THE PHILIPPINE MEDICINES POLICY

Strategic Directions on Access to Medicines for Filipinos 2011-2016
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**Philippine Medicines Policy**

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Philippine Pharmaceutical Association (PPHA)
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Lastly, we would like to dedicate this document to Ms. Luzviminda O. Marquez, one of our dear mentors who continue to be a major influence in the work of DOH- NCPAM.
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MESSAGE

The Philippine Medicines Policy is an instrument of commitment for ensuring access to essential medicines of assured safety and quality for all. As a goal, it commits to prioritize medium to long-term goals set by the government for the pharmaceutical sector which will also identify the main strategies to attain them.

Reliable access to quality medicines is now considered a fundamental part of the human right to health. Over the course of several years, the Department of Health has developed several policies related to improving access to medicines. Despite these, access to essential medicines remains difficult for a lot of Filipinos. Millions suffer from complications of diseases due to lack of access to cost-effective and essential medicines. Problems to access can be due to unavailability, high cost, as well as lack of facilities and trained health personnel. The piecemeal approach to health reform has not addressed the problem of access and availability. To ensure a comprehensive approach, the DOH has come up with the Philippine Medicines Policy which shall complement the strategic thrusts of the Universal Health Care agenda.

The Department of Health in the Philippines has taken a bold step in improving access to medicines in developing and establishing a National Medicines Policy for the country. This will not only ensure access to medicines but also promote partnership with the industry, private sector, health professionals, patients and the health sector as a whole geared towards shared responsibilities in meeting healthcare needs. The PMP is a product of a consultative and systematic process with all concerned parties, thus we hope that all involved partners and stakeholders will put their efforts to implement the strategies in the PMP. This will create a sustainable system and an enabling environment towards a common goal of ensuring equitable and timely access to affordable, safe and quality essential medicines for all.

Enrique T. Ona, MD
Secretary of Health
MESSAGE

I would like to congratulate the National Center for Pharmaceutical Access and Management of the Department of Health for the achievement in publishing the Philippine Medicines Policy (PMP).

Essential medicines are considered as one of the cost-effective tools for fighting illnesses, yet an estimated one-third of the country’s population lacks regular access to essential medicines. Meeting the needs of patients for essential medicines is a challenge for us to exhaust all possible means to improve access to quality health care.

The Philippine Government and healthcare providers have an obligation to see that the right to health is progressively realized. Essential medicines play a crucial role in many aspects of healthcare. If available, affordable, of good quality and properly used, drugs can offer a simple, cost-effective answer to many health problems. Despite the obvious medical and economic importance of drugs, there are still widespread problems with lack of access, poor quality, irrational use and wastage of medicines. To sum it up, essential medicines are not used to their fullest potential.

The PMP has a comprehensive framework that can address these complicated and interdependent problems. This will serve as a commitment to a goal and guide for action that involves public and private sectors and all main actors in the pharmaceutical field. It also prioritizes the medium to long-term goals set by the government for the pharmaceutical sector and identifies the major strategies in attaining them.

With the implementation of the PMP, all parties will be brought together and achieve a sense of collective ownership. The success of the PMP implementation lies in partnership. Let us all take the PMP together as a challenge, knowing that by improving access to essential medicines, we are assured that the right of every Filipino to enjoy the highest attainable standard of health is realized.

Paulyn Jean B. Rosell-Ubial, MD, MPH, CESO II
Assistant Secretary of Health
Support to Service Delivery Technical Cluster
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<td>Adverse Drug Event</td>
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<td>AMR</td>
<td>Antimicrobial Resistance</td>
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<td>ASEAN</td>
<td>Association of Southeast Asian Nations</td>
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<td>BFAD</td>
<td>Bureau of Food and Drug</td>
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<td>BNB</td>
<td>Botikang Barangay</td>
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<td>BoC</td>
<td>Bureau of Customs</td>
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<td>BOD</td>
<td>Burden of Disease</td>
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<td>COBAC</td>
<td>Central Office Bids and Award Committees</td>
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<td>CHD</td>
<td>Center for Health Development</td>
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<td>CO</td>
<td>Central Office</td>
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<td>DILG</td>
<td>Department of Interior and Local Government</td>
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<td>DOH</td>
<td>Department of Health</td>
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<td>DPRI</td>
<td>Drug Price Reference Index</td>
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<td>DSWD</td>
<td>Department of Social Welfare and Development</td>
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<td>DTC</td>
<td>Drug and Therapeutic Committee</td>
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<td>DTI</td>
<td>Department of Trade and Industry</td>
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<td>EC</td>
<td>European Commission</td>
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<td>EDPMS</td>
<td>Electronic Drug Price Monitoring System</td>
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<td>EM</td>
<td>Essential Medicine</td>
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<td>EML</td>
<td>Essential Medicines List</td>
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<td>EPI</td>
<td>Expanded Program on Immunization</td>
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<td>FDA</td>
<td>Food and Drug Administration</td>
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<td>FEFU</td>
<td>First Expiry / First Use</td>
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<td>FIFO</td>
<td>First In / First Out</td>
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<td>GDP</td>
<td>Gross Domestic Product</td>
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<td>GMAP</td>
<td>Government-mediated Access Price</td>
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<td>GMP</td>
<td>Good Manufacturing Practices</td>
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<td>GGM</td>
<td>Good Governance in Medicines</td>
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<td>GPPB</td>
<td>Government Procurement Policy Board</td>
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<td>GSP</td>
<td>Good Storage Practices</td>
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<td>HAI</td>
<td>Health Action International</td>
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<td>HHRDB</td>
<td>Health Human Resource Development Bureau</td>
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<td>HPDPB</td>
<td>Health Policy Development and Planning Bureau</td>
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<tr>
<td>HIV-AIDS</td>
<td>Human Immunodeficiency Virus- Acquired Immunodeficiency Syndrome</td>
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<td>HSRA</td>
<td>Health Sector Reform Agenda</td>
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<td>ICT</td>
<td>Information and Communications Technology</td>
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<td>IMS</td>
<td>Information Management Service</td>
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<tr>
<td>INN</td>
<td>International Non-proprietary Name</td>
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<td>IP</td>
<td>Intellectual Property</td>
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<td>IPO</td>
<td>Intellectual Property Office</td>
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<td>IRR</td>
<td>Implementing Rules and Regulations</td>
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<td>LGUs</td>
<td>Local Government Units</td>
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<tr>
<td>Acronym</td>
<td>Description</td>
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<td>MDG</td>
<td>Millennium Development Goals</td>
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<td>MDRP</td>
<td>Maximum Drug Retail Price</td>
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<td>MDRTB</td>
<td>Multi-drug Resistant Tuberculosis</td>
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<td>MeTA</td>
<td>Medicines Transparency Alliance</td>
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<td>MMD</td>
<td>Materials Management Division</td>
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<td>MTPDP</td>
<td>Medium Term Philippine Development Plan</td>
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<td>NBI</td>
<td>National Bureau of Investigation</td>
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<td>NCR</td>
<td>National Capital Region</td>
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<td>NCDPC</td>
<td>National Center for Disease Prevention and Control</td>
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<td>NCPAM</td>
<td>National Center for Pharmaceutical Access and Management</td>
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<td>NDP-PMU 50</td>
<td>National Drug Policy –Pharmaceutical Management Unit</td>
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<td>NHA</td>
<td>National Health Accounts</td>
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<td>NHIP</td>
<td>National Health Insurance Program</td>
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<td>NEMF</td>
<td>National Essential Medicines Facility</td>
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<td>NEC</td>
<td>National Epidemiology Center</td>
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<td>NGO</td>
<td>Non-Governmental Organization</td>
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<td>NSO</td>
<td>National Statistics Office</td>
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<td>OOP</td>
<td>Out-Of-Pocket</td>
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<td>OTC</td>
<td>Over the Counter</td>
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<td>PCHRD</td>
<td>Philippine Council for Health Research and Development</td>
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<td>PDIP</td>
<td>Parallel Drug Importation Program</td>
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<td>PITAHC</td>
<td>Philippine Institute of Traditional and Alternative Health Care</td>
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<td>PITC</td>
<td>Philippine International Trade Corporation</td>
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<td>PHIC</td>
<td>Philippine Health Insurance Corporation</td>
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<td>PHO</td>
<td>Provincial Health Office</td>
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<td>PMP</td>
<td>Philippine Medicines Policy</td>
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<td>PNDF</td>
<td>Philippine National Drug Formulary</td>
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<td>PNP</td>
<td>Philippine National Police</td>
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<td>PPI</td>
<td>PITC Pharma Incorporated</td>
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<td>PPP</td>
<td>Public-Private Partnerships</td>
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<td>PWD</td>
<td>Persons with Disability</td>
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<td>RDU</td>
<td>Rational Drug Use</td>
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<td>RHU</td>
<td>Rural Health Unit</td>
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<td>RA</td>
<td>Republic Act</td>
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<td>RITM</td>
<td>Research Institute of Tropical Medicine</td>
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<td>Rx</td>
<td>Prescription</td>
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<td>R&amp;D</td>
<td>Research and Development</td>
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<td>SEQ</td>
<td>Safety, Efficacy and Quality</td>
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<td>SHI</td>
<td>Social Health Insurance</td>
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<td>SPOC</td>
<td>Single-Point of Coordination</td>
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<td>SOP</td>
<td>Standard Operating Procedures</td>
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<tr>
<td>SSRS</td>
<td>Simplified Suppliers Registration System</td>
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<td>STG</td>
<td>Standard Treatment Guidelines</td>
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<td>TRIPS</td>
<td>Trade Related Aspects of Intellectual Property Rights</td>
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<td>VAT</td>
<td>Value Added Tax</td>
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<td>UHC</td>
<td>Universal Health Care</td>
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<td>WHO</td>
<td>World Health Organization</td>
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<td>WMS</td>
<td>World Medicines Situation</td>
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<td>WTO</td>
<td>World Trade Organization</td>
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PREAMBLE

As a principle, access to essential medicines pertains to the equitable and sustainable availability and affordability of safe, efficacious and quality medicines in a health facility or medicines outlet, within one hour’s walk from the patient’s home that enable a health system to achieve better health outcomes for its people. (World Medicines Situation, World Health Organization, 2004)

The "Universally Accessible and Affordable Quality Medicines Act of 2008" or Republic Act 9502, declared as a policy of the State to protect public health and, when public interest or circumstances so requires, it [the State] shall adopt appropriate measures to promote and ensure access to affordable quality drugs and medicines for all.1

As such, in line with this State policy to bring about equitable access to medicines for all Filipinos and attain Universal Health Care by 2016, the Philippine Medicines Policy (PMP) is hereby adopted anchored on the following key principles:

- Access to medicines forms part of the fulfilment of the human right to health where government plays a primary responsibility;

- Medicines are important in a well functioning health care system as they contribute to the achievement of the broader health objectives of reducing morbidity, mortality and burden of disease;

- The State plays the primary role in the progressive realization of equitable access to medicines for all its citizens, especially the poor. Filipinos shall not be denied access nor become impoverished because of high drug costs.

- The government, in partnership with all sectors, shall endeavour to provide access of individuals and the community to medicines and promote their rational use at all levels of care at all times;

- The Department of Health shall set the directions of the pharmaceutical sector and enforce this policy, the PMP, Strategic Directions on Access to Medicines for Filipinos 2011-2016.
INTRODUCTION

The Philippines is a low middle income country spending 3.84% of its Gross Domestic Product (GDP) on health care with 54.3% of health expenditures paid out of pocket (National Health Accounts, 2007). Pharmaceuticals represent the largest single item of health care expenditures currently at about 42% of family expenditures for medical care (FIES, 2009). They also form the second largest component of government expenditure in terms of payments made through the National Health Insurance Program (NHIP) at about one third of all reimbursements made by Philhealth in 2010. In the Philippines, at least 30% of Filipinos lack regular and sustainable access to essential medicines. In 2004, the World Medicines Situation Report identified the Philippines as one of 64 countries worldwide with low to medium regular access to essential medicines (WHO, 2004).

The gaps in access to medicines are alarming as expenditures for drugs and health services are largely borne by individuals and families. Limited and capped payments for inpatient drugs through the national health insurance program (NHIP) as well as the lack of outpatient drug benefits by the government lead to almost 90% of spending for medicines being made through out-of-pocket payments. Thus, more often, the poor are unable to start treatment or sustain a lifetime drug regimen especially when these drugs are exorbitantly priced beyond their reach.

In 2010, the total pharmaceutical market in the Philippines was reported to be about PhP 124 billion where PhP11-12 billion or 10% of the entire market comes from government spending. Included in this spending for pharmaceuticals are imports, Philhealth reimbursements and drug procurement of DOH, other national agencies and LGUs (IMS, 2010).

The government drug procurement system is currently fragmented at the national and local levels. Small, frequent and inefficient drug procurements are made with limited DOH central procurement of EPI vaccines and other drugs for several vertical programs on TB, malaria, HIV/AIDS, rabies, leprosy and other infectious diseases. Local governments units, on the other hand, are also distinct drug procuring entities responsible for assuring the supply of medicines in primary health centers as well as district and provincial hospitals. DOH-managed hospitals also conduct their own bidding process with the monitoring of compliance to rules made difficult at the national level.

Such a disjointed pharmaceutical financing and distribution chain in the public sector without a transparent and objective regulated pricing scheme leads to wide variation of drug prices as well as uneven availability of essential medicines across government health facilities. The system also leads to operational inefficiencies and high transaction costs which are barriers to the entry of potential suppliers in government tenders leading once more to failure in attaining real price competition. In 2006, a drug price survey by the WHO and the Health Action International (HAI) revealed that Filipinos are among those who pay the highest drug prices in Asia with innovator brands costing 16 times more and generic drugs costing 15 times more when compared with international reference prices.

The unavailability of essential medicines in the public sector also demonstrates key problems on access. In 2009, the availability of 15 key essential medicines in public health facilities was
found to be at only 53.3% while warehouses that supply the public health system registered mean availability at 33% (WHO Health Facility Survey 2009). A study conducted by the European Commission (EC) in 2010 across 234 primary health care facilities and 65 hospital pharmacies in 10 Regions for an extended list of 44 essential medicines shows an even worse situation with mean availability at only 25%. This persistent lack of stocks of medicines in sufficient quantities on a regular basis in the public sector compared to the private sector where there is complete availability leads to market failure - the de facto choice left to consumers are private retail outlets, most of which carry originator drugs and are likely to set higher margins for increased sales and profits. Presently, the largest channel for distribution of pharmaceutical products in the Philippines is controlled by the biggest drug retail chain which distributes approximately 60% of the total value of sales to consumers.

Thus far, the limited government financing for medicines through DOH and LGU budgets as well as PHIC reimbursements has had little penetration and impact to the market to affect overall drug prices and improve access. There are other obstacles which hamper access to medicines --- these include issues on regulations, rational drug use and information asymmetry which act as barriers for health providers, patients and consumers even as quality assured and low-cost generics are already widely available in the Philippine market.

Thus, the Philippine Government, in its Philippine Development Plan (PDP 2011-2016) and the Universal Health Care Agenda of the current administration otherwise known as Kalusugan Pangkalahatan, has taken on the highest level of political commitment to bring about better health outcomes for Filipinos through greater access to medicines.

Access to medicines is part of a sound socioeconomic policy that negates the adverse impact of disease and its complications especially when these cause impoverishment and financial hardships to individuals, families and communities. The goal is consistent with the country’s commitment to forge partnerships at the local and international level for improved access to medicines especially of the poorest people as indicated in the Millennium Declaration of 2000 where the Philippines is one of the 192 signatory countries. Access to medicines is also rooted in the WHO Medicines Strategy 2007-2010 which specifies and includes four components into the access framework, namely: 1) rational selection, 2) affordable prices, c) sustainable financing and 4) reliable health and supply systems.

A lot has been done to close the medicines access gap in the country particularly over the last decade when this vital issue was put at the center of national legislation and health policy. For more than 20 years, the Philippines has worked towards improving access to medicines with the National Drug Policy of 1987, the Generics Act of 1988 and the adoption of the Philippine National Drug Formulary (PNDF) to specifically address key health programs and priority diseases identified by the Department of Health.

At the turn of the millennium, the Philippine Government embarked on a mission to improve access to medicines with the MTPDP 2001-2004 / 2004-2010 clearly articulating its objective to "reduce the
prices of medicines commonly bought by the poor to half of their 2001 levels by 2010.” Government adopted measures to reduce the cost of medicines by initiating the Parallel Drug Importation Program (PDIP) to source lower priced medicines from other countries like India and Pakistan. Thousands of community drug outlets known as Botika ng Barangay were established at the grassroots level to fill the need in far-flung communities.

In the last two years, two major legislations were passed to reshape the pharmaceutical landscape in the country: the “ Universally Accessible and Affordable Quality Medicines Act of 2008” (Republic Act 9502) and the Food and Drug Administration Act of 2009 (Republic Act 9211). Taken together, these twin legislations provide the instruments to ensure wide access to both patented and non-patented life-saving quality medicines in ways that can serve the needs of the poor while preserving the need for future innovation that can enable the country to address current and emerging public health challenges. To operationalize, strategize and manage the National Drug Policy and RA 9502, the DOH-NCPAM was established on January 8, 2010 through Administrative Order No. 2010-0005 from an ad-hoc unit, the Pharma-50. Its primary goal is to attain and sustain universal access to medicines by 2015.

The challenges, however, remain. With intensive trade globalization, the implementation of the WTO-TRIPS agreement, the fast transnational flow of diseases and the emergence of new ones with the potential to become pandemics, a focused strategy to protect public health through a sustainable supply of life-saving medicines becomes even more an urgent priority. The Philippines already bears a significant part of the global burden of important health threats such as tuberculosis, malaria and rising chronic diseases. All of these can be significantly reduced through steady access to safe, quality and affordable essential medicines. Old and new disease threats exert a tremendous pressure on the health system to meet its obligation of bringing not only generic and off-patent drugs but even key patented medicines to poor populations regardless of their ability to pay (e.g. antiretrovirals, drugs against MDRTB, anticancer drugs).

To respond to the emerging realities and challenges of the times, there is a need to outline a new strategy and draw a comprehensive plan to ensure access to essential medicines for all Filipinos now and into the future.

The PMP 2011-2016 herein contained shall be the roadmap of the entire health sector and all other partners who bear responsibility for its outcome. This Roadmap builds on the reform initiatives and gains of the past decades in addressing the medicines access gap in the country. The Roadmap shall ensure that government adequately meets its obligation to protect public health through access to medicines while creating an investment climate conducive to the industry to continuously produce drugs and medicines compatible with the country’s public health needs. Since access to medicines is a complex social and public health challenge, it will require concerted and creative solutions from all stakeholders through open exchanges, a collective will, and effective partnerships where everyone must contribute, participate and act.
Chapter 1 General Principles
The SARAH Medicines Access Framework

The SARAH Medicines Access Framework encompasses the five major pillars of the Philippine Medicines Policy. These pillars cover all the components that are necessary to ensure that essential and quality medicines are accessible and available to achieve better health outcomes for all Filipinos, especially the poor.

SARAH articulates the values and principles that all stakeholders must pursue and adopt in a transparent, participative and harmonious manner to achieve health system goals while recognizing the importance of continuous innovation and the advancement and growth of the pharmaceutical industry towards making it an instrument for combating diseases of public health importance through the discovery of truly life-saving and life-enhancing drugs for patients.

As such, SARAH recognizes critical barriers (i.e. trade, economic, social, cultural, political, scientific) to access to medicines in the Philippine healthcare system and draws up a clear, coherent and comprehensive framework designed to overcome such barriers in coordination with all stakeholders.

In the SARAH medicines framework, the Department of Health outlines the five pillars for targeted and sustained action by the health and relevant sectors, namely: 1) Safety, Efficacy and Quality (SEQ) of medicines, 2) Affordability and availability, 3) Rational Drug Use, 4) Accountability, transparency and Good Governance and 5) Health Systems Support.
1. **Safety, Efficacy and Quality (SEQ)** is the first pillar of the PMP which includes all policies and strategies employed by the state and the tools for all stakeholders to constantly assure the safety, efficacy and quality of essential medicines along the supply chain and at all levels of care. This component shall ensure that the manufacture, packaging, procurement, import, export, distribution, supply and the sale of drugs, product promotion and advertising and clinical trials are carried out according to specified standards of safety, efficacy and quality. FDA shall be the lead agency in the setting of such standards for medicines and in adopting internationally accepted standards that will apply to the local situation in coordination with other appropriate government regulatory bodies.

2. **Affordability and Availability** is the pillar that pertains to the full range of mechanisms that government shall employ in a collaborative endeavour with all partners and sectors to ensure that Filipinos have adequate and timely access to medicines at all points of health service delivery. Likewise, government shall exercise its power to influence the local supply and demand of medicines through strategies that promote effective competition as well as transparent and rational pricing to assure that medicines are affordable to the individual, families and communities.

The adoption and use of generics shall be actively promoted in both the public and private sectors as government commits to increase financing for medicines and deliver the best health outcomes to more patients. Essential drug packages, once declared as entitlements by government, shall be provided for free or with reasonable co-payments for patients either through direct subsidy by the DOH or social health insurance and any other payment schemes of government. Drug prices shall be actively monitored by the DOH enabling transparent and objective price information sharing with drug procuring entities, consumers, health professionals and the public.
Other policy instruments shall be explored to reduce out-of-pocket spending such as reducing taxes on medicines, price negotiations with industry and tailored pooled procurement to ensure economies of scale. Government in cooperation with the private sector shall also exhaust patent flexibilities in making medicines, particularly single source products which are expensive but which are deemed to address diseases of public health concern in the country readily accessible to Filipinos.

Government shall also exert its power where necessary to regulate prices of medicines when market forces fail to make them affordable and accessible with the intent to improve health outcomes, as provided for by law.

3. **Rational use of medicines (RUM).** WHO defines rational drug use as the condition where “patients receive medicines appropriate for their clinical needs, in doses that meet their individual requirements, for an adequate period of time, and at the lowest possible cost to them and their communities.”

The DOH in collaboration with health providers as well as patients and consumers shall promote the rational and cost-effective use of medicines to achieve the best treatment outcomes for patients while generating efficiency and cost-savings in the healthcare system. The *Philippine National Formulary* (PNF) current edition shall be the basis of selection and procurement of medicines in all public health facilities. The PNF shall also govern the reimbursement of drugs by Philhealth in both public and private health facilities.

Patients and consumers shall be educated and informed on the quality, safety and proper use of medicines as well as their right to demand low-cost medicines through generic substitution. Health providers shall be educated on rational prescribing based on nationally accepted treatment guidelines as well as proper dispensing to eliminate unnecessary prescriptions, halt the emergence of antibiotic resistance and ensure that government funds are used for medicines that achieve the best health outcomes.

To ensure checks and balances in the provision of services related to medicines, the prescription, dispensing, safety monitoring and administration of medicines by health professionals shall be governed by laws that regulate their practice.

4. **Accountability, Transparency and Good Governance**

This pillar is anchored on the fact that strategies to improve access to medicines can only happen within a framework that institutionalizes accountability, transparency and good governance in regulatory and management systems along the medicines supply chain. Building on the gains and efforts of the Philippines as a pilot country for the *WHO Good Governance in Medicines* (GGM) program, Government shall continue to develop approaches and strategies to enforce rules, promote good practices and reduce vulnerabilities to corruption.
in the health system. Strategies shall include improving regulatory standards, building transparent and efficient support systems for medicines procurement and logistics management, developing performance tracking mechanisms, managing risks of corrupt practices and giving incentives to foster positive behavior of players.

Government shall encourage the industry and health providers to comply with laws and standards, pursue ethical research and development and uphold responsible and ethical business practices. Integrity development activities shall be continually pursued to promote proper norms of behavior and codes of conduct of health workers and professionals. Conflicts of interest shall be declared and managed to ensure that these do not adversely influence critical decisions, policies and strategies that aim to improve access to medicines.

To achieve transparency, a synergistic and constructive multi-stakeholder approach shall be fostered to address vulnerable areas of inefficiencies and corruption in medicines management.

To ensure efficiency in the provision of medicines, Government shall exert all efforts to address red tape and bottlenecks in the system and to streamline bureaucratic procedures while maintaining quality standards to enhance the delivery of medicines and other health services.

5. Health Systems Support

This pillar cuts across all the other components of the PMP with the government exercising its prime responsibility as key enabler.

The DOH recognizes that scaling up access to essential medicines needs to happen within an environment where there are enabling human, technical, technological and financial resources and instruments. A strong health system must be built to successfully implement the different pillars of the Philippine Medicines Policy. Thus, there must be absolute commitment from all stakeholders to marshal the needed health systems support comprising of additional financial investments, adequate and trained human resources, up to date knowledge-base/evidence, and information and communications technology (ICT), efficient systems and processes and incentives for good practices in drug management.

In line with Millennium Development Goal 8 to foster global partnerships for development, Government shall pursue public private partnerships (PPP) through various initiatives such as price-reduction schemes, increasing access points for medicines access programs, technology transfer, sharing of resources and expertise, research and development, among others.
Chapter 2 Objectives

1. **GENERAL OBJECTIVE:**

   The Philippine Medicines Policy shall provide the general directions and framework for improving access to essential medicines at all times and in all levels of health care. As such, it shall articulate the necessary values and principles to achieve equity in the provision of medicines emphasizing the roles and responsibilities of all stakeholders.

2. **SPECIFIC OBJECTIVES:**

   The PMP shall specifically aim to:

   2.1. Provide general strategies and operational guidelines for implementing existing legal mandates, such as the Generics Act of 1988, the Universally Cheaper and Quality Medicines Act of 2008 and the Food and Drug Administration Act of 2009;
   2.2. Ensure the safety, efficacy and quality of medicines in the country
   2.3. Create an environment where patients and consumers can access quality medicines from both the public and private sources
   2.4. Effect behaviour change among industry players, health providers and consumers with regard to rational use of medicines
   2.5. Foster accountability and good governance in implementing and complying with national standards and policies on medicines
   2.6. Guarantee that the necessary systems, whether public or private, contribute to the achievement of the health sector goal to improve health outcomes

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*Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times, in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford. The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility.*
Chapter 3 Key Pillars

I. Safety, Efficacy and Quality (SEQ)

The Food and Drug Administration (FDA) is the national authority for developing and implementing regulations concerning the safety, efficacy and quality of drugs in the Philippines. It is also the lead agency responsible for the enforcement of laws and regulations concerning the drug regulatory system involving all parties in the drug supply chain.

As such, in support of the PMP, the FDA shall play a prominent role for medicines regulations to assure the safety, efficacy and quality of medicinal products in the market and in pushing for other quality assurance measures that may involve other agencies of the government, non-government organizations and the private sector through the following strategies:

A. Strengthening of FDA and enforcement of regulatory standards

1. The government shall pursue the strengthening of the institutional system and capacity of the FDA by continuing to augment its budget coming from the national government as needed. It shall ensure the presence of competent administrative and technical staff and adequate personnel support in well equipped facilities in all regions of the country.

2. As stipulated in the FDA Law of 2009 (RA 9711), the FDA shall have fiscal autonomy to retain its income from registration, inspection, licensing and its other regulatory functions that shall be used for the improvement of its infrastructure, the training and hiring of more personnel and the improvement and modernization of its operations.

3. FDA shall participate and comply with ASEAN and other international harmonization of standards with regard to pharmaceutical quality assurance activities.

4. FDA shall ensure transparency and accountability in all its procedures and outcomes for all stakeholders.

5. FDA shall enforce full compliance to Current Good Manufacturing Practices (GMP) as well as good storage and distribution practices (i.e. GDP, GSP) and other additional requirements for licensing, registration and other regulations as mandated by law. It shall also regularly conduct inspections of manufacturing plants and healthcare facilities in relation to medicines quality assurance.
6. Pursuant to the Food and Drug Act of 2009, FDA shall establish regional field offices to institutionalize the quality assurance in the field system and develop tools and mechanisms for reporting and feedback.

7. FDA shall develop a mechanism for the registration, regulation and oversight of clinical trials in the country.

B. National Pharmacovigilance Program

A National Pharmacovigilance Program shall be established to ensure the safety of all drugs, vaccines and pharmaceutical products in the country and to promote responsible pharmacovigilance practices among all parties involved in the regulation, research, registration, marketing and use of such products.

1. The FDA shall develop systems and policies for pharmacovigilance. A National Pharmacovigilance Center shall be created for this purpose as part of the post-marketing surveillance of the FDA in collaboration with all stakeholders in the public and private sectors concerned with promoting and upholding patient safety and patient-centered care.

2. The National Pharmacovigilance Program shall be an objective, transparent and constructive mechanism that will enable the timely and adequate sharing of information on adverse drug reactions, drug alerts or any event which brings doubtful questions on the safety, efficacy and quality of drugs and biologicals such as vaccines, contrast media, traditional medicines, herbal products and food supplements.

3. The FDA shall establish a systematic, comprehensive and efficient national database for gathering reports on adverse drug events in the country. There shall be a scientific process of evaluating reports on suspected adverse drug reactions which shall be the basis of issuing timely drug alerts whenever a causal link is established between the adverse drug event/s and the medicine under investigation.

4. Consumers, pharmacists, doctors, nurses and all healthcare providers shall report all suspected cases of adverse drug experience through the channels provided by the FDA for proper evaluation. The reports shall be gathered and stored in a confidential database.

5. The sharing and reporting of information shall ensure accuracy, reliability and confidentiality of the data.
6. Information on drug safety and adverse events shall be provided to end users through timely drug alerts, bulletins, news and other means using appropriate means of communication upon clearance of the FDA.

C. **Combating counterfeit medicines**

Counterfeit medicines as defined under Philippine laws (i.e. Republic Act No. 82036) are medicinal products which are deliberately and fraudulently mislabelled with respect to identity and/or source sold under a product name without proper authorization. Both branded and generic medicines can be counterfeited. Counterfeiting results in the reduction of the drug's safety, efficacy, quality, strength or purity and as such are potentially harmful to patients.

The proliferation of counterfeit medicines erodes public confidence and trust in the health system as well as in the industry, health practitioners and health institutions alike. Thus there is a need to strengthen coordination among concerned government agencies (i.e. Bureau of Customs, Philippine Post Office, National Bureau of Investigation, Philippine National Police, etc.) and the private sector in strengthening medicines regulations against counterfeit medicines and in reporting and handling reports of counterfeit medicines.

The following strategies shall be pursued:

1. FDA shall establish the single-point-of-coordination (SPOC) program of the different agencies and the private sector in the fight against counterfeit medicines.

2. FDA shall designate a station in all possible ports of entry in coordination with the *Bureau of Quarantine*, the *Bureau of Customs* and other relevant agencies.

3. FDA shall strengthen the capacity of its staff to conduct inspection and detect counterfeit medicines.

4. Modern technology shall be employed for assessing, monitoring and reporting counterfeit medicines.

5. FDA shall coordinate with the *WHO Rapid Assessment of Surveillance* system for reporting counterfeit medicines.

6. Cooperation and partnership shall be forged with the private sector and the industry in the fight against counterfeit medicines.

FDA shall develop risk communication, public education and an alert and response system to communicate the dangers of counterfeit medicines to the public.
II. Availability and Affordability

The goal is to ensure the continuous availability of essential medicines in the health care system at prices that are within reach of patients, consumers and the government. All stakeholders shall work towards improving the availability and affordability of medicines to the entire population with the following strategies:

A. Generics Policy

The primary instrument recognized by the State to reduce prices of medicines is effective competition and the active promotion, adoption and use of generics. Generic medicines are health products that have the same quality and efficacy as branded innovator drugs but give patients more choice because of their lower price.

The PMP aims to promote generic drugs in both the public and private sectors in accordance with applicable national policies such as the Generics Act of 1988 and the Cheaper Medicines Act of 2008. It intends to improve compliance to treatment, reduce out-of-pocket spending for medicines and provide quality and affordable choices to expensive branded counterparts.

Pursuant to this, the following priority areas for action in line with the generics policy shall be pursued:

a. For qualified generics industry
   a.1. tax breaks
   a.2. fast lane for market registration of generics
   a.3. government assistance as a priority investment area
   a.4. preferential sourcing from local suppliers that provide low-cost generic medicines

b. For the health providers,
   b.1. enforcement of the generics-only policy in all government health facilities
   b.2. generics substitution
   b.3. generics menu card
   b.4. generic labels and other labelling materials
   b.5. use of generics only terminology in all government transactions which include bidding, procurement, consignment and donations, among others

c. For the consumers
   c.1. informed choice through education
   c.2. preferential reimbursement of essential generic products for all Philhealth members
B. Pricing of medicines

A fair, transparent and rational system of pricing of medicines in the country shall be established. Prices of essential medicines are said to be fair if their costs are according to the capacity of the individual, community and the health system to pay. Prices and mark-ups on medicines shall be made transparent to promote consumer choice and awareness. Government interventions on pricing shall be guaranteed in extreme situations such as health emergencies and manifest overpricing. Government shall work with the private sector to make medicines more affordable through price negotiations and other measures such as tax incentives and special discounts for vulnerable populations.

To ensure the affordability of medicines, Government shall undertake the following measures:

1. **Price Advisory Council.** A *Price Advisory Council* as provided for by law shall be established to monitor drug prices and recommend policy options for fair and rational pricing of medicines. The *Advisory Council* shall be composed of relevant stakeholders where all interests and opinions shall be well represented and respected. Expertise from non-Council members shall be solicited where necessary.

2. **Electronic Essential Drug Price Monitoring System (e-EDPMS) and Drug Price Reference Index (DPRI).** The e-EDPMS and the DPRI shall be implemented to foster transparency and accountability in the pricing of essential medicines and to monitor trends and impacts of government policies and interventions on pricing. All stakeholders shall regularly submit relevant pricing information to serve as evidence for DOH in determining appropriate policies and improving consumer awareness on prices of medicines.

3. **Voluntary Drug Price Reduction.** The Government shall negotiate with the industry to voluntarily reduce prices particularly for medicines that are included in the *Philippine National Formulary.* The benefits of voluntary drug price reductions may foster better compliance to medicines by patients, good value for money for government procuring agencies and increased market share for industry proponents.

4. **Price regulation.** Where drug prices hamper access to life-saving medicines and are deemed excessive and prohibitive to the achievement of national health goals by the Government, the President of the Philippines as recommended by the Secretary of Health by virtue of the RA 9502 has the authority to regulate the prices of drugs as a reserve instrument.

Price regulation of medicines shall be based on clearly defined criteria, such as those with large public health benefits, and which will benefit not only those using them, but also others whose risk of illness is reduced.
5. **Tax incentives.** The government shall endeavour to reduce taxes or move for the exemption from taxes, tariffs and/or duties of life-saving pharmaceutical products or its active ingredients. Such moves shall be employed to achieve the lowest possible costs for essential medicines.

6. **Special discounts for medicines.** Government shall enforce special discounts for medicines especially those provided for Senior Citizens and People with Disabilities (PWDs) by virtue of the *Expanded Senior Citizens Act of 2010* and the *Magna Carta for PWDs*, and their Implementing Rules and Regulation, respectively.

**C. Sustainable financing and basic entitlements for the poor**

The government shall ensure adequate, equitable and sustainable financing for medicines and provide entitlements for the poor with the following strategies:

1. **Increasing budget allocation.** National and local government agencies shall earmark an adequate budget for medicines appropriate to meet public health priorities. Government shall endeavour to increase funding and spending for medicines for priority diseases which will be sustained in the medium and long-term.

2. **Philhealth reimbursement of medicines (NHIP Act, IRR of RA 9502).** The DOH shall provide Philhealth with the list of medicines and their prices that shall be covered for reimbursement. Philhealth shall reimburse inpatient and outpatient medicines to effectively reduce out-of-pocket expenditure of patients;

3. **Cost-containment measures.** Pursuant to RA 9502 (Section 3), cost-containment measures shall be employed which include generics use, reference pricing, pooled procurement and limiting unethical profits and excessive marketing and drug promotion expenditures of the industry

4. **Medicines entitlement.** The DOH, Philhealth and other relevant government agencies shall employ strategies that will provide free medicines to the poor or a population of patients that addresses priority diseases (e.g. TB, HIV, malaria, cancers). Where applicable, medicines shall be provided for free especially in primary healthcare facilities.

**D. Reliable supply and distribution system**

The government through DOH shall ensure efficient and uninterrupted supply and delivery systems for medicines at all levels of health care, primarily securing the supply of medicines in the public sector adhering strictly to *Republic Act 9184* also known as the *Government Procurement Reform Act.*
Annual government procurement of medicines shall be appropriately forecasted and planned using an acceptable formula that takes into account current morbidity/mortality data, the burden of disease (BOD), the annual growth rate of the population, the size of the population targeted to be served, current drug prices and latest consumption data, among others.

Government shall undertake the following strategies to ensure the availability of drugs in the public health care system:

1. **National Essential Medicines Facility.** The DOH with other relevant government agencies shall establish a transparent, autonomous and functional *National Essential Medicines Facility (NEMF)* with the capacity to provide a national pooled procurement service for DOH programs and a responsive and timely “pull” system for distributing medicines to national and local government health facilities. The drug facility shall coordinate a system that harmonizes procurement processes and implement a nationally adopted standard protocol for supplier selection and cost and quality assurance for medicines along the supply chain. The national drug facility shall also have the capacity to do international sourcing of drugs where necessary and shall have fully trained staff and optimal use of automation to enable it to perform large-scale procurement, distribution and storage of medicines for government health facilities.

2. **Simplified suppliers registration system (SSRS).** DOH shall create a system for prequalifying suppliers at the national level to facilitate eligibility for procurement in all levels of the health system. The SSRS shall contain the list of qualified suppliers which can ensure the quality of medicines meeting approved standards (i.e. CPR, cGMP, GDP, GSP) and offering the best cost advantage to government.

3. **E-procurement system for the public sector.** A web-based procurement, inventory and tracking system for essential medicines at the national and local levels shall be facilitated to better forecast needs, monitor drug prices and institute good management practices.

4. **Parallel Drug Importation and mandatory carry.** Sourcing of medicines through Parallel Drug Importation (PDI) as per RA 9502 and its IRR will be allowed subject to compliance with the necessary regulatory requirements.

5. **Reliable distribution system.** An efficient and cost-effective distribution system for drugs, vaccines and medical supplies shall be developed to assure that needed medicines are carried in public health facilities. Distribution arrangements appropriate to the local situation shall be employed such as the establishment of depots,
contracting out distribution and other services, public-private partnerships and any other measures as deemed appropriate by Government.

6. **Proper stock and inventory management.** Expiration of medicines shall be avoided through practices such as First-in/First-out (FIFO) and First expiry/first use (FEFU). Cold chain management shall be up to par with DOH and FDA standards.

7. **Essential medicines package.** The DOH shall define the essential health package or minimum provision of essential medicines at different levels of the health care system. The national and local governments shall ensure that these essential health packages are available in public health facilities.

8. **Consignment or forward-stocking.** Where inadequate financing limits availability of medicines in public health facilities, consignment or forward-stocking of medicines shall be allowed at no cost to the government. Such activities shall comply with systems and guidelines as espoused by the DOH and the Government Procurement Policy Board (GPPB).

9. **Community pharmacies.** DOH shall continuously build a network of community pharmacies (i.e. Botika ng Barangay and Botika ng Bayan) linked to the primary and local health system to provide the basic medicine needs particularly in far-flung and underserved communities.

### E. Patented Medicines

1. **Use of TRIPS flexibilities.** Trade related aspects of intellectual property rights (TRIPS) flexibilities shall be employed by government for high-priced patented medicines that are deemed important to address priority public health threats as declared by the Secretary of Health in coordination with the Intellectual Property Office (IPO) and the Department of Trade and Industry (DTI). The use of such instruments shall adhere to strict guidelines which conform with the WTO/TRIPS protocol as contained in RA 9502 and its IRR. A transparent and participatory process shall be created in decisions where the DOH deems it necessary to implement the government use of TRIPS agreement.

2. **Special access programs through private initiatives.** Government shall encourage the private sector to launch innovative access programs for patented medicines that will benefit low-income and vulnerable populations. Patients, especially the poor who are unable to afford costly treatments are also encouraged to participate in such access programs.
3. **Low-cost variants.** Pursuant to RA 9502, the Government shall support efforts of drug companies to manufacture low-cost variants of their innovator products, especially if such medicines improve survival and disease outcomes.

**F. Building domestic self-reliance**

The government shall encourage local research and development (R&D) and strengthen domestic capacity to manufacture essential vaccines, drugs and medicines. A business plan and an incentives system will be developed with the private sector to support the local industry to enhance its competitive advantage in the manufacture of essential biotechnology and pharmaceutical products.

**G. Traditional and alternative medicines**

Traditional and alternative medicines approved by the DOH give patients wider choices to low-cost and effective treatment while providing a local source of livelihood and income to local manufacturers.

The DOH shall work with the *Philippine Institute of Traditional and Alternative Health Care (PITAHC)*, the academe and other stakeholders to advance and integrate *Complementary and Alternative Medicine* into the national healthcare system through building the local knowledge base, education and training of healthcare professionals and the application of rigorous standards in ensuring the quality, safety and efficacy of nationally accepted alternative modes of therapies.

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**III. Rational Use of Medicines**

The goal is to promote quality use of drugs in the public and private sectors using cost-effective and rational treatments that will result in the best health outcomes for patients.

**A. National Standard Treatment Guidelines (NSTG) and the Philippine National Formulary (PNF)**

Evidenced-based national standard treatment guidelines (NSTGs) shall be developed for education and training of health providers as well as to guide rational prescription and drug use in the health sector.

1. The *National Standard Treatment Guidelines (NSTGs)* shall address common conditions seen in the primary, secondary and tertiary levels of healthcare. The DOH shall take the lead in appraising and adopting the clinical practice guidelines.
2. The NSTGs shall be reviewed, updated and published regularly. These shall be made available to health providers, relevant stakeholders and the general public.

3. The Guidelines shall take into account special therapeutic needs of vulnerable populations such as infants and children, pregnant and lactating women, patients with chronic conditions and the elderly.

4. The NSTGs shall be disseminated to health providers and the academe as part of training and the health care curriculum. They shall also be the primary guide in the delivery of health services to patients at different levels of care.

5. The NSTGs shall be the basis of inclusion/exclusion of medicines in the Philippine National Formulary (PNF). For diseases where there is no appraised NSTGs locally, the DOH may include medicines within the PNF subject to the criteria of clinical and cost-effectiveness, relative safety profile among Filipino patients and other criteria by which the concept of essential drug list is based upon.

6. The PNF shall be reviewed and updated regularly to ensure that it meets the needs of the health care system. All updates shall be published and/or posted in the DOH website. Mechanisms for health technology assessment and other evidence-based criteria shall be used to ensure that cost-effective medicines are included in the list.

**B. Rational Prescribing, Dispensing and Use of Medicines**

Rational use of medicines entails proper knowledge and behaviour on the use of medicines at the right dosage and form given in the right place and time for the right indications at the lowest possible cost to patients and their communities.

Rational drug use is emphasized to assure that the best health outcomes are achieved and there is cost-effectiveness in the delivery of health services. Attaining improved access through rational drug use is also key in the prevention of adverse consequences such as drug resistance as well as drug overdose/underdose and wastages, among others. In line with rational drug use, the following strategies shall be pursued:

1. The DOH in coordination with professional health organizations and medical societies shall craft, develop and disseminate prescribing, dispensing and administration guidelines for rational use of medicines. Such guidelines shall conform with the following:

   a. **NSTGs.** Irrational prescribing, dispensing and administration of medicines and the use of inappropriate therapies where there are no indications should be avoided. Likewise, the manufacture, sale, distribution and donation of medicines with dosages not in accordance with NSTGs shall be discouraged.
b. **Norms of ethics on professional behaviour.** The patient’s welfare should be the main motivation for the prescribing, dispensing and administration of medicines. Outside influences such as intensive marketing by drug companies and financial or material incentives given to health providers shall not be the basis for giving treatments to patients.

2. Prescription audits that monitor compliance to generics prescribing and national standard treatment guidelines shall be conducted regularly to assure quality and rational use of medicines. Such shall not, in any way, impinge on the principles of physician-patient confidentiality.

3. Medical and allied health courses shall incorporate the module for rational prescribing and use of drugs in their curriculum. The DOH shall conduct training, updates and seminars on rational drug use for healthcare providers, in both the public and private sectors.

4. Consumer information activities shall be provided in cooperation with relevant stakeholders in accordance with existing policies and ethical rules and regulations.
   
a. Consultation with a competent health provider shall be emphasized on the use of medicines.
b. Adherence to treatment based on accepted standards of treatment is paramount to ensure that desired health outcomes are achieved.
c. Unnecessary use of medicines, particularly those with potential for harm and abuse, shall be discouraged.

5. Prevention and Control of Anti-Microbial Resistance

Special attention shall be given to the prevention and control of Antimicrobial Resistance as resistance to low-cost first line antibiotics force the health sector to use high-generation and more expensive antimicrobials. This development impacts on health outcomes as costly antibiotics threaten patient compliance and is more difficult to acquire due to cost and other considerations. It is further complicated by the fact that the industry pipeline for new antibiotics is limited in the face of emerging strains of new organisms resistant even to the strongest antibiotics known today.

Locally, an upward trend in resistance rates for many microorganisms has been documented by the Research Institute of Tropical Medicine (RITM) since the surveillance program was institutionalized in 2002.

Thus, the DOH through its various offices and through strategic partnerships with stakeholders shall develop and implement a broad-based program to control the emergence and spread of resistant microorganisms in the community and healthcare settings with the following strategies:
a. Expand the active antimicrobial resistance surveillance in both public and private health facilities and communities

b. Conduct training and education among health professionals on the rational and quality use of antibiotics and the implementation of strict infection control measures

c. Publish up-to-date and evidence-based antibiotic guidelines following most recent information on antibiotic resistance patterns at the national and local levels. NSTGs shall be guided and updated according to these emerging resistance patterns.

d. Educate patients and consumers on the benefits of rational drug use and compliance with complete antibiotic therapy

C. Regulating medicines promotion

Medicines promotion shall be guided by well-articulated rules and ethical standards. The promotion of medicines may come in different forms including the provision of information of quad-media, detailing to health facilities and providers, the giving of incentives and perks by companies, sponsorships of continuing professional education and events, among others. These activities should not influence clinical judgment that are not in the best interest of the patient and must be regulated in accordance with the following rules:

1. Pharmaceutical companies shall ensure that the information materials about their products are truthful, correct, evidence-based and compliant with existing ethical guidelines on advertisement and promotion. False claims, misleading information and activities that circumvent existing ethical and legal rules and regulations are strongly prohibited.

2. In the interest of safety and the protection of public health, the FDA shall exert its authority to approve the content of the information materials on medicines prior to use and dissemination.

3. Direct-to-consumer (DTC) promotion of ethical medicines including web-based advertisements, giving of free samples and other similar forms shall be prohibited. Empowering patients to make informed choices and consumer education shall be a main strategy to counter asymmetric information brought about by medicines promotion.

4. Professional behaviour of health providers shall comply with existing national codes of conduct on the promotion of health products. As a rule, health providers are discouraged in engaging in activities that promote particular brands of medicines and other health products.

5. All health care providers, specialty groups, professional associations, training hospitals and academic institutions are required to declare all sponsorships, donations or the likes provided by pharmaceutical and device companies.
6. Drug companies shall publish every year the list of healthcare professionals and associations who receive company sponsorships for continuing education, training, medical conferences and other events.

D. Drug Therapeutic Committees (DTCs)

All health facilities shall establish drug therapeutic committees with well defined roles and functions. Selection of members of DTC’s shall be based on clearly defined criteria. All conflicts of interest shall be declared by members of the DTC. The DTCs main responsibilities include, but are not limited, to the following:

a. Champions of rational prescribing, dispensing and use of medicines. Ensure compliance of health providers and patients with standards on rational use of medicines
b. Preparation of hospital formulary in line with NSTGs and PNF
c. Tailoring procurement of medicines based on prevailing morbidity and mortality profiles
d. Monitoring and reporting of ADEs and counterfeit medicines, among others

4. Accountability, Transparency and Good Governance

The goal is to institutionalize transparency, accountability and good governance along the registration, regulation, selection, procurement and management of medicines in the health sector in accordance with government-wide efforts to pursue integrity development and anti-corruption initiatives. This shall be pursued through the following mechanisms:

A. Access to information. Pursuant to RA 9502 and its IRR, there shall be transparent data and information sharing amongst all agencies, manufacturers, retailers, service providers, and consumer groups with regard to medicine prices, drug registration status, status of regulatory compliance, and other critical transactions, decisions and processes with regard to medicines.

B. Managing conflicts of interests. The DOH shall provide a clear criteria in the selection and appointment of members to decision-making committees, which include among others, the Formulary Executive Council and all sub-committees covered by it, the Bids and Awards Committees (BACs) as well as Drug Therapeutic Committees at all levels. All members of such committees shall be required to declare conflicts of interest. Any individual who is employed or has relations with pharmaceutical companies shall declare potential or real sources of conflicts of interest in any decision-making or policy-making body that concerns medicines.
C. **Efficient, transparent and accountable processes.** The government shall improve protocols for registration, selection, procurement, distribution and quality assurance of medicines to shorten time frames, reduce red tape, promote fair competition among suppliers and create an environment conducive to the improvement of medicines access. It shall push for an accountable and responsible medicines industry by ensuring compliance with the following:

a. Government procurement rules following RA 9184
b. FDA and DOH regulations and standards on the safety, efficacy and quality of medicines as well as initiatives to create a One-Stop Shop for regulating and accrediting medicines facilities
c. Integrity development and corruption reduction initiatives which include proper norms of behavior for health providers and government employees, anti-red tape, no gift-giving policy, public disclosure and whistle blowing and reporting of mismanagement and corrupt practices
d. Existing ethical codes of conduct governing the norms of behavior of health professionals
e. ethical standards in research and development, medicines promotion and advertisement; and
f. internationally accepted standards on the regulation of medicines, where applicable;

D. **Standards of Good Governance.** A rewards and incentives system shall be developed and implemented for Good Governance in Medicines. This shall be linked to a performance audit of local government units, health facilities and the industry with regard to their efforts to build mechanisms for accountability and transparency and contribute to the public health sector goal of providing equitable access to essential medicines. The *Philippine Pharmaceutical Benchbook* shall be used in setting the standards of GGM performance.

5. **Health Systems Support**

The goal is to ensure that there is adequate health systems support from government and all stakeholders to ensure the effective implementation of the PMP in the following areas:

A. **Human resources**

1. The government shall ensure the presence of adequately trained, motivated, competent and committed human resource for implementing the *PMP*. The minimum standards of competency for the provision of services related to medicines access shall be clearly defined.
2. Rational and equitable distribution of health human resources shall be planned and enforced. In cases where there are shortages and mal-distribution of human resources, the appropriate skills mix shall be developed and supported through adequate technical training, proper incentives and legal assistance.

3. To ensure the quality of services provided by health human resources that deal with medicines, continuing education and other postgraduate programs, fellowships or on the job training shall be provided.

4. An incentives system shall be put in place to reward those who contribute to the delivery of quality services and promote access in underserved and other priority areas.

B. Local Research & Development

The DOH-NCPAM shall encourage local research and development (R&D) through partnerships with the academe, the industry and different stakeholders. Data and information relevant to the implementation of the PMP shall be regularly collated, assessed and analyzed on the following:

1. Basic, clinical and applied pharmaceutical research
2. Impacts of government laws, policies and strategies to improve access
3. Pharmaceutical market analysis
4. Building domestic capacity towards self-reliance in manufacturing pharmaceuticals

C. Medicines Information System

To address information asymmetry, a medicines information system shall be established to educate and advocate on the proper use of medicines to all stakeholders and the general public. Relevant data and information shall be regularly collated, assessed, shared and analyzed. Information and communications technology (ICT) shall be used to facilitate operations, monitoring, feedback and reporting in the following areas such as but not limited to:

1. Drug Price Monitoring
2. Information and Alert Systems for Adverse Drug Events (ADEs), counterfeit products and emergence of drug resistance, among others
3. Inventory and Supplies Management
4. Drug Registration
5. Web-based medicines procurement
6. Patent status of medicines
D. **Local Government Support**

The DOH shall provide support to LGUs for enforcing policies concerning medicines and ensuring proper drug management in a decentralized system. This shall be done through the following mechanisms:

1. Providing technical support for improving efficiency and instituting good practices for medicines selection, procurement and management

2. Issuing technical guidelines on the minimum provision of essential packages of medicines at the LGU level taking into account local health needs and priorities

3. Strengthening the DOH Centres for Health Development (CHDs) in collaboration with training institutions which they shall manage as local training hubs for local capacity building that will respond to the needs of local health managers, officials and drug therapeutic committees

4. Deputizing LGU agents and officials for the implementation of the different pillars of the PMP

5. Conducting regular performance review and assessment of local health system

6. Enhancing product surveillance systems at the local level, such as quality testing of medicines in the field.

E. **Public Private Partnerships (PPPs) and multi stakeholder collaboration**

In line with the *Target 8e of Millennium Development Goal (MDG)* 8 to forge global partnerships for development through promoting cooperation with pharmaceutical companies in providing access to affordable essential drugs in developing countries, the government shall ensure representation of other government agencies, the private sector, health professionals, patient/consumer welfare groups and other key stakeholders in the implementation and review of the PMP.

*Public-private partnerships shall be pursued through but not limited to the following strategies:* out-sourcing of services, monitoring of impact of national drug policies, increasing quality access points for medicines, partnering in making medicines affordable and available, research and development and encouraging rational and quality use of medicines.
Chapter 4 Framework for Implementation

I. Over-all responsibility

The over-all responsibility for the management, monitoring and evaluation of the Philippine Medicines Policy shall be the DOH-NCPAM. The NCPAM shall be the lead Office in the formulation of other technical guidelines and policies on medicines as well as systems and strategies crucial to the implementation of the PMP. It shall also ensure the smooth implementation of the PMP through close coordination with other offices of the DOH and key agencies of Government, as well as the LGUs and other stakeholders in the public and private sectors.

II. Roles and Responsibilities of Other Partners

A. Other DOH Offices

1. National Center for Disease Prevention and Control (NCDPC)
   - Take the lead in the creation of the National Standard Treatment Guidelines
   - Partner with the academe and health professional bodies in the development, adoption and dissemination of treatment protocols at all levels of healthcare

2. National Center for Health Facilities and Development (NCHFD)
   - Oversee the creation of Drug Therapeutic Committees (DTCs) in public hospitals in coordination with the Operations Clusters
   - Develop guidelines and standard monitoring system to ensure compliance to generics policy, drug pricing and rational drug use in hospitals
   - Integrate programs on ADRs/ADEs, counterfeit medicines and ARSP into the National Patient Safety Program

3. Bureau of Health Facilities and Services (BHFS)
   - Require the creation of Drug therapeutic Committees in private health facilities
   - Monitor compliance to generics policy, drug pricing and rational use of medicines in private hospitals
   - Ensure the implementation of Patient Safety Programs in private health facilities which include systems for preventing, monitoring and
controlling ADRs/ADEs, drug resistance and the spread of counterfeit medicines

4. Health Human Resource Development Bureau (HHRDB)
   o Collaborate with medical societies and the Professional Regulations Commission in integrating the pillars of the PMP in formal training/education as well as CME courses on rational use of medicines, generics prescribing and good governance in medicines, among others

5. Central Office Bids and Awards Committee/Materials Management Division (COBAC/MMD)
   o Ensure objective, transparent and efficient processes in the DOH procurement of medicines consistent with RA 9184
   o Local and international sourcing of medicines for use by the public health care system
   o Safeguard the quality of DOH-procured medicines through proper logistics management including warehousing, storage, stock management as well as distribution and delivery to the end users

6. Operations Clusters
   o Oversee the implementation of programs on access to medicines by The Centers for Health Development

7. Centers for Health Development (CHDs)
   o Implement and monitor national drug policies at the local level
   o Provide technical assistance to local government units and health providers in implementing and localizing DOH standards and policies
   o Report and feedback the status of implementation and emerging issues and concerns on drug management to the DOH-NCPAM through the Operations Clusters
   o Oversee policy implementation in their CHDs

B. DOH-Attached Agencies

1. Food and Drug Administration (FDA)
   o Promote a sensible regulatory regime for medicines to ensure SEQ of all pharmaceutical products
   o Provide timely, accurate, and quality medicine information and drug label information for consumers and the public
   o Pursue international harmonization of standards
2. Philippine Health Insurance Corporation (PHIC)

- Implement and improve in-patient and out-patient benefits schemes for medicines through the NHIP
- Accredit health facilities and pharmacies for drug reimbursements

3. Philippine Institute for Traditional and Alternative Health Care (PITAHC)

- Conduct research and development on complementary and alternative modes of therapy that has practical use in the local setting
- Accredit and recognize complementary and alternative modes of therapy with proven safety, efficacy and quality
- Build domestic capacity for large-scale manufacture and production of alternative drugs and modes of treatment

C. Other Government Agencies

1. Department of Trade and Industry (DTI)

- Ensure a stable and conducive business environment for the industry
- Monitor drug prices in the market in collaboration with DOH-NCPAM

2. Board of Investments (BOI)

- Develop a business plan to ensure the growth and viability of the local pharmaceutical industry
- Create PPPs with industry to improve and modernize local production facilities and support infrastructure
- Identify niches where the Philippines can have competitive advantage in the local manufacture of biotechnology and pharmaceutical products

3. Intellectual Property office (IPO)

- Provide information on the patent status of all registered medicines in the country
- Guide the DOH on the use of TRIPS flexibilities to improve access to single-source patented medicines that are deemed essential to address priority diseases
- Ensure country compliance with WTO-TRIPS in the use of TRIPS flexibilities

4. Department of Interior and Local Government (DILG)

- Encourage LGUs to implement good governance in medicines and other national programs that aim to increase access to medicines
o Assist the DOH in the monitoring and evaluation of the strategies defined in the PMP 2011 at the LGU level
o Help in the advocacy and promotion of the SARAH access framework in all local government activities to enhance the delivery of health services

5. Local Government Units (LGUs)
o Enforce national policies and standards that aim to increase access to safe, effective, quality and cost-effective medicines in the health system
o Implement the strategies of the SARAH access framework at the local level
o Partake in efforts to continually improve the system through information sharing on drug availability and prices as well as submitting monitoring and evaluation reports to the DOH
o Participate in the DOH advocacy for good governance in medicines along the medicines supply chain and exercise transparency and accountability in all their systems and processes

D. Industry
o Provide essential medicines at reasonable cost
o Comply with regulatory standards in research and development; conduct of clinical trials; production, manufacture, storage and distribution of drugs, and; marketing and promotion of pharmaceutical products
o Give truthful, balanced and understandable drug information to health practitioners and consumers about medicines;
o Promote ethical business practices and corporate social responsibility in responding to the needs of the poor and most vulnerable

E. Health professionals
o Provide patients/consumers with information and counseling to promote quality use of medicines
o Rational prescribing, dispensing, administration and use of medicines
o Adhere to strict ethical standards in participating in clinical trials as well as in the practice of their profession in delivering treatments and other health services to their patients

F. Academe
o Research and development and educational initiatives for health professionals
o Education of peers and adoption of clinical practice guidelines and treatment standards
G. Consumers/Patients
   o Use medicines rationally and responsibly
   o Access quality medicines information
   o Responsible reporting of issues that affect medicines (e.g. adverse drug events, overpricing, counterfeit medicines)

III. Operational framework

Upon the official adoption of this Philippine Medicines Policy, the NCPAM shall develop implementing guidelines to include targets, monitoring, evaluation and process for review. Specific guidelines and issuances shall be issued in support of the PMP.

IV. Review and Evaluation

The Philippine Medicines Policy may be reviewed at least every five years, or more frequently as necessary. The Secretary of Health may opt to create a National Committee for the review and evaluation of the Philippine Medicines Policy.

1Section 2.declaration of Policy, RA 9502
### NATIONAL OBJECTIVES FOR 2011-2016

<table>
<thead>
<tr>
<th>Strategic Objectives</th>
<th>Indicator</th>
<th>Data Source</th>
<th>Latest Baseline</th>
<th>Annual Targets</th>
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<tbody>
<tr>
<td>To improve access to quality essential medicines at all levels of health care</td>
<td>1. Per cent of drug manufacturing facilities with quality seal</td>
<td>FDA</td>
<td>142 (50%)</td>
<td>75%</td>
<td>100%</td>
<td>100%</td>
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<td>2. Total public expenditure on medicines in USD</td>
<td>M8G8 indicators, 2007 (WHO)</td>
<td>730,807,000</td>
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<td>3. Public per capita expenditure on medicines in USD</td>
<td>M8G8 indicators, 2007 (WHO)</td>
<td>$8.47</td>
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<td>4. Population covered by public health insurance</td>
<td>Philhealth</td>
<td>38%</td>
<td>10.8 million families in CCT areas</td>
<td>Universal Coverage</td>
<td>Universal Coverage</td>
<td>Universal Coverage</td>
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<td>5. Public expenditure (including public health/social insurance) on pharmaceuticals as % of total pharmaceutical expenditure</td>
<td>IMS Health, PHIC, DOH, NHA</td>
<td>10%</td>
<td>25%</td>
<td>35%</td>
<td>45%</td>
<td>55%</td>
<td>75% PHIC members, 100% for PHIC sponsored members</td>
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<td>6. Median Per cent availability of essential medicines in public health facilities</td>
<td>EC Study 2009; DOH-NCPAM annual survey</td>
<td>25%</td>
<td>35%</td>
<td>50%</td>
<td>60%</td>
<td>70%</td>
<td>80%</td>
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<td>7. Average availability of 30 essential medicines in public health facilities</td>
<td>W4O/HAI Health Facility Survey, 2009</td>
<td>Generic = 7.1 % Branded = 26.8%</td>
<td>35% availability</td>
<td>50% availability</td>
<td>60% availability</td>
<td>70% availability</td>
<td>80% availability</td>
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<td>8. Average availability of 30 selected essential medicines in private health facilities</td>
<td>W4O/HAI Health Facility Survey, 2009</td>
<td>Generic = 14.6% Branded = 21.7%</td>
<td>35% availability</td>
<td>50% availability</td>
<td>60% availability</td>
<td>70% availability</td>
<td>80% availability</td>
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<td>9. Median consumer price ratio of 30 selected essential medicines in public health facilities</td>
<td>W4O/HAI Health Facility Survey, 2009</td>
<td>Generic = 30.23 Branded = 10.81</td>
<td>less than 4x the International Reference Price</td>
<td>less than 4x the International Reference Price</td>
<td>less than 4x the International Reference Price</td>
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<td>10. Median consumer price ratio of 30 selected essential medicines in private health facilities</td>
<td>W4O/HAI Health Facility Survey, 2009</td>
<td>Generic = 37.10 Branded = 10.76</td>
<td>less than 4x the International Reference Price</td>
<td>less than 4x the International Reference Price</td>
<td>less than 4x the International Reference Price</td>
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<td>12. Generics share in the market</td>
<td>IMS Health 2010</td>
<td>60% share by Volume, 40% share by Value</td>
<td>70% share by Volume, 40% share by Value  75% share by Volume, 35% share by Value  75% share by Volume, 35% share by Value  80% share by Volume, 30% share by Value  80% share by Volume, 30% share by Value</td>
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<td>13. Increase the number of Functional BnBs (in level 2) level 2 BnBs: earning at least P18,000/year</td>
<td>EC Study 2009</td>
<td>27% of all established BnBs</td>
<td>40% of all established BnBs  60% of all established BnBs  80% of all established BnBs  90% of all established BnBs  100% level 2 BnBs functional</td>
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<td>To ensure rational use of medicines by prescribers, dispensers and patients</td>
<td>14. Existence and year of last update of a published Philippine National Formulary (PNF)</td>
<td>NCPAM, DOH, IMS</td>
<td>The last update of a published PNF was in 2008.</td>
<td>continuous update of the PNF  continuous update of the PNF  continuous update of the PNF  continuous update of the PNF  Quarterly updating/uploading</td>
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<td>15. A survey on rational use of medicines has been conducted. Write the year of the survey</td>
<td>WHO Level 2 and 3 Survey</td>
<td>2008 (every three years)</td>
<td>conduct survey</td>
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<td>16. Average number of medicines prescribed per patient (outpatient)</td>
<td>WHO Level 2 and 3 Survey</td>
<td>acute: 1.75 medicines; chronic: 1-9 medicines</td>
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<td>17. Per cent of medicines in outpatient public health care facilities that are prescribed by INN (generic) name</td>
<td>CHDs, FDA, DOH Hospitals</td>
<td>no data</td>
<td>100%  100%  100%  100%  100%</td>
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<td>18. Per cent of medicines prescribed in outpatient public health care facilities that are in the EML</td>
<td>CHDs, FDA, DOH Hospitals</td>
<td>no data</td>
<td>100%  100%  100%  100%  100%</td>
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<td>To institutionalize transparency and good governance in the pricing and procurement of medicines in the public and private sectors</td>
<td>19. Per cent of drug facilities in complying with the eEDPMS</td>
<td>NCPAM, DOH, IMS</td>
<td>3%</td>
<td>60%  70%  80%  90%  100%</td>
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GLOSSARY

The following terms as used in this Philippine Medicines Policy shall be defined as follows:

❖ **ACCESS** – Ability to utilize available health services without any significant barriers or obstacles.

❖ **AFFORDABILITY** - Cost of treatment in relation to peoples’ income. In the WHO/HAI survey, this is defined by the number of days the lowest paid unskilled government worker would have to work in order to afford the cost of the complete course of treatment.

❖ **ADVERSE DRUG REACTION (ADR)** - Any response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for modification of physiological function.

❖ **ANTIMICROBIAL RESISTANCE (AMR)** - The ability of certain microorganisms to withstand attack by antimicrobials, and the uncontrolled rise in resistant pathogens threatens lives and wastes limited healthcare resources.

❖ **BASIC NECESSITIES** - includes: rice; corn; bread; fresh dried and canned fish and other marine products; fresh pork, beef, and poultry meat; fresh eggs; fresh and processed milk; fresh vegetables; root crops; coffee; sugar; cooking oil; salt; laundry soap; detergents; firewood; charcoal; candles; and drugs classified as essential by the Department of Health

❖ **CLINICAL TRIAL** - Any systematic study on pharmaceutical products in human subjects, whether in patients or other volunteers, in order to discover or verify the effects of, and/or identify any adverse reaction to, investigational products, and/or to study the absorption, distribution, metabolism and excretion of the products with the object of ascertaining their efficacy and safety.

❖ **CONSIGNMENT** - Method of assuring availability of stocks wherein the Consignor places its goods at the pharmacy of the of the Consignee for sale, and the former being paid by the latter for only the actual quantity consumed using the money generated from the sale of the consigned goods within an agreed period of time.

❖ **CONFLICT OF INTEREST** – arises when a DOH official or employee is a member of a board, an officer, a substantial stockholder of a private corporation, an owner or one who has substantial interest in a business such that the interest of such a corporation or business, or his rights or duties therein may be opposed to or affected by the faithful performance of official duty; may also exist when the objectivity of a DOH official or employee in performing official duties is impaired or may reasonably appear to be impaired by the personal concerns
of a DOH official act results in unwarranted personal benefit oh his/her part or that of his/her relatives.

- **CURRENT GOOD MANUFACTURING PRACTICES (CGMP)** - The current system of quality assurance aimed at ensuring that products are consistently manufactured to a quality appropriate for intended use. It is thus concerned with both manufacturing and quality control process and procedures.

- **DISPENSING** - Act by a validly registered pharmacist of filling a prescription or doctor’s order on the patient’s chart.

- **DRUG OUTLETS** - Drugstores, pharmacies, and any other business establishments which sell drugs or medicines to the public in general.

- **DRUGS AND MEDICINES** - Drugs and Medicines refer to any chemical compound or biological substance, other than food, intended for use in the alleviation of symptoms and the treatment, prevention or diagnoses of diseases in humans or animals, including but not limited:

1. Articles recognized in the current official United States Pharmacopoeia-National Formulary (USP-NF), official Homeopathic Pharmacopeia of the United States, Philippine Pharmacopeia, official Philippine National Drug Formulary (PNDF), British Pharmacopeia, European Pharmacopeia, Japanese Pharmacopeia, Indian Pharmacopeia, any national compendium or any supplement to any of them;

2. Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

3. Articles other than food intended to affect the structure or any function of the human body or animals;

4. Articles intended for use as a component of articles specified in clauses (1), (2), or (3) not including devices or their components, parts, or accessories; and Herbal and/or traditional drugs which are articles of plant or animal origin used in folk medicine that are:
   a. Recognized in the Philippine National Drug Formulary Vol. 1 (Essential Drugs List);
   b. Intended for use in the treatment, cure or mitigation of diseases symptoms, injury or body defects in humans;
   c. Other than food, intended to affect the structure or any function of the human body;
   d. In finished or ready-to-use dosage form; and
   e. Intended for use as a component of any of the articles specified in clauses a-d.
EFFICIENCY – Use of energy, time, and money to produce maximal outputs. It involves dimensions to technical efficiency (generating a specific output at least cost) and allocative efficiency (selecting the right mix or set of outputs to get the best results out of resources).

ESSENTIAL MEDICINES - Those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.

ESSENTIAL MEDICINE LIST - Essential Medicine List or National Drug Formulary refers to a list of drugs prepared and periodically updated by the Department of Health on the basis of health conditions obtaining in the Philippines as well as on internationally accepted criteria.

FOOD SUPPLEMENT - A processed food product intended to supplement the diet that bears or contains one or more of the following dietary ingredients: vitamin, mineral, herb or other botanical, amino acid, and dietary substance to increase the total daily intake in amounts conforming to the latest Philippine recommended energy and nutrient intakes or internationally agreed minimum daily requirements. It usually is in the form of capsules, tablets, liquids, gels, powders or pills and not represented for use as a conventional food or as the sole item of a meal or diet or replacement of drugs and medicines.

GENERIC MEDICINES - Drugs that have the same active pharmaceutical ingredient as the innovator drugs and are not covered by patent protection. These drugs are labeled by their international non-proprietary or generic name and may or may not have brand names.

HEALTH PRODUCTS - Means food, drugs, cosmetics, devices, biological, vaccines, in-vitro diagnostic reagents and household/urban hazardous substances and/or a combination of and/or a derivative thereof. It shall also refer to products that may have an effect on health which require regulations as determined by FDA.

HERBAL PRODUCTS - Medicinal products containing, as active ingredients, exclusively plant material and/or preparations. This term is generally applied to a finished product.

INDIGENT - Person who has no visible means of income, or whose income is insufficient for the subsistence of his family.

INNOVATOR DRUG - A drug with an active pharmaceutical ingredient or molecule that was first or originally marketed anywhere in the world on the basis of documentation of quality, safety and efficacy by a specific company or an entity which is expresses in its
international non-proprietary name and usually carries a brand name. Such may be patented, non-patented or off-patent.

- **Licensing** - Process of approval of an application to operate or establish an establishment prior to engaging in the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and where applicable the use, testing, promotion, advertisement, and/or sponsorship of health products.

- **Manufacture** - Any process or part of a process for making, altering, finishing, packing, labeling, breaking or otherwise treating or adapting any drug with a view to its sale and distribution, but does not include the compounding or dispensing of any drug in the ordinary course of retail business.

- **Manufacturer** - Any establishment engaged in the operations involved in the production of a drug with the end view of storage, distribution, or sale of the product.

- **National Center for Pharmaceutical Access and Management (NCPAM)** - An office created under the Office of Secretary of Health tasked to implement, strategize, maximize and monitor the impact of RA No. 9502, otherwise known as the “Universally Accessible Cheaper and Quality Medicines Act of 2008”

- **National Health Insurance Program** – Compulsory health insurance program of the National Health Insurance Act of 1995 (RA 7875), which shall provide universal health insurance coverage and ensure affordable, acceptable, available, and accessible health care services for all Filipinos

- **Out-of-Pocket Payment** – Amount that a family is required to pay for health care. This could arise because the family has no social health insurance cover or has to pay user fees in public facilities. Even if the family has health insurance, out-of-pocket payment could arise as a result of co-payments, deductibles, or benefit limits or exclusions, or from the use of medical savings account which individualize family health expenditure.

- **Parallel Drug Importation** - Importation without the consent of the patent-holder of a patented product marketed in another country either by the patent holder or with the patent-holder’s consent. The principle of exhaustion states that once patent holders, or any party authorized by him, have sold a patented product, they cannot prohibit the subsequent resale of that product since their rights in respect of that market have been exhausted by the act of selling the product.

- **Patented Medicines** - Drugs covered with patent protection as recognized by the Philippine Government regulating body.
- **PHARMACOVIGILANCE** - The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.

- **PRESCRIPTION** – The written order and instruction of a validly-registered physician, dentist or veterinarian for the use of specific drug product for a specific patient.

- **PRICE CEILING** - means the maximum price at which any basic necessity or prime commodity may be sold to the general public

- **QUALITY** – Compliance of goods and services with a prescribed standard. The standard may involve dimensions of quantity (number), structure (facility, equipment, supplies, or drugs used), or processes (skill or practice, “decision making”). Compliance with quality standards are linked to payment of benefit packages, and client satisfaction.

- **RETAILER** - A licensed establishment carrying on the retail business of sale of drugs and medicines to customers; any establishment which sells or offers to sell any health product directly to the general public.

- **REGISTRATION** - The process of approval of an application to register health products prior to engaging in the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and where applicable, the use, testing, promotion, advertisement, and/or sponsorship of health products.

- **TRADITIONAL MEDICINE** - The sum total of knowledge, skills, and practice on health care, not necessarily explicable in the context of modern, scientific philosophical framework, but recognized by the people to help maintain and improve their health towards the wholeness of their being, the community and society, and their interrelations based on culture, history, heritage, and consciousness.

- **TRIPS AGREEMENT/ WTO-TRIPS** - TRIPS Agreement/ WTO-TRIPS or Agreement on Trade –Related Aspects of Intellectual Property Rights refers to the international agreement administered by the World Trade Organization (WTO) that sets down minimum standards for many forms of intellectual property regulation.
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