and roll out a pre- and on-job professional development mechanism on registration of medicines	January 2019 / June 2020						Responsible: DFDA
2.v	Develop and roll out an integrated registration management information system to improve efficiency in registration/renewal of medicines	January 2019 / December 2020						Responsible: DFDA
2.vi	Conduct needs assessment of the network of quality control laboratories in terms of technology, technical capacity and resource availability to meet the quality control testing requirements at the central and regional levels for all essential medicines	July 2018 / December 2021						Responsible: DFDA
2.vii	Advocate with the MoHS to increase the number of positions at the central and regional level quality control laboratories	July 2018 / December 2021						Responsible: DFDA

No.	Activity	Planned Start / Completion target	Monitoring Codes (1–5) 1. Not Started, 2. Started (+ month), 3. On Target, 4. Deferred (to year), 5. Achieved					Comments/evaluation
			2018	2019	2020	2021	(2022)	
2.viii	Review and update the regulations, operational procedures and governing mechanism of the Department Quality Control of the DFDA	January 2019 / December 2020						Responsible: DFDA
2.ix	Review and update pharmaco-vigilance framework, regulations, operational procedures in the country	January 2019 / December 2020						Responsible: DFDA/DPH/DMS
2.x	Design and roll out an advocacy campaign on pharmacovigilance for health-care service providers, pharmaceutical manufacturers and importers	January 2020 / December 2021						Responsible: DFDA/DPH/DMS
2.xi	Design and roll out a roadmap to strengthen a pharmacovigilance information management system at the central, regional and hospital levels	January 2019 / December 2021						Responsible: DFDA/DPH/DMS
2.xii	Advocate with the MoHS to improve the availability and capacity of human resources for pharmacovigilance activities at the central, regional and hospital levels	January 2019 / December 2021						Responsible: DFDA/DPH/DMS
2.xiii	Review, update and roll out framework, regulations and operational procedures on market surveillance and quality assurance; advertisements, promotional materials and activities of medicines	January 2019 / June 2020						Responsible: DFDA

No.	Activity	Planned Start / Completion target	Monitoring Codes (1–5) 1. Not Started, 2. Started (+ month), 3. On Target, 4. Deferred (to year), 5. Achieved					Comments/evaluation
			2018	2019	2020	2021	(2022)	
2.xiv	Develop and roll out the mandatory licensure and accreditation system for all medicine outlets	January 2020 / December 2020						Responsible: DFDA
2.xv	Advocate with the MoHS to address the human resource needs of the Drug Inspectorate at the central, state/regional and township levels	January 2019 / December 2021						Responsible: DFDA
2.xvi	Design and conduct trainings on market surveillance and quality assurance of medicines at the central, regional and township levels	January 2019 / December 2021						Responsible: DFDA
2.xvii	Design and roll out advocacy campaigns; enforcement of regulations to discourage and mitigate the use of unregistered medicines by health practitioners, i.e. clinicians, pharmacists, paramedics and sellers of traditional medicine	January 2019 / December 2021						Responsible: DFDA
2.xviii	Establish surveillance, quality assurance and communication (rapid alert system) in collaboration with customs and other relevant departments, to mitigate the entry of illegal, falsified and substandard medicines at the borders	January 2019 / December 2021						Responsible: DFDA

No.	Activity	Planned Start / Completion target	Monitoring Codes (1–5) 1. Not Started, 2. Started (+ month), 3. On Target, 4. Deferred (to year), 5. Achieved					Comments/evaluation
			2018	2019	2020	2021	(2022)	
Strategy 3. To improve rational use of medicines at all levels								
3.i	National consultative workshop to discuss comprehensive package of rational use interventions; Essential Health Services Packages in line with STGs; clearly define roles and responsibility of different stakeholders	January 2019 / December 2019						Responsible: DMS/DPH
3.ii	Draft and enforce regulations on prevention of perverse prescribing financial incentives	January 2020 / June 2020						Responsible: DMS/DPH/DFDA
3.iii	Strengthening and expanding WHO problem-based pharmacotherapy training (*Guide to Good Prescribing*)	January 2020 / June 2020						Responsible: DMS/DPH/DFDA
3.iv	National training workshop on *Guide to Good Prescribing* involving teachers at the medical schools	July 2020 / December 2020						Responsible: DMS/DPH/DFDA
3.v	Develop an essential medicines formulary by updating the Myanmar Medicines Formulary for use at health facilities	January 2019 / December 2020						Responsible: DMS/DPH/DFDA
3.vi	Develop and enforce regulation on prescription-based dispensing ("No prescription = No medicines") except OTC medicines; Qualified person-based pharmacy ("No pharmacist = No pharmacy")	January 2019 / December 2020						Responsible: DFDA/DMS/DPH

No.	Activity	Planned Start / Completion target	Monitoring Codes (1–5) 1. Not Started, 2. Started (+ month), 3. On Target, 4. Deferred (to year), 5. Achieved					Comments/evaluation
			2018	2019	2020	2021	(2022)	
3.vii	Review, develop and implement guidelines on good dispensing and pharmacy practices	January 2019 / December 2019						Responsible: DFDA/DMS/DPH
3.viii	Develop an electronic prescription recording and dispensing tool and use of technology at health facility and community pharmacies to promote counselling and feedback of patients treatment adherence and mitigation of antimicrobial resistance	January 2019 / December 2021						Responsible: DFDA/DMS/DPH
3.ix	Promote the role of the pharmacist in community pharmacy	January 2019 / December 2021						Responsible: DFDA/DMS/DPH
3.x	Develop and use an essential medicines information booklet for patients to be used by pharmacists	July 2018 / December 2019						Responsible: DFDA/DMS/DPH
3.xi	Review, design and institutionalize rules, guidelines and operational procedures to establish Pharmacy and Therapeutic Committees (PTC) at the central and state/regional health departments; and secondary and tertiary hospitals at all levels of the health system	July 2018 / June 2020						Responsible: DMS/DPH
3.xii	Establish PTC and develop their capacity regarding the rules, guidelines and operational procedure at all levels	July 2018 / June 2020						Responsible: DMS/DPH

No.	Activity	Planned Start / Completion target	Monitoring Codes (1–5) 1. Not Started, 2. Started (+ month), 3. On Target, 4. Deferred (to year), 5. Achieved					Comments/evaluation
			2018	2019	2020	2021	(2022)	
3.xiii	Define and roll out indicators to monitor the availability of essential medicines, their utilization and compliance with STGs	January 2019 / December 2019						Responsible: DMS/DPH
3.xiv	Design and roll out a campaign to promote rational use of antibiotics and mitigate antimicrobial resistance	January 2019 / December 2021						Responsible: DMS/DPH
3.xv	Draft rules and advocate for bilingual labelling and leaflets to promote adherence	January 2019 / December 2019						Responsible: DFDA
3.xvi	Establish a drug information centre to improve access to unbiased information on medicines	January 2019 / June 2020						Responsible: DFDA
3.xvii	Develop and disseminate electronic advocacy messages pertaining to the NMP, essential medicines, rational use and promotion of generic use in prescribing and dispensing	January 2019 / December 2021						Responsible: DFDA
Strategy 4. To strengthen human resource on medicine management in all departments of the health sector								
4.i	Review and design organizational structure of all departments related to medicine management with clear scope and functions	January 2018 / December 2019						Responsible: DFA/DFDA/PSD/ DMS/DPH
4.ii	Design clear hierarchy, roles and responsibilities of different posts within various departments related to medicine management	January 2018 / December 2019						Responsible: DFA/DFDA/PSD/ DMS/DPH

No.	Activity	Planned Start / Completion target	Monitoring Codes (1–5) 1. Not Started, 2. Started (+ month), 3. On Target, 4. Deferred (to year), 5. Achieved					Comments/evaluation
			2018	2019	2020	2021	(2022)	
4.iii	Conduct needs assessment to identify the gaps in terms of availability and capacity of human resource in various departments of medicine management	January 2019 / December 2019						Responsible: DFA/DFDA/PSD/ DMS/DPH
4.iv	Advocate with the MoHS for additional staff on the basis of defined need and skill-mix	January 2019 / December 2021						Responsible: DFA/DFDA/PSD/ DMS/DPH
4.v	Review, develop and institutionalize the university curriculum for graduate and postgraduate students of pharmacy and other health-related disciplines to respond to the needs of the public and private sectors in medicine management	July 2018 / June 2020						Responsible: PSD/DFDA/DPH/ DMS
4.vi	Develop pre- and on-job training curriculum and training methodologies at various levels of the health system to respond to the professional development needs in medicine management	July 2018 / December 2020						Responsible: PSD/DFDA/DPH/ DMS
4.vii	Develop and roll out a training plan to improve the capacity and efficiency of human resource at all departments related to medicines at all levels	July 2019 / December 2020						Responsible: PSD/DFDA/DPH/ DMS
4.viii	Design and roll out a performance management and appraisal mechanism for pharmacists, pharmacy technicians and dispensers at all levels of the health system	January 2019 / December 2020						Responsible: DFA/DFDA/PSD/ DMS/DPH

No.	Activity	Planned Start / Completion target	Monitoring Codes (1–5) 1. Not Started, 2. Started (+ month), 3. On Target, 4. Deferred (to year), 5. Achieved					Comments/evaluation
			2018	2019	2020	2021	(2022)	
Strategy 5. To strengthen collaboration, communication, coordination and evaluation of nmp implementation at the national and subnational levels								
5.i	Define roles for collaborative partners at the supervisory, middle management and senior management levels for implementation of the NMP	January 2018 / December 2021						Responsible: DMS, DPH
5.ii	Define monitoring indicators on accessibility, quality and utilization of essential medicines for analysing progress of implementation of the NMP	January 2019 / December 2020						Responsible: DMS, NIMU, DPH
5.iii	Establish pooled data for exchange of information among all stakeholders and better decision-making	January 2019 / December 2021						Responsible: DMS, DPH
5.iv	Regular coordination meetings at the national, regional and township levels to address any barriers to implementation of the NMP where remedial action should be decided	January 2018 / December 2021						Responsible: DMS, DPH

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