



**THE REPUBLIC OF THE UNION OF MYANMAR**  
**Ministry of Health and Sports**

**NATIONAL MEDICINES POLICY**

**June 2019**





**THE REPUBLIC OF THE UNION OF MYANMAR**  
**Ministry of Health and Sports**

**NATIONAL MEDICINES POLICY**

**June 2019**



# Contents

- Acknowledgements..... v
- Foreword..... ix
- Executive Summary..... xi
- I. Introduction..... 1
- II. Goal, mission and objectives..... 1
- III. Elements of national medicine policy ..... 2
  - Strategic area 1: Accessibility, availability, affordability and procurement – supply management of essential medicines ..... 2
  - Strategic area 2: Quality, safety and efficacy of medicines; medicine regulations; and quality assurance system..... 5
  - Strategic area 3: Rational use of medicines..... 9
  - Strategic area 4: Strengthening human resource for management of medicines in all departments of the health sector ..... 10
  - Strategic area 5: Collaboration, coordination and evaluation..... 10
- IV. Annex..... 12
  - I. Glossary..... 12
  - II. Technical working groups – terms of reference and members..... 14
  - III. Bibliography ..... 15



# Acknowledgements

The development of the Myanmar National Medicines Policy 2018 was led by the Department of Medical Services with extensive contribution from a Technical Working Group (TWG) appointed by H.E. Union Minister of Health and Sports. The TWG comprised the following:

## Department of Medical Services

- (1) Dr Thida Hla, Deputy Director General (Medical Care)
- (2) Dr Win Naing, Deputy Director General (Procurement and Supply)
- (3) Dr Myat Wanna Soe, Head of Naypyitaw Health Services Department
- (4) Dr Yin Thandar Lwin, Central Level Hospitals Coordinator, MS, Retired Service Personnel's Hospital
- (5) Dr Kyaw Soe Min, Director (Procurement)
- (6) Dr Soe Naing, Director (Supply)
- (7) Dr Win Thein, Director, National Health Laboratory
- (8) Dr Khin Thidar Aye, Deputy Director (Supply), Central Medical Store Depot, Yangon
- (9) Dr Ywel Nu Nu Khin, Deputy Director, Project Manager, MEMP
- (10) Dr Ye Wint Kyaw, Assistant Director (Procurement)
- (11) Dr Phyu Phyu Win, MS, Leway (100-bedded) Township Hospital

### **Department of Public Health**

- (1) Dr Thaung Hlaing, Deputy Director General (Public Health)
- (2) Dr Tun Tin, Director (CD)
- (3) Dr Kyaw Kan Kaung, Director (NCD)
- (4) Dr Marlar Soe, Director (Procurement)

### **Department of Food and Drug Administration**

- (1) Dr Htin Linn, Deputy Director General (Headquarters)
- (2) Dr Theingi Zin, Director (Medicines)

### **Department of Human Resources Management for Health**

- (1) Dr Zaw Linn Aung, Professor and Head, Medicines Department, University of Medicine-1, Yangon
- (2) Dr Nu Nu Aye, Professor and Head, Pharmacology Department, University of Medicine-1, Yangon
- (3) Dr Cho Yee Myint, Assistant Professor and Head, Department of Pharmaceutics, University of Pharmacy, Mandalay

### **University of Traditional Medicine**

- (1) U Win Soe, Assistant Professor and Head, University of Traditional Medicine, Mandalay
- (2) Daw Kyi Kyi Oo, Research Scientist, University of Traditional Medicine



## **Ministry of Health and Sports**

- (1) Dr Phyu Win Thant, Assistant Director, NIMU

## **INGO**

- (1) Dr Moe Kyaw Kyaw, Health Director, PSM
- (2) WHO Policy Consultant
- (3) Country Director, UNICEF

In addition to several rounds of internal discussions, the TWG also had consultations with other stakeholders both within and outside the MoHS including NGOs and development partners, and their inputs are acknowledged with thanks. Finally, technical and financial support from WHO in facilitating discussions and development of the documents is noted.



## FOREWORD

The National Health Plan (NHP) 2017-21 has underlined medicines (as a component of Infrastructure) as one of the four Pillars for progress on Universal Health Coverage (UHC). The health-related Sustainable Development Goals (SDGs) too recognize that without access to essential medicines for all, countries shall not be able to progress towards achieving the health-related SDGs.

The Ministry of Health and Sports has made notable efforts to improve access to medicines, including strengthening of procurement and supply chain management. However, significant challenges remain in some key areas such as accessibility, availability and affordability of essential medicines; safety, efficacy and quality of all medicines to combat substandard and falsified medicines; and rational use of medicines.

The urgency to address these challenges requires updating and finalization of National Medicines Policy (2015) and, importantly, the development of a Strategy and Implementation Plan. For this, a Technical Working Group (TWG) with representatives from relevant Departments of Ministry of Health and Sports was formed. The TWG had consultations with officials from other departments as well as a wider group of stakeholders including NGOs for revision and finalization of National Medicines Policy (2015). This inclusive process provided insights from all actors and their continued support will be critical for successful implementation of the Strategy.

It is to be emphasized that Policy and Strategy should be realistic, all-inclusive and feasible. I am pleased to note the inclusion of an Implementation Plan that provides systematic guidance to operationalization the five strategic areas of the Policy and Strategy to address main challenges, including human resources needs.

A policy without implementation has no value. Therefore, Policy Implementation Plan (2018-2021) was developed and linked with NHP (2017-2021) to ensure reliable supply of safe and good quality medicines. The purpose is to use medicines rationally by health care providers and consumers to support better health services and improved health outcomes of Myanmar People.

The Myanmar National Medicines Policy and Strategy (2018-2021) shall be the reference document for equitable access and rational use of safe, efficacious and good quality medicines in Myanmar. I encourage all partners to collaborate fully with its implementation to advance Universal Health Coverage (UHC) in Myanmar.

MH  
19.6.19  
Dr Myint Htwe

Union Minister

Ministry of Health and Sports



# Executive Summary

This document is prepared in two sections: a National Medicine Policy (NMP) 2018 and a National Medicine Strategy 2018–2021 with an Implementation Plan and Monitoring and Evaluation Framework.

## Section I – National Medicine Policy

The NMP 2018 and its corresponding Implementation Plan 2018–2021 have been developed as part of the National Health Plan 2017–2021 to support the goals of the Universal Health Coverage (UHC) Policy, based on primary health care (PHC) through health system strengthening. Three Technical Working Groups (TWGs) were appointed by the Ministry of Health and Sports (MoHS): on Access and Supply Chain Management; on Safety, Quality and Regulations; and on Rational Use of Medicines. The review and revision of the NMP were undertaken through a consultative process by the three TWGs and involving all MoHS stakeholders for addressing the current situation and challenges regarding medicines.

### Goal, mission and objectives

**Goal** – Health for all the people of Myanmar

**Mission** – Equitable access to good quality essential medicines and their rational use by health-care providers and consumers to support better health services and improved health outcomes for the people of Myanmar

**Objectives** –

- (1) To ensure accessibility, availability and affordability of essential medicines

- (2) To ensure safety, efficacy and quality of all medicines and to combat substandard and falsified medicines
- (3) To promote rational use of medicines.

## Strategic areas and elements of NMP 2018

The NMP 2018 (see Part I) are divided into five strategic areas covering 23 policy elements, namely

- (1) **Strategic area 1 on improving accessibility, availability, affordability and procurement of essential medicines** to cover components: (1) selection of essential medicines; (2) procurement, distribution and storage; (3) local production; (4) affordable pricing and generics; (5) sustainable and efficient financing; and (6) medicine donation.
- (2) **Strategic area 2 on improving quality, safety and efficacy of medicines, combating substandard and falsified medicinal products** to cover components: (7) Medicines Regulatory Authority; (8) regulations of medicinal products registration; (9) manufacturing regulations; (10) quality assurance regulations and combating substandard and falsified medicinal products; (11) safety surveillance – pharmacovigilance; (12) separating prescribing from dispensing; (13) regulations for medicine marketing and promotion; and (14) regulations of traditional medicines.
- (3) **Strategic area 3 on improving rational use of medicines among health-care providers and the general public** to cover elements: (15) promoting rational use among health-care providers and the general public; (16) hospital medicine or pharmacy and therapeutic committee; and (17) drug information centre.

- (4) **Strategic area 4 on strengthening human resource in management of medicine in all departments of the health sector** to cover elements: (18) human resource needs in the medicine sector; and (19) code of conduct.
- (5) **Strategic area 5 on collaboration, coordination and evaluation between stakeholders to improve the implementation of the NMP** to cover elements: (20) medicine policy coordination; (21) collaboration on operational research; (22) technical cooperation; and (23) monitoring and evaluation.

## Section II – National Medicine Strategy 2018–2021

The **Strategy** consists of recommended actions that need to be undertaken to deal with specific current issues and challenges identified during the situation analysis under each of the five areas mentioned above. Relevant feasible actions are then selected and plotted into a realistic **Implementation plan with a Monitoring and Evaluation Framework**.

### Key Recommendations

- (1) The NMP 2018 and its Strategic Implementation Plan 2018–2021 of the Republic of the Union of Myanmar should be widely disseminated among all stakeholders, both in the public and private sectors, at the national and subnational levels, and from within and beyond the MoHS.
- (2) Monitoring of the implementation of the NMP 2018 and its Strategic Implementation Plan 2018–2021 has to be undertaken regularly, using relevant indicators on availability, affordability, rational use of medicines, and last

but not the least the legality and the quality of products in the market.

- (3) A forum for coordination, collaboration and communication at the national, regional and township levels has to be organized periodically to review the progress of implementation of the NMP based on the monitoring data on availability, affordability, quality as well as use of medicines.



## I. Introduction

The Government of the Republic of the Union of Myanmar is committed to the goal of health for all where the entire community can have equitable access to quality health care leading to an economically and socially productive country. The National Health Plan (NHP 2017–2021) (1) highlights Myanmar’s vision of the Universal Health Coverage (UHC) Policy based on primary health care (PHC) and orientated to health systems strengthening. An essential package of health services has been identified, to be rolled out in three phases aligned with the five-year cycle of the NHP, i.e. a progressive realization of UHC through delivery of successive basic, intermediary and comprehensive packages. Keeping in perspective the significance of essential medicines and vaccines as well as their appropriate usage, the government identified the prerequisite to review and revise the National Medicine Policy (NMP) and a corresponding Implementation Strategy (2018–2021). Three Technical Working Groups (TWGs) were appointed by the Ministry of Health and Sports (MoHS) on: (i) access and supply chain management; (ii) safety, quality and regulations; and (iii) rational use of medicines. The review and revision were undertaken through a consultative process with the MoHS and all stakeholders to address the current situation and challenges in the medicine sector.

## II. Goal, mission and objectives

**Goal** – Health for all the people of Myanmar

**Mission** – Equitable access to good quality essential medicines and their rational use by health-care providers and consumers to support better health services and improved health outcomes for the people of Myanmar

## Objectives

- (1) To ensure accessibility, availability and affordability of essential medicines
- (2) To ensure safety, efficacy and quality of all medicines and to combat substandard and falsified medicines
- (3) To promote rational use of medicines.

## III. Elements of national medicine policy

### Strategic area 1: Accessibility, availability, affordability and procurement – supply management of essential medicines

#### 1. *Selection of essential medicines*

- 1a The provision of medicines in all health-care facilities should be based on the essential medicines list.
- 1b The selection of essential medicines shall be based on the evidence of therapeutic efficacy, safety, quality, cost and morbidity patterns in Myanmar and linked with standard treatment guidelines.
- 1c The selection and revision of essential medicines shall be undertaken by a special task force appointed by the MoHS.

#### 2. *Procurement, distribution and storage*

- 2a The government shall strengthen the procurement, distribution, storage and management systems at all levels of health-care services.

- 2b An effective coordination mechanism for procurement and distribution between the national, regional, state health authorities and hospitals shall be established.
- 2c Medicines shall be procured from both local and foreign sources; however, quality assured affordable local generics shall be preferred.
- 2d Guidelines for good practices for distribution, inventory management and monitoring shall be developed and pursued.
- 2e. Good storage practices shall be adopted and implemented by the public and private sectors as specified in the National Drug Law and Drug Law Notification No. 5/93. The MoHS shall ensure the development and implementation of national guidelines for safe disposal and management of pharmaceutical waste and environmental protection.

### **3. *Local production***

The government will encourage local production of essential medicines to meet the domestic needs, including the production of vaccines and antisera.

### **4. *Affordable pricing and generics***

- 4a The government shall exercise control over the markup margins for medicines prices and review them regularly.
- 4b Procurement prices at the central and all regional, state health authority and hospitals shall be monitored and an effective mechanism for collective price negotiation and procurement shall be pursued at the national level.

- 4c The government shall encourage production, marketing, prescribing and dispensing of generic medicines. If a drug is marketed under a brand name, the generic name must be displayed prominently on the label.
- 4d Generic substitution shall be allowed as part of the policy, when feasible.
- 4e The Government of Myanmar will continue its obligation to comply with the multilateral/bilateral international agreements related to protection of patents in medicines. However, in the interest of equitable access to essential medicines, public health safeguards could be instituted in line with national legislation.

## **5. Sustainable and efficient financing**

- 5a The Government of Myanmar shall provide funding for the cost of medicines and services covered in the essential package of health services while mobilizing possible resources.
- 5b In line with the Myanmar National Health Financing Strategy, the government shall provide the mechanism for social health insurance and reimbursement to cover the cost of medicines to minimize out-of-pocket expenditure.

## **6. Medicine donation**

- 6a Donated medicines shall be need-based, quality assured and comply with the essential medicines list, and labelled in user-friendly language.
- 6b The government shall develop and implement comprehensive guidelines for donation of medicines.

## **Strategic area 2: Quality, safety and efficacy of medicines; medicine regulations; and quality assurance system**

### **7. *Medicines regulatory authority***

- 7a In accordance with the National Drug Law (1992), the Department of Food and Drug Administration under the MoHS, established in 1995, is the designated agency for the regulation of food and medicines in Myanmar.
- 7b The government shall support the strengthening of the Department of Food and Drug Administration in discharging its regulatory functions.
- 7c The National Drug Law shall be revised and updated periodically.

### **8. *Regulations of medicinal products registration***

- 8a All medicines marketed and used in Myanmar must be registered with the Department of Food and Drug Administration of the MoHS, on the basis of evaluation of evidence of safety, efficacy, quality and needs. Registration of medicines is valid for a period of five years. The medicines will be re-evaluated for safety, efficacy, quality and needs upon re-registration.
- 8b Import, distribution and sales of medicines must be done only by registered importers, distributors and retailers.
- 8c Illegal and unregistered products shall be confiscated by the authorities.

## **9. *Manufacturing regulations***

- 9a Production of medicines must be undertaken only by licensed manufacturers under the supervision of qualified personnel. The Department of Food and Drug Administration is authorized to grant licences for manufacturing.
- 9b All pharmaceutical manufacturers must adhere to the guidelines for current Good Manufacturing Practices (cGMP).

## **10. *Quality assurance regulations and combating substandard and falsified medicinal products***

- 10a The Department of Food and Drug Administration of the MoHS shall maintain and reinforce the legal, regulatory and technical aspects of the quality assurance system.
- 10b Substandard and falsified medicinal products shall be confiscated and appropriate regulatory action shall be taken.
- 10c Infrastructure of the national and subnational quality control laboratories including reference laboratories shall be strengthened. In addition, a drug inspectorate and enforcement section will be set up with adequate trained staff and facilities.
- 10d Collaborative mechanisms to mitigate the illegal points of entry shall be devised.

## **11. *Safety surveillance – pharmacovigilance***

- 11a A safety surveillance system in compliance with the Good Pharmacovigilance Practices (GPV) and regulations shall be

developed and implemented by the Department of Food and Drug Administration of the MoHS.

- 11b The MoHS shall establish a national pharmacovigilance centre under the Department of Food and Drug Administration.
- 11c The government shall ensure that pharmaceutical manufacturers and importers have mandatory pharmacovigilance centres for acquiring aggregate data of all authorized medicinal products and sharing database with the national pharmacovigilance centre.
- 11d Hospitals shall have pharmacovigilance units for recording and processing Individual Case Safety Reports (ICSRs), on standardized formats to be reviewed by the national pharmacovigilance centre.
- 11e Health service providers are to be encouraged to make timely and thorough reports to the surveillance system in case of adverse reactions.
- 11f The Department of Food and Drug Administration shall enable appropriate advocacy, communication and collaboration among stakeholders for effective pharmacovigilance.

## **12. *Separating prescribing from dispensing***

- 12a Prescribers are medically qualified personnel who are legally authorized to write a prescription.
- 12b Dispensers are pharmacists who are legally authorized to dispense prescribed medicines.

- 12c Regulations shall be devised to prohibit prescribers from dispensing. Special permissions may be granted for resource-scarce rural areas.
- 12d Licensing of medicine outlets shall be mandatory.
- 12e Guidelines for Good Dispensing Practices shall be developed and implemented; while Good Pharmacy Practices (GPP) shall be revised and continue to be reinforced.

### **13. *Regulations for medicine marketing and promotion***

- 13a The Department of Food and Drug Administration of the MoHS shall exercise control over advertisements of medicines as per Notification No. 7/93 of the Drug Law.
- 13b Regulations defining promotional materials/activities shall be devised and implemented.

### **14. *Regulations of traditional medicines***

- 14a The Department of Traditional Medicines under the MoHS is responsible for registration, manufacturing, marketing, monitoring, quality testing and evaluation of traditional medicines according to the Traditional Drug Law enacted in 1996, which ordains that the manufacturers and distributors shall comply with the law.
- 14b Regulations shall be devised to prevent the adulteration of traditional medicines with Western medicinal ingredients and to prohibit production of injectable preparations. The regulations shall prevent unproven and unrealistic claims of efficacy.
- 14c Proper quality testing must be undertaken to detect any contamination with toxic substances such as arsenic and mercury.



## **Strategic area 3: Rational use of medicines**

### **15. *Promoting rational use among health-care providers and the general public***

- 15a The MoHS in collaboration with other stakeholders shall undertake continuous promotion of rational use of medicines by all means.
- 15b The MoHS shall ensure that all health-care providers have the licence and necessary competence with regard to diagnosing, prescribing and dispensing.
- 15c Regulations for prevention of perverse financial incentives for prescribing shall be devised and implemented.
- 15d The MoHS shall implement the Antibiotic Stewardship Programme (ASP).
- 15e The MoHS shall effectively educate the general public on rational use of medicines.

### **16. *Hospital medicine or pharmacy and therapeutic committee***

A multidisciplinary medicines/pharmacy and therapeutic committee shall be established at all hospitals to monitor the use of medicines and promote their rational use.

### **17. *Drug information centre***

A drug information centre shall be established by the MoHS to provide information on safe and effective use of therapeutic and diagnostic pharmaceuticals among health-care professionals and the general public.

## **Strategic area 4: Strengthening human resource for management of medicines in all departments of the health sector**

### ***18. Human resource needs in the medicine sector***

The MoHS shall assess the human resource requirement in the health sector, in line with the Human Resource for Health (HRH) Strategy.

### ***19. Code of conduct***

Guidelines on good governance, transparency, management of conflicts of interest and code of ethical conduct shall be introduced to officials and staff. The guidelines should be in line with the Civil Services Code of Conduct rules, which are integrated with the current NMP.

## **Strategic area 5: Collaboration, coordination and evaluation**

### ***20. Medicine policy coordination***

An effective mechanism of coordination involving relevant stakeholders and the MoHS shall be developed and implemented at all levels to address the problems in procurement, supply, availability, quality, safety, surveillance and utilization of medicines.

### ***21. Collaboration on operational research***

The MoHS shall facilitate collaboration with academic, health and research institutions for facilitating the implementation of the NMP.

## **22. *Technical cooperation***

- 22a The government shall encourage multifaceted technical cooperation in the pharmaceutical sector with other countries including the ASEAN countries, and encourage harmonization of regulations in national interest.
- 22b Technical cooperation shall be facilitated between the MoHS and allied ministries.

## **23. *Monitoring and evaluation***

The progress of implementation of the NMP shall be monitored periodically, and practical indicators for availability, quality and utilization of medicines shall be collected.

## IV. Annex

### I. Glossary

**Adverse drug reaction (ADR):** a response to a drug, which is noxious (harmful) and unintended, and which occurs at doses normally used in humans for prophylaxis, diagnosis or therapy of disease, or for modifying some physiological function (2).

**Antibiotics:** medicines used to prevent and treat bacterial infections (3).

**Code of conduct:** a set of conventional principles and expectations that are considered binding on any person who is a member of a particular group (4).

**Distribution:** the mechanism of procuring, purchasing, holding, storing, selling, supplying, importing, exporting or movement of pharmaceutical products, with the exception of dispensing or providing pharmaceutical products directly to patients or their agents/relatives (5).

**Essential medicines** satisfy the priority health-care needs of the population; they are selected for their relevance to public health, evidence on efficacy and safety and comparative cost-effectiveness (6).

**Falsified medicines:** medicinal products that deliberately/fraudulently misrepresent their identity, composition or source (7).

**Good distribution practice (GDP):** part of quality assurance to ensure that the quality of a pharmaceutical product is maintained by adequate control throughout the numerous activities that occur during the distribution process (5).

**Good manufacturing practice (GMP):** part of quality assurance to ensure that pharmaceutical products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization (8).

**Good storage practice (GSP):** part of quality assurance to ensure that the quality of pharmaceutical products is maintained by means of adequate control throughout their storage (9).

**Hospital pharmacy:** a health-care service that comprises the art, practice and profession of choosing, preparing, storing, compounding and dispensing pharmaceuticals and medical devices, advising health-care professionals and patients on their safe, effective and efficient use (11).

**Manufacture:** all operations of purchase of materials and products, production, packaging, labelling, quality control, release, storage and distribution of pharmaceutical products, and control of related activities (5).

## **Medicine**

- a. a substance or combination of substances presented as having properties for treating or preventing disease in humans.
- b. a substance or combination of substances that may be used in or administered to humans either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or for making a medical diagnosis (10).

**National pharmacovigilance centre:** a government-recognized centre (or integrated system) within a country with the clinical and scientific expertise to collect, collate, analyse and give advice on all information related to drug safety (11).

**Pharmacovigilance:** the science and activities related to the detection, assessment, understanding and prevention of adverse drug effects or any other possible drug-related issues (12).

**Polypharmacy:** the administration of many medicines at the same or the administration of an excessive number of medicines (10).

**Quality assurance:** a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the aim of ensuring that pharmaceutical products are of the quality required for their intended use (13).

**Quality control:** all measures taken, including the setting of specifications, sampling, testing and analytical clearance, to ensure that raw materials, intermediates, packaging materials and finished pharmaceutical products conform to established specifications for identity, strength, purity and other characteristics (5).

**Rational use of medicines:** patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community (14).

**Substandard medicines:** also called “out of specification”; these are authorized medical products that fail to meet either their quality standards or specifications, or both (7).

**Traditional medicine:** the sum total of the knowledge, skill and practices based on theories, beliefs and experiences indigenous to different cultures, whether

explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness (15).

**Unregistered/unlicensed:** medicinal products that have not undergone evaluation and/or approval by the national regulatory authority for the market in which they are marketed, distributed or used, subject to conditions permitted under national or regional regulation and legislation (7).

**Vaccine:** a biological preparation that improves immunity to a particular disease (16).

## II. Technical working groups – terms of reference and members

### A. Terms of reference – Technical Working Group on Access and Supply Chain Management

- (1) To undertake situational analysis (SARA) and collect updated information related to access, supply, availability and affordability of medicines
- (2) To identify policy, strategies, major priorities and interventions related to access, supply, availability and affordability of medicines
- (3) To review and update the draft NMP and strategic plan based on the situational analysis and priorities
- (4) To assess the need for human resource in pharmaceuticals in respective areas and to recommend a mechanism for coordination
- (5) To report to the MoHS Executive Committee on the revised draft NMP and strategic plan.

### B. Terms of reference – Technical Working Group on Quality, Safety and Regulations

- (1) To undertake situational analysis GBT for Food and Drug Administration and collect updated information related to quality and safety including quality assurance during procurement
- (2) To identify priorities IDP of Food and Drug Administration and interventions related to quality and safety of medicines
- (3) To review and update the draft NMP and strategic plan based on the situational analysis and priorities

- (4) To assess the need for human resource in pharmaceuticals in respective areas and to recommend a mechanism for coordination
- (5) To report to the MoHS Executive Committee on the revised draft NMP and strategic plan.

**C. Terms of reference – Technical Working Group on Selection and Rational Use**

- (1) To undertake situational analysis (SARA) and collect updated information related to the selection and utilization of medicines and their rational use
- (2) To identify major priorities and interventions related to the selection and rational use of medicines
- (3) To review and update the draft NMP and strategic plan based on the situational analysis and priorities
- (4) To assess the need for human resource in pharmaceuticals in respective areas and to recommend a mechanism for coordination
- (5) To report to the MoHS Executive Committee on the revised draft NMP and strategic plan.

### III. Bibliography

National Health Plan (2017–2021); December 2016 (<http://mohs.gov.mm/Main/content/publication/national-health-plan-2017-2021-eng>, accessed 8 March 2019).

WHO Technical Report no 498, WHO International Drug Monitoring, The role of National Centers. Geneva: the institute; 1972.

World Health Organization antibiotic resistance (website). WHO (<http://www.who.int/news-room/fact-sheets/detail/antibiotic-resistance>, accessed 8 March 2019).

English\_Glossary.pdf. WHO ([http://www.who.int/medicines/areas/coordination/English\\_Glossary.pdf](http://www.who.int/medicines/areas/coordination/English_Glossary.pdf), accessed 8 March 2019).

WHO Good Distribution Practices for Pharmaceutical Products. WHO Technical Report Series, No. 957, 2010, Annex 5. Ethiopia. Essential Medicines and Health Products Information Portal, a World Health Organization resource (website) (<http://apps.who.int/medicinedocs/en/m/abstract/Js18678en/>, accessed 8 March 2019).

WHO Health Topics, Essential medicines (website). WHO. ([http://www.who.int/topics/essential\\_medicines/en/](http://www.who.int/topics/essential_medicines/en/), accessed 8 March 2019).

WHO Essential medicines and health products. Definitions of Substandard and Falsified (SF) Medical Products (website). WHO. (<http://www.who.int/medicines/regulation/ssffc/definitions/en/>, accessed 8 March 2019).

WHO, Biologicals Good Manufacturing Practices (website). WHO. ([http://www.who.int/biologicals/vaccines/good\\_manufacturing\\_practice/en/](http://www.who.int/biologicals/vaccines/good_manufacturing_practice/en/), accessed 8 March 2019).

Guideline for Good Storage Practices, Good Distribution Practice, and Pharmaceutical Product Recall. First edition, September 2015 – Ethiopia. Essential Medicines and Health Products Information Portal, a World Health Organization resource (website) (<http://apps.who.int/medicinedocs/en/m/abstract/Js23059en/>, accessed 8 March 2019).

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies. (<http://whocc.goeg.at/>, accessed 8 March 2019).

The importance of pharmacovigilance – safety monitoring of medicinal products: glossary. Essential Medicines and Health Products Information Portal, a World Health Organization resource (website). WHO (<http://apps.who.int/medicinedocs/en/d/Js4893e/9.html>, accessed 8 March 2019).

WHO pharmacovigilance indicators: a practical manual for the assessment of pharmacovigilance systems. WHO and iris (website). WHO (<http://apps.who.int/iris/handle/10665/186642>, accessed 8 March 2019).

World Health Organization, editor. Quality assurance of pharmaceuticals: a compendium of guidelines and related materials. Volume 2: Good manufacturing practices and inspection. Second updated edition. Geneva: World Health Organization; 2007: p.409.

WHO, Essential medicines and health products. The pursuit of responsible use of medicines: sharing and learning from country experiences (website). WHO ([http://www.who.int/medicines/areas/rational\\_use/en/](http://www.who.int/medicines/areas/rational_use/en/), accessed 8 March 2019).

WHO, Traditional, complementary and integrative medicine. WHO traditional medicine strategy: 2014–2023 (website). WHO ([http://www.who.int/traditional-complementary-integrative-medicine/publications/trm\\_strategy14\\_23/en/](http://www.who.int/traditional-complementary-integrative-medicine/publications/trm_strategy14_23/en/), accessed 8 March 2019).

WHO, Health topics. Vaccines (website). WHO (<http://www.who.int/topics/vaccines/en/>, accessed 8 March 2019).