



**World Health  
Organization**

# **NATIONAL MEDICINES POLICY AND PLAN OF ACTION**



**FY2023/24-FY2027/28**

**Ministry of Health**

## MINISTER OF HEALTH'S FOREWORD

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I am pleased to present this second edition of Samoa's National Medicines Policy and Plan of Action FY2023/24-FY2027/28.

This policy is to provide direction and guidance for Samoa's health sector including all stakeholders in Samoa's pharmaceutical sector.

This new edition has been informed by the review of the previous National Medicines Policy for Samoa 2008 and the need to strengthen pharmaceutical systems as a key component of Samoa's health system to meet the ever-changing needs of the population. It is also in line with national health priorities articulated in the Pathway for the Development of Samoa FY2021/22-FY2025/26 Key Priority Area 2: Improved Public Health and Samoa's Health Sector Plan FY2019/20-FY2029/30 vision for a Healthy Samoa. This policy shall be implemented through a 5-year strategic plan, supported by a monitoring and evaluation framework.

I wish to express my deepest gratitude to the World Health Organization for provision of technical support and other sector partners whose immense contributions and support have made this second edition of Samoa's National Medicines Policy FY2023/24-FY2027/28 a success.

I urge all stakeholders to support and align their programs, investments and resources to this policy to strengthen the implementation process.

Ma le fa'aaloalo lava.



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Hon. Valasi Luapitofanua To'ogamaga Selesele  
**MINISTER OF HEALTH**

## DIRECTOR GENERAL OF HEALTH'S MESSAGE

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The Samoa National Medicines Policy and Plan of Action FY2023/24-FY2027/28 is developed to define medium and long-term goals of Samoa's pharmaceutical sector. This policy document is the commitment of Samoa government and health sector partners both in the public and private sectors towards achieving its pharmaceutical related national health priorities articulated in the Pathway for the Development of Samoa (PDS) FY2021/22-FY2025/26 and Health Sector Plan FY2019/20-FY2029/30.

The overarching goal of this policy is to improve health outcomes of Samoa population by promoting equitable and sustainable access to essential medicines, promoting rational and use of medicines, and ensuring quality, safety, effectiveness and affordability of medicines as well as responsible use by both healthcare providers and users.

The access to essential medicines is another important part of promoting Universal Health Coverage. Hence, this policy document is intended to express Samoa's commitment towards achieving Universal Health Coverage.

This is the second edition after the full review of the previous National Medicines Policy 2008 which was held in the beginning of this year.

The National Medicines Policy and Plan of Action FY2023/24-FY2027/28 for Samoa has been developed through the collective inputs of various stakeholders within the economic, health, pharmaceutical and community sectors.

I would like to take this opportunity to sincerely show my deep gratitude to the following partners and stakeholders for their immense contribution to the review of the previous National Medicines Policy 2008 and the development of this new policy document for Medicines for Samoa (National Medicines Policy 2023-2028).

- (i) WHO Samoa Country Office
- (ii) WHO Fiji Country Office
- (iii) UNICEF Office in Samoa
- (iv) President of Samoa Pharmacy Association
- (v) Chair of Samoa Pharmacy Council
- (vi) Scientific Research Organization of Samoa (SROS) and
- (vii) Ministry of Health Executive Management and Relevant Senior Officials.

Ma le fa'aaloalo lava.

A handwritten signature in blue ink, which appears to read 'Aiono', written over a horizontal line.

Aiono Dr. Alec Akeroma  
**DIRECTOR GENERAL OF HEALTH**

## LIST OF ABBREVIATIONS

AMR	Antimicrobial Resistance
AMU	Anti-microbial use
ATM	Access to Medicines
AWaRe	Access, Watch, Reserve
CDs	Communicable Diseases
CW	Central Warehouse
DHIS	District Health Information Software
DTCs	Drugs and Therapeutics Committee
EML	Essential Medicines List
EUA	Emergency Use Authorization
GTIN	Global Trade Item Number
HR	Human Resource
HSP	Health Sector Plan
INN	International Non-Proprietary Name
LMIS	Logistics Management Information Systems
M&E	Monitoring and Evaluation
MOF	Ministry of Finance
MOH	Ministry of Health
NGOs	Non-Governmental Organizations
NMSGC	National Medicines Selection and Guidelines Sub-Committee
NTDs	Neglected Tropical Diseases
PDS	Pathway for the Development of Samoa
PICs	Pacific Island Countries
PIMS	Pharmacy Information Management System
PPMR	Policy Planning Budget and Research
PSS	Pharmaceutical Society of Samoa
PV	Pharmacovigilance
RUM	Rational Use of Medicines
SC	Steering Committee
SMA	Samoa Medical Association
STG	Standard Treatment Guidelines
UHC	Universal Health Coverage
WHO	World Health Organization
SROS	Scientific Research Organization of Samoa

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## INTRODUCTION

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Samoa comprises four main islands, of which the largest two are Upolu and Savaii, and is located in the Polynesian part of the Pacific Ocean. Samoa had a population of around 205,557 (2021). Samoa is classified as a lower-middle-income country with a Gross Domestic Product - Nominal SAT \$ 2.0billion (FY 2020/21). Real GDP SAT\$ 1.9 billion (FY2020/21). GDP per capita SAT \$ 10.188, USD\$ 3,822. Overseas development aid funded an estimated 40 percent of government expenditure as of 2014. The Government of Samoa through the Ministry of Health (MoH) continues to place emphasis on providing assistance to support the implementation of its Health Sector Plan FY2019/20 – FY2029/30.

The Government in their commitment to the Samoan people as outlined in the Pathway for the Development of Samoa FY20021/22-FY2025/26<sup>1</sup> rightly stated that all persons receive quality health care services as a social contract with the people of Samoa with following expected outcome:

- Health care services and facilities improved
- Prevalence of Non-Communicable Diseases and infectious diseases reduced and
- Life expectancy increased.

The Pathway for the Development of Samoa describes the efforts in the following: ‘Through the Health Sector Plan, the Non-Communicable Diseases (NCD) Policy will be rigorously pursued, supported, and implemented in partnership with communities and others so that there is greater awareness and promotion of healthy living. It went on to define measures to combat the incidence and spread of Communicable Diseases (CDs) and Neglected Tropical Diseases to increase, including vaccination efforts across the country’.

The Government is committed to having a policy framework that can effectively plan, manage and maintain health care services and facilities. From an operational perspective, the health sector will make further investments in Health Information Systems to increase the efficiency of services and support improvements in managing the procurement and dispensary of all medical supplies which is a strategic decision. Measures to improve healthcare services will be underpinned by investments in the development of skills and competencies, accreditation, and career pathways for key medical and clinical staff. This includes those staff working in special care services for the elderly and people with disabilities. The commitment to raise the ratio of doctors and nurses per patient remains the same. The assumption is that the increment in ratio would affect pharmacists to population ratio as well. The geographic distribution of healthcare workers as envisaged in the Samoa Human Resources for Health Strategy<sup>2</sup>, sustainable infrastructure and equipment, and the availability of medicine and medical consumables will improve. The capability of Village Health Centres will be strengthened to support the district hospitals’

The overarching objective of the health contractual arrangements is to improve access to, and utilization of effective, efficient and quality health services to improve the health status of Samoa’s population in line with the Health Sector vision of “A Healthy Samoa”. Based on the Health Sector Plan strategic areas, key outcomes and priorities, the proposed activity will serve to improve the delivery of health services in Samoa.

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<sup>1</sup> Pathway for the Development of Samoa FY2021/22-FY2025/26

<sup>2</sup> Samoa Human Resources Strategy FY2021/21- FY 2025/26

The Health Sector Plan FY2019/20-FY2029/30<sup>3</sup> envisaged that ‘there is also scope to improve efficiency and value for money through more strategic use of the pharmaceutical budget.’ Samoa, like all other Pacific Island Countries (PICs) has little alternative other than to pay prices for pharmaceuticals that are significantly above WHO median prices (World Bank, 2018). However, what is within the span of control of the MOH is to ensure that funds spent on pharmaceuticals will achieve good outcomes. This is important because Government expenditure on pharmaceuticals was SAT\$4.5million in 2018/19, or 4.4% of the current health budget.

The demand for pharmaceuticals will and should inevitably increase as PEN Fa'a Samoa scales up under this Sector Plan and more individuals are identified and prescribed medicines. Research suggests Samoa spends less on pharmaceuticals than would be considered appropriate for the country given its disease burden and level of income (World Bank, 2018:11). Samoa can achieve significant efficiencies and cost savings in pharmaceutical purchases by investing resources in secondary prevention throughout the country and doing everything possible to ensure patients continue with their medication and do not drop out of or become lost in the health system. Conversely, pharmaceutical costs can be unaffordable and unsustainable if secondary prevention is weak and diabetes and / or hypertension progresses in a patient. This Sector Plan will therefore update training of front-line health workers, especially community health workers, beginning in 2019/20, on the strategic importance of secondary prevention, including patients' adherence to medications so as to avert or at least postpone the progression of high burden / high cost diseases such as diabetes and hypertension.

At the launch of Samoa's Pharmaceutical Warehouse in 2016 the Prime Minister then, declared and it is intuitive: ‘This warehouse is vital for Samoa's national health services. This purpose-built facility will allow government to buy, store and maintain better quality and larger quantities of medicine, which is important when planning ahead and ensuring we are prepared for any eventuality such as supplier delays or natural disasters,’ said Hon. Tuilaepa Sailele Malielegaoi. August 2016<sup>4</sup>

There is a much-welcomed push by the World Health Organization (WHO) Member States including Samoa to implement the concept of Universal Health Coverage (UHC) and thus to ensure that all people obtain the health services they need without suffering financial hardship when paying for them. UHC requires strong, well-run health systems, sustainable and equitable methods to finance health services, sufficient capacities of well-trained and motivated health workers, and finally “access to essential medicines and technologies”.

The people of Samoa are suffering from various kinds of diseases: emerging and re-emerging Neglected Tropical Diseases (NTDs), Communicable Diseases (CDs) and Non-Communicable Diseases<sup>5</sup> due to their lifestyle habits. Medicines and vaccines remain the strategic face of the health outcomes and the first aid preferred by every disease. When medicine is required, its rational use demands the appropriate medicine to be prescribed; that it be dispensed correctly with the right dose, that it be safe and in good quality, and should be available at the right time, at the affordable price. Hence, the review of the existing National Medicines Policy 2008 for Samoa will help in identifying policy issues and gaps from the 2017 National Medicines Policy Gap Analysis and Health Sector Plan 2008-2018 Full Review Report, as well as other priority areas that need to be factored in the new National Medicine Policy for the next five years. The extent to which it has helped in the development of better access to medicines in Samoa. By assessing and analysing the situation for the medicines policy and other relevant health policies, this

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<sup>3</sup> Health Sector Plan FY2019/20-FY2029/30, Ministry of Health, 2019

<sup>4</sup> Internet Samoa News accessed 23<sup>rd</sup> May 2023

<sup>5</sup> National Non Communicable Disease Revised Policy 2018-2023



review seeks to highlight trends, barriers, and bottlenecks in the realization of better access to essential medicines in Samoa.

## Purpose of the Medicine Policy Review

Health Technologies are an important part of protecting and maintaining the health of all people including Samoans. Medicines or health technologies are required for the prevention, management, and control of illness, and most of all to offer remedies in terms of treatment of illnesses. When medicine is required, its rational use demands that the appropriate medicine be prescribed, that it be made available at the right time, at a price people can afford, that it be dispensed correctly, and that it be taken in the right dose at the right intervals for the right length of time. The appropriate medicine must also be effective and of acceptable quality of safety. WHO states that the formulation by governments of a National Medicines Policy is fundamental in ensuring rational medicines use. The Samoa Medicines Policy was thus formulated to define a philosophy in Samoa, which will guide the many public and private sector individuals and organizations involved in the prevention, treatment, management, and control of the illness process. The Policy was designed as a useful tool to combat irrational medicines use which might lead to shortages, adverse events, and similar unwanted situations. The existing National Medicines Policy 2008 needs to be reviewed and updated as this will contribute to identifying priority areas for pharmaceutical services that need to be reflected in the new National Medicines Policy 2023-2028 which will guide and strengthen the delivery of pharmaceutical services both in public and private pharmacies in Samoa in the next five financial years. This must also align to the Ministry of Health strategic plan and the Samoan Development Plan.



## SITUATIONAL ANALYSIS

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The concept of access, as described by the WHO Access framework<sup>6</sup>, is a general concept that summarizes a set of more specific dimensions (availability, accessibility, affordability and acceptability as the 4As). The framework describes the fit between the patient and the health care system, was grounded by rational selection and use of essential medicines, affordable prices, sustainable financing, and reliable supply systems. While the above has shaped thought about access to medicines, recent analysis<sup>7</sup> reveals that the typical 4As of access may not be enough in framing the access problem in Samoa, which is even more complex in a fragile island health system. It reports that barriers to access to medicines is complex and occurs at multiple levels of the health system; that existing frameworks for Access to Medicines (ATM) do not address complexity of these barriers and their interconnectedness. A wider health system perspective may offer an opportunity to entrench ATM in the emerging debate around complex adaptive systems and their application to health. This analysis recommends a health system approach to access that is adaptive to the varying configurations of access at the individual, household and community level; health service delivery level; health sector level; public policy level; as well as the regional and international level.

The access framework therefore, remains relevant especially when distributed along the levels of the health system, in a manner that bring context and adaptation in a weak and challenging terrain with capacity issues guided the analysis of the Situation in Samoa.

### Key Policy Areas and Findings

The following analysis describes observations from each component of a national medicine policy as described by WHO<sup>8</sup> and includes recommendations on priority actions to overcome current limitations in the implementation of NMP 2008-2013. Figure 1 in Appendix 1 shows the overall policy implementation and figure 2 described the strengths, weaknesses, opportunities and threats of the current situation.

#### *Selection of Medicines*

To ensure rational use and adequate forecasting, the selection and prescribing of medicines should be guided by the Essential Medicines List (EML) and Standard Treatment Guidelines (STG).

Samoa has an EML<sup>9</sup> that comprises about 170 medicines. The key performance area of this statement is the existence of a National Medicines and Therapeutics committee comprising experts in medical and pharmaceutical fields and additional co-opted members for special purposes. From interview with key informants, the committee does not appear to be currently functional. However, there was an ad hoc committee that was formed to review the Essential Medicines List 2022.

There is no current STG however, the Essential Medicines List 2022 was developed. It was also observed that the review considered clinical evaluation without economic evaluation. This part of the policy does not also give a clear means of selecting herbal medicines as essential medicines for use in Samoa. Some

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<sup>6</sup> WHO Access Framework (indicate year of publication)

<sup>7</sup> B. M *et al.*, “Access to medicines from a health system perspective,” *Health policy and planning*, vol. 28, no. 7, pp. 692–704, Oct. 2013, doi: 10.1093/HEAPOL/CZS108

<sup>8</sup> How to develop and implement a national drug policy. — 2nd ed, World Health Organization 2001

<sup>9</sup> The Essential Medicines List 2022

experts complained they were not included as experts in the current EML review. Key areas of building capacity for the Experts in both clinical and economic evaluation may be useful and strategic for the next steps.

### **Key Actions:**

- A functional all-inclusive National Expert Committee for reviewing Standard Treatment Guidelines (STG) and Selection of Medicines to include all stakeholder experts is strategic
- STG must inform Essential Medicines List (EML)
- A chairperson for such an expert group must be a specialist in internal medicine and must be appointed with terms of Reference
- All Expert Committee members must sign a Conflict-of-Interest document for all their meetings to ensure members are not conflicted in one way or the other.
- Financing should be provided for the Committee of Experts
- Capacity building for Experts in clinical and economic evaluation principles is essential
- There must be a secretariat for the Expert Committee

### ***Affordability***

The Samoa Medicines policy recognizes the need to ensure a fair markup of medicines in the private sector to ensure the affordability of medicines. The policy also lists key measures the government should adopt to ensure Samoans could afford the medicines they need. What the policy does not come clear on is how markup should be done in the private sector to reduce cost and increase affordability. The policy states the government's commitment to ensure affordability and that was through heavily subsidized prices for patients with NCDs. Population of 15 years and below and Pensioners of 65 years are exempted from paying for health care. A literature search on relevant government platforms revealed that there are no pricing policies but there is a framework from mSupply that provided pricing of medicines at the warehouse for the public sector. The general impression is that the measures to ensure the affordability of medicines both in the public and private health sectors in Samoa must be thoroughly reviewed to ensure the people of Samoa has access to quality and safe medicines which are reasonably priced. There is no Essential Health Package in Samoa to support Universal health Coverage

### **Key Actions:**

- A Step wise approach to gradual introduction of health insurance as a risk protection strategy is recommended to protect the poor and vulnerable who are currently not covered under any of the current schemes
- Develop an Essential Health services package that is covered by Health Insurance to support risk protection strategies
- Private sector engagement in support of any affordability program is critical
- Performance for Results (P4R) program may provide a baseline for action for a national Health insurance for the population.
- Develop a pricing policy as a tool for access to medicines for both public and private

### ***Financing Pharmaceuticals***

In Samoa, healthcare resources are stretched by the demographic shift to older populations, with more costly chronic diseases. The policy promises measures to improve usage and prevent waste. However, the

means of drug financing are not clear. The use and scope of user charges as a drug financing option have not been clearly defined.

### **Key Actions:**

- Government currently finances 100% of medicine needs of the public sector however unable to provide timely payments to suppliers
- Develop effective ways to deal with medicine shortages
- Sustainable financing of medicines must be linked to sustainable Financing of Health

### **Supply systems**

There is an mSupply program on going providing great data for decision making which is a plus for Samoa. However, the supply chain data is not linked to epidemiological data which sits at the office of ACEO Health Information, Monitoring and Evaluation. The policy follows an operational principle for good pharmaceutical procurement but a well-coordinated supply system is not in place to ensure that public funds available for pharmaceutical purchases are used effectively to maximize access, obtain good value for money, and avoid waste. While Medicine supplies are coordinated at the Warehouse, however, laboratory, dental and other supplies are on their own. Framework contracting as a tool for procurement exists. It was also observed that delays of Suppliers due to late payments exist leading to shortages of supplies in the health facilities. Expiries remain a challenge for the supply systems and stock management principles may be reinforced to manage expiries. As a small island country, local production of pharmaceuticals is not currently on the agenda for the Government of Samoa. It is not too clear whether Samoa operates a PUSH or PULL systems for supplies. Stores operating procedure guidelines were sighted. Apart from Government paying for medications, Samoa also gets a lot of donations from WHO, UNDP, UNICEF, UNFPA and bilateral donations from China, India, Australia among others. List of essential consumables has also not been sighted during the review. A donation guideline has also not been sighted during this review either through the desk review and key informant interviews.

### **Key Actions:**

- Consolidate supplies for Health, so the medical, laboratory and dental supplies are procured through a similar mechanism to unify the procurement systems and increase efficiency
- IT for supplies to be linked with Health information
- Inventory management systems to be agile to manage and if possible, prevent expiries
- Develop Essential Consumable List (adopt and adapt the WHO lists)
- Build capacity for supply chain officers at the warehouse
- Develop or review and disseminate widely a National Donation Guideline to ensure bad products are not dumped on the people of Samoa
- Supplier monitoring and if possible blacklisting suppliers for untimely delivery of stocks

### **Regulation and Quality Assurance**

The government is committed to controlling drug use, which includes the requirement for a strong legislative foundation and sufficient human and financial resources. Samoa has five legislative documents that provide an overarching legal framework for the National Medicines Policy, namely: the Drugs Act 1967, Narcotics Act 1967, Ministry of Health Act 2006, amended in 2019, National Health Services Act 2006, and Poisons Act 1968 which are all included in the Samoa Health Legislation Handbook. The

Ministry of Health is in charge of regulating medicines in Samoa through the Quality Assurance Division. However, not all regulatory actions are performed by the Quality Assurance division. The legal frameworks are quite old to support the new developments in the pharmaceutical sector. The review did not cite any measures to ensure that drug information is unbiased. The policy also strongly speaks to the need and potential for systems of adverse drug reaction monitoring, however there are no established procedures to ensure reporting of adverse drug reactions.

The bottlenecks are, in Samoa, medicine supply functions and the organizations responsible for supply management are not entirely segregated from drug regulatory functions. There are no set-up procedures to ensure transparency in the work of drug regulatory functions. It might be very necessary to entirely segregate medicine supply functions from drug regulatory functions to maintain independence and prevent conflicts of interest. Also, although there is a partly a stepwise approach to drug registration in the Samoa Medicines Policy, the core elements of drug regulation (i.e., quality, safety, efficacy, and Information) are not clearly inculcated in the review for product registration. Samoa is also part of the Pacific Medicine testing program, which is a program led by Therapeutics Guide Administration (TGA) by the laboratories branch, so each Pacific Island country has a total of 5 free products to be tested every year. So, Samoa participates with the rest of the Pacific, and they can send samples of suspected medicines that have some quality defects or medicines that are related to some adverse events. So, they send 5 samples to TGA for free. What happens when there are more than 5 products require some additional costs to Samoa. The country therefore depends on the reliance mechanisms from Australia and New Zealand for importation of pharmaceuticals but in country regulation activities is over seen by the Quality Assurance Division who reports to the Director General. Commitment to good storage practices (GSP) as a regulatory function, inspection, and law enforcement and commitment to ensure Quality Control facilities may not be available to ensure the quality of imported products is not specified in the policy. Post market surveillance has been challenged. UNICEF and WHO through the Expanded Program on Immunization has a well-functioning Adverse Events Reporting (AEFI) For routine Immunization which was escalated during COVID 19 vaccine immunization with a call centre to report community incidents of adverse events. Samoa is not a member of the WHO Program for International Drug Monitoring (PIDM). They are not consistently tracking adverse drug reactions, or they don't have any system in place for monitoring adverse drug reactions. There are no clinical trials done in Samoa. There are no field detection devices (minilabs) to support quality assurance of pharmaceuticals. Scientific Research Organisation for Samoa (SROS) exists with accredited laboratories however mandated by Act of Parliament for research and development. Last but not least, there are no procedures laid down to regulate traditional and herbal medicines. Through the informants, Samoa seems to have abundant herbal medicines and traditional healers, and the Traditional Practitioners association is affiliated to the Allied Health Professionals Council. Veterinary medicines to also be regulated in line with the National AMR action Plan and within the One Health agenda. The herbal medicines would be dealt with in another chapter.

### Key Actions:

- Regulatory Framework for Pharmaceuticals is urgently needed. An abbreviated Global Benchmarking Tools (GBT) assessment would help identify priority actions
- Review of the Drugs Act 1967 and related Acts is strategic for the pharmaceutical sector
- Autonomous regulation of medicines is required for safety and quality of pharmaceuticals and technologies
- Establish a centre for reporting of Post market Surveillance, and adverse drug reactions
- System for adverse drug reactions to be established across health facilities with targeted training and awareness for reporting

- Explore the possibility of acquiring field detection devices at least for the warehouse (Minilabs) in the interim
- Build on the EPI systems to establish an all-inclusive Pharmacovigilance Program for medicines and vaccines
- Explore membership to WHO Program for International Drug Monitoring (PIDM)
- Regulate Herbal medicines
- Regulate veterinary medicines within the One Health agenda

### *Rational Use of Medicines*

The Samoa National Medicines policy is very emphatic on means to promote the rational use of medicines. To ensure rational use, the prescription of medicines should be guided by the Samoa EML and corresponding STGs. Development of evidence-based clinical guidelines, as the basis for training, prescribing, drug utilization review, drug supply, and drug reimbursement is encouraged. Measures to ensure the establishment and support of Drugs and Therapeutics Committees (DTCs) are available but according to informants, these are not functional. The policy promotes the concepts of essential drugs, rational drug use, and generic prescribing in basic and in-service training of health professionals. There is a commitment to continuing education and independent, unbiased drug information. Consumer education and ways to deliver it are stated in the policy but there is no evidence of this being done except during the World Antibiotic Awareness week. However regulatory and managerial strategies are not in place to promote rational drug use. Laboratory results are not timely and so clinicians' resort to empirical treatment. During the community engagements it was obvious the community longed for consumer education program. The policy however does not promote the potential for and necessity of providing training and capacity building and possible certification programs for dispensers and also, financial incentives for DTCs to promote rational drug use are not defined in the policy. Safe disposal of pharmaceutical waste including expired medicines and technologies is currently managed by Health Care Waste Management Office of the Ministry of Health. The human resource capacity is challenged with only four (4) pharmacists in the public Sector and a total of 13 pharmacists in Samoa<sup>10</sup>. The human resource constraints would require some political will and reengineering strategies to support rational use of medicines. Improvement in HR limitations is a key in the implementation of the NMP and overall pharmaceutical activities in the country.

### **Key actions:**

- Review the Standard Treatment Guidelines as a basis for EML and ensure all stakeholders are on board
- Develop guidelines for Drug and Therapeutic Committees, train and build capacity of members
- Functional Drug and Therapeutic Committees to monitor rational use of medicines
- Identify Champions of Antimicrobial stewardship programs in response to the AMR action Plan
- Regular updates of Medicines in stock to clinicians
- Documentation of medication and dispensing errors
- Collaboration with laboratory to ensure culture and sensitivity tests results are shared promptly for effective patient management
- Training for dispensers to use the current IT infrastructure at the point of practice to document and enable monitoring of medicine use indicators
- Increase public awareness of rational use of medicines and targeted education of the Public for NCD clients and other emerging diseases

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<sup>10</sup> Verbal communication with the President of Samoa Pharmacists Association, Mrs Maria Westerlund-Hunter of Maria Health care and Pharmacy on 16<sup>th</sup> May 2023

- Public awareness and promotional programmes to the population regarding the Rational Use of Medicines.

## Research

Research is highly considered a crucial part of the components of the Samoa Medicines Policy 2008. The policy emphasizes the necessity of conducting operational research on drug availability, quality, and rational use. It also encourages participation in clinical medical research and development. However, there seem to be no programs in place to encourage operational research and the application of the research's findings to the development of public policy. In addition, it has been observed that no research publications especially on the pharmaceutical sector had been sighted during this review. Samoa has The Health Research Guideline that directs how research should be conducted in the Samoa health sector. SROS also exists to provide research and development for the people of Samoa. The policy has provisions that guarantee the international exchange of information and collaboration with international research bodies.

### Key Actions:

- Develop and establish an implementation research strategy to guide the new policy's implementation
- Develop research in pharmaceutical sector and clinical research
- Explore consistent measurement of rational use of medicines through the current IT infrastructure established through the mSupply network
- Targets to be set for key stakeholders to publish at least one paper on their thematic area of work since the IT infrastructure has enough data to support such a drive.
- Establish some collaboration and partnerships with the Academia for win-win publications that provide evidence to inform public policy

## Human Resources Development

There are strategies in place to ensure continuous human resources development. A strategic Health Workforce Development Plan and the Human Resources for Health Strategy<sup>11</sup> have been developed by the Samoa Ministry of Health in collaboration with relevant health sector partners to consider continuous human resource development. The strategic plan also encourages long-term plans essential for ensuring a balance between training activities and human resources needs. Details of education and minimum level of training required for each category of service have been stated. The policy permits cooperation when needed, with national and international organizations that are qualified to perform a given duty, such as drug evaluation and drug information services. However pharmaceutical workforce training remained largely inadequate. Pharmacy Technicians are trained on the job and this depends on the Pharmacist in charge. Efforts to provide modular courses in a coordinated manner to build capacity are needed and after training the officers be bonded for a number years could define the next steps.

### Key Actions:

- Political will and increase Government scholarship scheme to cover training of Pharmacists and pharmaceutical work force
- Enhance capacity building in pharmaceutical work force in the short, medium and long term

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<sup>11</sup> Human Resources for Development Plan for Samoa FY2021/21- FY 2025/26

- Collaborate with the universities to begin modular training programs that allow for certification of middle level practitioners to support policy implementation.
- Training for nurses especially in the district hospitals and other health professionals on good dispensing practises
- Continuous professional development series for pharmaceutical staff to be linked to the annual issuance or renewal of practising certificates

### *Monitoring and Evaluation*

The Samoa medicines policy includes monitoring and evaluation as its components. The Ministry of Health has established a monitoring and evaluation capability with the function of following the implementation of The Medicine Policy and Plan of Action and defining indicators for measurement of progress towards achieving policy objectives. The policy's aims are measured using clear, practical, quantifiable, dependable, and credible indicators; however, this is not linked to the Ministry of Health M&E Framework<sup>12</sup>. This makes it impossible to capture pharmacy reports in the sector-wide monitoring and evaluation annual reports. During this review there was one evaluation report<sup>13</sup> of the medicines policy sighted, which was done in 2018.

### **Key Actions:**

- Clear indicators for monitoring the NMP plan linked to the MOH M&E framework
- Medicines Policy Indicators to be captured into the IT infrastructure for ease of measurement
- Mid-term evaluation of policy implementation and independent external evaluation of Policy
- Policy implementation indicators to be part of the Sector-wide indicators
- Quarterly and Annual progress reports on policy implementation to the MOH Policy unit

### *Traditional Medicines*

Traditional medicines are widely used in Samoa; however, they have not been properly covered in the NMP 2018. Incorporating infection, prevention, and control into how traditional healers prepare their medicines to enhance their safety.

One challenge is that there are fewer available resources to enhance the monitoring of traditional medicines to ensure that their safety is not compromised. There is a council for traditional healers under the allied health professionals; however the products are not regulated. Herbal medicines usage has not been fully documented but clinicians<sup>14</sup> complained that clients especially with NCD's sometimes revert to traditional healers and return with very poor prognosis. From the regional perspective, the focus now is to regulate complementary medicines imported into the country and other components of traditional medicines. It is important traditional medicines are assessed to explore the possibility of integrating step by step into the health care system as a primary health care. SROS is currently researching into promising herbal products and effective collaboration could speed up the integration process.

### **Key actions:**

- Assessment of the Traditional/Herbal medicine practice and evaluation of their safety and efficacy of products to enable the determination of its use as a primary health care

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<sup>12</sup> MOH Monitoring and Evaluation Framework is under construction 2023

<sup>13</sup> National Medicines Policy 2008 Review

<sup>14</sup> Verbal communication with clinicians during the consultation on 2<sup>nd</sup> June 2023



- Engage Samoan Health Professionals and traditional practitioners to agree on rules of engagement
- Regulation of products linked to the overall regulation of Medicines in Samoa
- Step by step integration of the practice into national health system

## General Recommendations

The Samoa National Medicines Policy was launched in 2008. The following recommendations are made based on observations during this review through informant interview as well as desk review and current global events and health system challenges. The COVID-19 Pandemic has identified many lessons for countries like Samoa, including interdependence, cooperation and partnerships for survival. Access to health technologies and biologics as a health system challenge, their safety and rational use has become very fundamental to the 'right to life'.

### 1. *Pharmaceutical sector assessments*

One of the key findings of this assessment is that relatively very little is published in peer reviewed as well as grey literature on the pharmaceutical sector in Samoa.

- (i) It is recommended that key assessments be done on the pharmaceutical sector in Samoa to yield data to inform the implementation of the Medicines Policy and Plan.
- (ii) Such assessments to address access include (but not limited to):
  - i. Price and availability surveys (for Availability and Affordability)
  - ii. Pharmaceutical Sector Profiling (for Governance, Structures and Function)
  - iii. Mapping of Pharmacy Outlets (for Geographical Access and Accessibility)
  - iv. Product Quality Assessments in both public and private sectors including NGOs (For Quality and Safety)
  - v. Assessment of Adherence to treatment guidelines (for Rational Use)

### 2. *Governance and Coordination*

The health service within which the pharmaceutical services are to be provided is a multi-tiered system, with very tight human capacity issues a situation which required very effective and efficient coordination and governance systems. The old policy had no coordination mechanism to ensure policy implementation arrangements. Hence, it is recommended to:

- (i) Strengthen political commitment by recognizing and promoting efficient, accessible and safe medicines and pharmaceutical products through relevant policies and legislations of other government sectors
- (ii) Establish a Steering Committee to provide Governance for Policy implementation for stakeholders operating within the sector, should operate in a manner that aligns, strengthens and builds capacity for the Samoan people
- (iii) Establish a Co-ordination Unit and appoint coordinators
- (iv) Develop restrictive policies in pharmaceutical sector to ensure accountable and transparent process of enforced prescription and pricing strategies of medicines.
- (v) The Ministry of Health governance over the private sector through effective regulatory oversight

### *3. Partnerships and Collaboration*

- (i) Effective partnerships and collaborations are required to ensure value for money implementation. This would bring to bear the needed synergies and sustainability required to optimize the ongoing external and internal investments in the health system in Samoa and would progressively improve on the health and pharmaceutical sector indicators.
- (ii) Develop partnerships and collaboration with other government sectors to create enabling supportive systems in Medicine Procurement, supply, regulation, and financing

### *4. Legislation review:*

The legislations governing the pharmaceutical sector are out dated and require a review to support real actions for the sector to:

- (i) Review and enforce related Legislations in place to reflect changes occurring in the health sector and all pharmaceutical related services. (Drugs Act 1967, Narcotics Act 1967, Pharmacy Act 2007, NHS Act 2006, Poisons Act 1968)
- (ii) Establish criteria to control and regulate medicine and pharmaceutical product promotion and advertising including herbal medicines

### *5. Emerging issues:*

- (i) Public Health Emergencies and Pharmaceuticals, making provisions for government projects and programmes that require the use of pharmaceuticals and health technologies.
- (ii) COVID 19 Pandemic and the emergency use authorisations by countries for COVID 19 health technologies requires that we provide guidance documents for future emergencies and health programs
- (iii) Global Trade, Pharmaceuticals and Regional mechanisms for cooperation to increase access to medicines e.g. Pool Procurement.

### *6. Implementation arrangements*

- (i) It is recommended that a systematic and phased approach be taken to strengthen the pharmaceutical sector alongside Ministry of Health current reforms and strategies. This would in-turn contribute to the local economy through job creations,
- (ii) Private sector involvement with measured regulatory mechanism is also recommended especially in the import of pharmaceuticals may need to have a local partner or any form of presence in the country for the sake of accountability and transparency

## Recommendations on a phased approach to implementation

It is recommended that the sector strategy to incrementally address the following areas in the pharmaceutical sector. However, this recommendation would be subjected to stakeholder engagement and analysis

Phase	Policy area
<b>Phase 1</b>	<ol style="list-style-type: none"><li>1) National Medicine Policy implementation, Governance and Coordination</li><li>2) Supply Chain and Logistics Management Information Systems</li><li>3) Develop or review Donations Guidelines</li><li>4) Importation and role of Local partners</li><li>5) Review of the legislations governing the Pharmaceutical Sector</li><li>6) Regulation and Quality Assurance of Pharmaceuticals</li><li>7) Pharmacy Practice, Patient Safety, Rational use of medicine and health technologies</li><li>8) Human Capital Development for Pharmaceutical sector</li><li>9) Financing of Essential medicines and Health technologies</li><li>10) Public Health Emergencies and Pharmaceuticals</li><li>11) Selection, Prioritization, Economics and Health Technology Assessments for Essential medicines and Health technologies</li><li>12) Traditional Medicines</li><li>13) Antimicrobial use and stewardship</li><li>14) Pharmaceutical sector Research and development</li><li>15) Effective Monitoring and Evaluation</li><li>16) Partnerships and Collaborations</li></ol>
<b>Phase 2</b>	<ol style="list-style-type: none"><li>17) Financial risk protection measures in support of the Right to Life as contained in the Samoan Constitution</li><li>18) Pricing in the Pharmaceutical Sector</li><li>19) Private Pharmaceutical sector and health sector governance</li><li>20) Global trade in pharmaceuticals and health technologies</li><li>21) Good governance, transparency and accountability</li></ol>

## POLICY STRATEGIC AGENDA






### Vision:

*“Ensuring safe, effective, reliable, quality, essential medicines to be available at affordable cost at all times to the entire population of Samoa”*

### Mission:

*“ To make sure all people of Samoa have fair, timely, reliable and affordable access to safe high-quality medicines and medicines services; medicines are used safely and correctly; and people have the information they need to make an informed choice as well as that is well organized and based on their needs”*

### Guiding Principles and Values

 People-centered	Make sure users have the information they need to take part in making decisions. Recognize the person’s goals, diversity and experience. This includes improving people’s health, digital and medicines knowledge so that they can understand the information they are given. Support people and their families and carers to be involved at all levels of this policy document.
 Fairness and access	Focus on achieving positive health results that matter to people and their communities. Make sure all Samoans have timely, safe and reliable access to effective, high-quality medicines including access culturally safe medicines services and information. Make sure everyone has access regardless of their background, age, disability, location or personal circumstances.
 Partnership and Shared Responsibility	Set up active, respectful conversations and collaboration between partners. Listen to and recognize the wisdom and expertise of each partner. All partners act responsibly.
 Transparency	Hold all partners responsible for their actions and for working towards achieving the policy. Do all activities and share information in a respectful, ethical and transparent way.
 Sustainable	Encourage all partners to focus on improving how medicines are used. Partners will look at the health, social and economic effect and how sustainable their strategies and programs are.

## Objectives:

### *Policy objective*

The broad objective is to promote sustainable and equitable access to pharmaceuticals and related health technologies for all persons living in Samoa.

### *Specific Objectives:*

Specific objectives of this assessment are as follows:

1. To strengthen the governance structures, processes and systems within the pharmaceutical sector to support implementation of the policy
2. To strengthen the pharmaceutical supply chain to deliver efficacious, safe and affordable treatments in sustainable and equitable manner as well as their responsible use for all persons living in Samoa
3. To strengthen the regulatory framework and quality management processes within the pharmaceutical sector of the Government of Samoa
4. To build capacity and strengthen health systems to deliver sustainable and equitable pharmaceutical access
5. To strengthen critical partnerships and collaborations with all stakeholders, including relevant sectors, in order to promote access and address cross-cutting pertinent issues such as research and antimicrobial resistance.

## Policy Statements:

### *1. Governance, Coordination and Partnerships*

Governance is central to this policy framework for the Government of Samoa. The processes of interaction between all actors (whether through standards, laws, guidelines, power/mandate, among others) is an important component of this policy, to ensure that policy objectives are achieved. Governance would ensure that the policy process, including implementation and evaluation (with feedback for continuous improvement), is contained in a system that ensures optimal operational control to deliver on the objectives subscribed to. In this context good governance would be achieved through the application of the principles of sustainability, equity, quality, efficiency and transparency in all processes relating to implementation of this policy.

The health service within which the pharmaceutical services are to be provided is a multi-tiered system, with very tight human resource capacity issues; a situation which requires very effective and efficient coordination and governance systems. The old policy had no coordination mechanism to ensure policy implementation arrangements. Effective partnerships and collaborations are required to ensure value for money implementation. Strengthening political commitment by recognizing and promoting efficient, accessible and safe medicines and pharmaceutical products through relevant policies and legislation review in partnership with other government sectors.

## Key Strategic Areas

### **1.1 *Effective coordination, collaboration and governance***

- 1.1.1 Establish a Steering Committee to provide Governance for Policy implementation that parties operating within the sector, should operate in a manner that aligns, strengthens and builds capacity for the Samoan people.
- 1.1.2 Establish a Co-ordination Unit and appoint coordinators.
- 1.1.3 Develop restrictive policies in pharmaceutical sector to ensure accountable and transparent process of enforced prescription and pricing strategies of medicines.
- 1.1.4 The Ministry of Health governance over the private sector through effective regulatory oversight.
- 1.1.5 Develop partnerships and collaboration fora with other government sectors to create enabling supportive systems in Medicine Procurement, supply, regulation and financing. The Ministry of Health **shall collaborate** with all implementing stakeholders towards effective and efficient implementation of the pharmaceutical policy towards a measurable impact and outcomes.

### **1.2 *Implementation Arrangements***

- 1.2.1 The Ministry of Health shall commit to systematic, and inclusive implementation of the pharmaceutical sector policy and plan, through human resource capacity building, incremental investments in the sector, alongside the current health sector reforms agenda, with measurable contribution of the sector to the general economy of Samoa.
- 1.2.2 With respect to investments in the pharmaceutical sector, the Ministry of Health shall create a platform for harmonized and synergistic action; in order to optimize the ongoing external and internal investments in the pharmaceutical sector in Samoa and would progressively improve on health and pharmaceutical sector indicators.
- 1.2.3 The Ministry of Health shall establish a **platform for annual or biannual peer-review mechanism** for mutual accountability, sharing of best practices to facilitate peer learning and ensure collective growth in the pharmaceutical sector. These annual peer-review mechanisms:
  - a. shall be based on pre-defined set of performance indicators (aligned with M&E framework), shall be presented within the context of a pharmaceutical situation report
  - b. shall be supported by built-in incentives for facilities in a League Table analysis/rankings

- c. shall include and engage development partners in a development agenda setting mechanism, which would guide tailored investments to drive development at the States level

### **1.3 Information management, data governance and M&E**

- 1.3.1 The Ministry of Health shall ensure that data on pharmaceutical sector is readily available through appropriate management information systems aligned with the Monitoring and Evaluation framework of the Ministry of Health.
- 1.3.2 The Ministry of Health shall work with the ACEO ICT to manage a platform for mutual data sharing among policy implementing stakeholders, agencies, partners and ministries to share information on pharmaceutical policy implementation in a peer review environment.
- 1.3.3 The Ministry of Health acting through its Directorates for Warehouse, **shall conduct key periodic assessments to yield data on the pharmaceutical sector** in the context of access to medicines. This shall include but not limited to:
  - The Pharmaceutical Sector Scan (for Governance, Structures and Function)
  - Assessment for Good governance of medicines (for Governance, Processes, Transparency and Accountability)
  - WHO level 2 assessment on pharmaceuticals
  - Product Quality Assessments in both public and private sectors including NGOs (for Quality)
  - Supply chain assessments/mapping (for Supply functions)
  - Mapping of Medicines Outlets (for Geographical Access and Accessibility)
  - Pricing and price component studies (for Price, Availability and Affordability)
  - Household surveys (for Rational Use in the community)
  - Assessment of Adherence to treatment guidelines (for Rational Use within health facilities)

### **1.4 Antimicrobial Resistance stewardship in 'One health'**

- 1.4.1 The Ministry of Health shall collaborate with relevant stakeholders in the Agricultural, Fisheries, and Environment sectors as well as other stakeholders to implement the specific policy for Anti-microbial use (AMU) as outlined in the AMR Plan for Samoa.

Emphasis should put on awareness creation, infection prevention, and optimization of use and AMR stewardship, economic case for investments in AMR and governance.

### **1.5 Health Security and Emergency Preparedness and Response**

- 1.5.1 The Ministry of Health shall collaborate with relevant stakeholders to develop a policy for Emergency Preparedness and Response in alignment with the Global Health Security agenda and also develop guidelines for selection and procurement of pharmaceuticals and related health technologies in emergencies and pandemics



- 1.5.2 Public Health Emergencies and Pharmaceuticals, making provisions for government projects and programmes that require the use of pharmaceuticals and health technologies.
- 1.5.3 Experience with COVID-19 Pandemic and issuance of emergency use authorisations (EUAs) by countries for COVID-19 health technologies requires that we provide guidance documents for future emergencies and health programs
- 1.5.4 Global Trade, Pharmaceuticals and Regional mechanisms for cooperation to increase access to medicines e.g., Pool Procurement

## **1.6 *Legislation Review***

- 1.6.1 Review and enforce related Legislations in place to reflect changes occurring in the health sector and all pharmaceutical related services. (Drugs Act 1967, Narcotics Act 1967, Pharmacy Act 2007, Poisons Act 1968)
- 1.6.2 Establish criteria to control and regulate medicine and pharmaceutical product promotion and advertising, including herbal medicines

## **1.7 *Inter-sectoral partnerships***

- 1.7.1 The Ministry of Health shall collaborate with other relevant Ministries, Departments and Agencies to ensure effective implementation of pharmaceutical policy of Samoa.
- 1.7.2 Effective partnerships and collaborations are required to ensure value for money implementation
- 1.7.3 This would bring to bear the needed synergies and sustainability required to optimize the ongoing external and internal investments in the health system in Samoa and would progressively improve on the health and pharmaceutical sector indicators.
- 1.7.4 Develop partnerships and collaboration fora with other government sectors to create enabling supportive systems in Research, Medicine Procurement, supply and financing and also towards the Legislative review.

## **2. *Pharmaceutical Systems Strengthening***

The health systems building blocks of Leadership and governance, Service delivery, Health system financing, Health workforce, medical products, vaccines and technologies, Health information systems, requires that pharmaceutical system be framed as part of the health system.

The specific entities (structures and processes) and their interactions to ensure sustainable, equitable and timely access to safe, effective, quality-assured pharmaceuticals and related technologies and services as well as their responsible use in a cost-effective manner to improve health outcomes cuts across the health system. Access would be assured through continual investments to build strong systems which ensure that the right medicines, as well as services, are accessible by the right patient, at the right time, at the right dose, at acceptable quality, at an affordable price, in a sustainable manner. System strengthening interventions are deliberate, decisive, interventions which deliver sustainable improvements in the structures, people, assets

and processes serving as the components of the pharmaceutical system in order to ensure resilience and responsiveness.

Government funds essential medicines at all public sector facilities however, shortages of essential medicines are reported at all levels in the public health system, including antibiotic for children. Private sector complements the reported low availability of medicines in the public sector, though there are concerns on rational use, price, quality of product and service due to reported weak regulation of the private sector, complicated by the low numbers of professionals within the system in general. Human Resource (HR) remains a challenge to the Samoan pharmaceutical sector. There are an estimated 13 pharmacists in Samoa with less than 4 working in the public sector. At the time of the review, no University in Samoa is training pharmacists or pharmaceutical workforce at the time of this assessment although at the stakeholder plans were advanced to establish training of pharmaceutical work force. However, it was noted that plans are advanced by the bilateral arrangements to work with the Ministry of Health to start a program for these cadre of health staff. There is no regulatory body regulating pharmacy technicians or assistants at the time of this assessment. Clear human resource gaps exist and require intervention on the short as well as medium to long term. There is an active role for academia to collaborate with the Ministry of Health, the Regulatory bodies as well as the Pharmaceutical Society of Samoa among others to bridge this gap of training and certification of the cadre of staff.

While local manufacture may not be an immediate priority, private sector regulation, growth and development is critical to support the reforms in the public sector to secure access to medicines for all persons living in Samoa in a more sustainable way.

## **Key Strategic Areas**

### **2.1 *Financing and Affordability***

- 2.1.1 In Samoa, healthcare resources are stretched by the demographic shift to older populations, with more costly chronic diseases. The policy promises measures to improve usage and prevent waste. However, the means of drug financing are not clear. The use and scope of user charges as a drug financing option have not been clearly defined. There is an Overseas Treatment Program that is available but criteria for its implementation are not too clear. Treatment abroad strategy to be evaluated to encourage capacity building and support local health professionals deliver on the 'Healthy Samoa Strategy'. Key issues of Health service package could become an efficiency tool to manage the limited resources.
- 2.1.2 Evaluate the Overseas Treatment Abroad Program to explore the capacity building and support local health professionals for the overall 'Healthy Samoa' agenda.
- 2.1.3 A step-wise approach to gradual introduction of health insurance as a risk protection strategy is recommended to protect the poor and vulnerable who are currently not covered under any of the current schemes.
- 2.1.4 Private sector engagement in support of any affordability program needs to be strengthened.

- 2.1.5 Performance for Results (P4R) program may provide a baseline for action for a national Health insurance for the population.
- 2.1.6 Develop effective ways to deal with medicine shortages.
- 2.1.7 Develop essential Health Services package to support any risk protection strategy.
- 2.1.8 Sustainable financing of medicines must be linked to sustainable Financing of Health
- 2.1.9 Budgetary allocation to pharmaceuticals shall be structured to address the following in order to ensure value-for-money:
- procurement and supply of essential medicines and related health technologies,
  - improvements in system and supply efficiency,
  - responsible use of medicines,
  - supplier monitoring and if possible blacklisting suppliers for untimely delivery of stocks.
- 2.1.10 The Ministry of Health shall set up a price monitoring mechanism that shall form the basis for a Pricing Policy in Samoa

## ***2.2 Technical collaboration, partnerships and system-level capacity development***

- 2.2.1 The Ministry of Health shall provide guidance on the design and development of the pharmaceutical sub-sector within the health sector.
- 2.2.2 The Ministry of Health shall establish and or coordinate a platform of stakeholders and partners working within the pharmaceutical space in a multi-stakeholder process to ensure optimized allocation of resources in the pharmaceutical sector in Samoa.
- 2.2.3 The Ministry of Health to collaborate with and partner with research institutions to support access to medicines

## ***2.3 Human resource development and management***

- 2.3.1 The Ministry of Health shall adopt a strategic perspective to strengthen the Human resource Development, Deployment, and retention mechanism within the pharmaceutical sector to support the implementation of this policy, with special emphasis on addressing the HR gaps in the public sector. Key priorities shall include:
- Establishment of a scholarship programme with local and international training institutions, with retention policy modalities including the bonding of beneficiaries to serve for a minimum of 3 years in the public sector and clear optional exit criteria
  - Collaborations with local Academia, the Pharmaceutical Society of Samoa and other Stakeholders in the design and development of tailored training

programmes for continuous professional development for pharmacists and pharmaceutical staff

- 2.3.2 The Ministry of Health shall advocate for performance-based improvements in the conditions of service and incentives for pharmacist and pharmaceutical staff in the public sector.

## **2.4 Public and community education**

A comprehensive, public education and sensitization programme on responsible use of medicines shall be developed and coordinated by the Ministry of Health in collaboration with partners, to sensitize the general public and the community level on rational use of medicines as well as health seeking behavior, using tailored communication strategies for the local context. This shall also be leveraged for awareness creation on antimicrobials use and resistance and other health education matters.

## **2.5 Private sector strengthening**

The government of Samoa shall create an enabling environment through such initiatives as tax incentives, among others, for the development of the pharmaceutical private sector to enhance its contribution to the general economy.

This would be preceded and informed by an assessment of the pharmaceutical market structure in Samoa estimating the size of consumption in both public and private sectors;

In the short term, pooled procurement with local content, among others, could be leveraged to stimulate the needed private sector growth to create the financial space with parallel regulatory capacity development and support.

## **2.6 Research and development**

The Ministry of Health in collaboration with Academia and SROS shall develop and regularly update the research agenda for the pharmaceutical sector in response to the pharmaceutical sector development needs. This would be supported by resource mobilization initiatives for focal areas such as:

- Anti-microbial stewardship
- cost-effectiveness analytics,
- selection and optimization sciences,
- implementation research to guide pharmaceutical sector policy processes and guidelines,
- drug utilization studies; among other priorities responsive to the needs of the people of Samoa.

## **3. Selection, Supply Chain and Responsible Use**

The rational and systematic selection of medicines and other related health technologies coupled with effective supply and the responsible use of such health technologies are critical functions of pharmaceutical systems in countries. This is a critical function which must be performed optimally in order to promote access to medicines. Evidence-based, context-driven consensus on medicines selection ensures stakeholder buy-in and alignment with the downstream sector-wide implications of the selection process. The processes for medicines selection, coupled with the mechanism for guiding their use, should be given as much emphasis as the medicines selected.

The supply chain is the mechanism and structures through which selected medicines would be made available at the service delivery points for patient use.

The provision of guidance on the use of medicines should be evidence-based and should address medicines use in health care settings as well as the communities.

While processes for the selection of medicines and guidance for their use are in place, current edition (2022) of the Samoa Essential Medicines List (EML) was not informed by the Standard Treatment Guidelines (STG 2012). The selection process is not documented. The EML is aligned with the WHO AWaRe Classification for antibiotics and organized according to the levels of care within the health system.

The quantification, forecasting, procurement and supply chain are supported by mSupply IT infrastructure who provide end-to-end support for selected health facilities. The shortfalls of the PUSH and PULL system are available, stock-outs still exist due to delay in Supplier payments.

There are reported constraints with rational/responsible use of medicines at health care settings as well as the community level. This includes the use of unstandardized traditional medicines at the community level especially in settings where access to orthodox medicines is critically limited as well as in settings where these are supported by the local cultural context. Through the community stakeholder engagement, it was also reported misuse of antimicrobial agents in both public and private sectors, while some health professionals also report lack of access to antimicrobial agents are part of the general reported low availability of medicines. The agenda for antimicrobial stewardship is in the plan but not functional at service delivery points Disease specific areas for example, Mental Health and Non-Communicable diseases require specific interventions leveraging on the current global interventions on access to medicines.

## Key Strategic Areas

### ***3.1 Selection of medicines and related-health technologies***

- 3.1.1 Ministry of Health shall compile and regularly update a list of medicines and related health technologies (the Samoa Essential Medicines List [EML], which shall reflect the principles underpinning universal health coverage and shall be categorized by level of use, including specialist as well as medicines selected for public health programmes. The EML would guide:
  - procurement and supply of medicines by all partners
  - donation of medicines to the Government of Samoa
  - public sector investments in pharmaceuticals
  - all policies and programmes on medicines
- 3.1.2 The EML shall be a responsive list of medicines and shall be updated (every 3 years) in line with new evidence for safety, efficacy/effectives and cost-effectiveness and in sync with the Standard Treatment Guidelines, which shall provide guidance on the use of the selected medicines and related health technologies, in both public and private health sectors.

- 3.1.3 The MOH shall establish a National Medicines Selection and Guidelines Subcommittee (NMSGC), under the Steering Committee with clear Terms of Reference to regularly review/update the Standard Treatment Guidelines, aligned with the EML. The constitution of the NMSGC, shall include but not limited to experts in clinical care, pharmaceutical care, nursing and allied health practice, public health and health policy as well as health economics ensuring also that every meeting conflict of interest forms are signed by each expert and secretariat.
- 3.1.4 The MOH shall resource and empower the ACEOs of Warehouse/Pharmaceuticals, to coordinate the process for the review/update of the Samoa-STG, and the Samoa-EML. The medicines selection process shall:
- be evidence-based and context-guided and shall be through a consultative process, which includes clinicians, pharmacists, nurses, relevant professional bodies, Academia and training institutions, among others, with all partners and programmes in alignment for effective implementation of the resulting Samoa-EML i.e. the process should consider the local context in the application of evidence as well as multi-stakeholder inclusion
  - leverage international best practice in priority setting and assessment of health technologies
  - apply evidence for safety, efficacy/effectives and cost-effectiveness in decision making
- 3.1.5 The Samoa EML and STG Coordinating mechanism shall ensure that selection process is documented with clear criteria for addition, deletion and alteration of medicines and related health technologies on the EML in a transparent and consultative process. Such criteria shall include evidence for safety (including risk to benefit), efficacy and cost-effectiveness.
- 3.1.6 The Samoa-EML and STG Coordinating mechanism working with all relevant stakeholders shall ensure, that the selection and listing, including updates of such as medicines shall be by International Non-proprietary Name (INN) only.
- 3.1.7 The Ministry of Health working through the Samoa-EML and STG Coordinating mechanism in collaboration with partners, would ensure extensive dissemination of the EML and STG in the appropriate formats including physical and electronic formats. In order to promote adherence at the primary care level, clinical job aids shall be developed e.g., simplified flowcharts and treatment algorithms to support the use of the STG, with training of health professionals.
- 3.1.8 Adherence to the STG and EML shall be assessed based on standard methodology to yield data to inform mandatory continuous education and continuous professional development for health personnel.

## 3.2 Supply Chain

- 3.2.1 The MOH, working with all partners including the mSupply foundation, shall collaborate to implement supply chain initiatives to secure access to medicines. The mandate of the central warehouse would include but not limited to implementing national policies, strategies on the pharmaceutical supply chain in line with the business, operational and financial model of the MOH upholding the principles of equity, quality, efficiency, transparency and accountability, sustainability, adherence to best practice and standards
- 3.2.2 Develop or review and disseminate widely a National Donations Guidelines to ensure adequate quality, safety and efficacy of products donated to Samoa
- 3.2.3 Coordinating resource mobilization and investments in the medicines supply chain in Samoa
- 3.2.4 Inventory management systems to be agile to manage and if possible, prevent expiries
- 3.2.5 Coordinating the development of infrastructure to support the supply chain
- 3.2.6 Managing the Central warehouse and supervising district facilities and other service delivery points.
- 3.2.7 Build capacity for supply chain officers at the central warehouse
- 3.2.8 Implementing systems and standards for supply chain performance
- 3.2.9 Organizing quarterly supply chain performance multi-stakeholder fora for mutual accountability and transparency, data sharing (based on agreed supply chain indicators and variables), collaboration and inclusion as well as feedback for continuous improvements
- 3.2.10 Coordinating the financing and implementation of a rapid response mechanisms to deliver supplies during emergencies
- 3.2.11 submitting quarterly and annual reports based on an agreed format to the Ministry of Health and all other relevant stakeholders
- 3.2.12 The MOH shall mobilize resources to consolidate supplies for Health and support the pharmaceutical supply chain through incremental budgetary allocation and resource inputs from the Government of Samoa. In order to ensure sustainability, the Supply Chain entity working with all stakeholders, shall develop the above funding model for medicines, which shall focus on the following:
  - ✓ Consolidate all supplies through a similar mechanism to unify the procurement systems and increase efficiency
  - ✓ Procurement and supply chain efficiency, prevention of wastage, as well as economic efficiency
  - ✓ Optimized design and distribution of service/commodities packages



- ✓ Investments in infrastructure including cold-chain facilities at the service delivery points to maintain cold chain of pharmaceuticals and
  - ✓ Investments in attracting, retaining and developing, optimal human resource cadre, to support supply chain management functions
- 3.2.14 The supply chain shall be governed and managed with a business and operational model which highlights the under listed, which shall be prioritized as part of supply chain initiatives for systems strengthening at all levels:
- ✓ professional capacity building and organizational development of all supply chain officers;
  - ✓ continuous investments and efficient procurement storage and distribution;
  - ✓ security and safety of product personnel and equipment,
  - ✓ quality service delivery,
  - ✓ private sector involvement,
  - ✓ prevention of waste, and safety of all products, warehouses, equipment and people and
  - ✓ risk management including insurance for product, equipment and personnel
- 3.2.15 The MOH in close collaboration with partners, shall strengthen the Medicines Supply Chain in Samoa for more PULL systems than a PUSH supply system and this shall be informed by quantified and forecasted need aggregated from the point of use. This process shall be managed through the current mSupply system and also build capacity for data management, forecasting and quantification at the service delivery points, supply chain data reporting, among others.
- 3.2.16 The MOH, shall develop and implement a comprehensive change management plan with the current MOH reforms
- 3.2.17 Government shall leverage its financial contributions for procurement of medicines and related health technologies as well as its capital investments in the supply chain to drive growth of the private pharmaceutical sector in Samoa, with adherence to regulatory standards or any reliance mechanism. This would be expressed in a procurement process which prioritizes the Samoa private pharmaceutical sector with due cognizance to quality. This way, the local pharmaceutical entities would grow as a key partner to government in ensuring access to medicines.
- 3.2.18 Donation of medicines shall be in line with a National Donations Guidelines, disseminated and implemented throughout the supply chain at all levels and among all bilateral and multilateral Development Partners. Drug donation guidelines shall uphold the following principles:
- ✓ Medicines donated are above 70% of remaining shelf life; and a collated need, distribution and consumption can be established before the expiry date
  - ✓ Medicines donated are listed on the Samoa-EML

- ✓ Medicines donated are quality assured through the regulatory mechanism or a collaborating regulatory entity or any reliance mechanism.

### **3.2 *Pharmaceutical Information Management***

- 3.3.1 The MOH current IT infrastructure to be deployed, harmonized, integrated and modular logistics management information system (LMIS) to support the pharmaceutical supply chain, under data governance framework of The MOH with training on system operations. The LMIS would among other functions:
- ✓ ensure data visibility and security for the supply chain
  - ✓ ensure traceability e.g., through compliance to global standards such as the Global Trade Item Number (GTIN), among others
  - ✓ provide readily available data for quantification and forecasting of pharmaceutical needs
  - ✓ optimized distribution of medicines
  - ✓ provide data for policy on supply chain
  - ✓ establish data linkages with the health data information
- 3.3.2 The MOH would work with relevant stakeholders to establish minimum standards for information management systems and reporting at all levels of medicines use. This would provide data to support the monitoring and evaluation of the implementation of the medicines policy. The PMIS would permit:
- ✓ seamless operations and electronic report submission
  - ✓ readily available data for quantification and forecasting of pharmaceutical needs from the points of use to inform optimized distribution of medicines
  - ✓ data consistency between health facilities managing paper-based records and those managing electronic records, with gradual transition from paper-based to electronic records
  - ✓ provide data for supply chain planning and forecasting at the health facility level; to inform quantified and forecasted needs to be aggregated from the point of use.

### **3.3 *Responsible use of medicines and patient safety***

- 3.4.1 The MOH shall support a functional Drugs and Therapeutic Committees (DTCs) in tertiary facility to cascade to secondary level facilities as an entity to drive rational use of medicines at the health facility level. The operations of the DTCs shall include but not limited to:
- ✓ design and implementation of rational use of medicines programs at the health facility level
  - ✓ assessments of drug utilization, prescribing and dispensing at the health facility
  - ✓ Identify Champions and institutionalizing AMR stewardship programs
  - ✓ Regular updates of medicines in stock to clinicians
  - ✓ conducting clinical meetings
  - ✓ supporting drug management functions at the health facility

- 3.4.2 Prescribing and dispensing shall be in line with the STGs and EMLs across all levels of care and in both the public and private sectors
- 3.4.3 The MOH shall work with relevant stakeholders and partners to design and implement a nationwide programme on rational/responsible use of medicines and medicines safety, including rational/responsible use of antimicrobials in a 'one health' approach. Rational/responsible use of medicines shall also be introduced during pre-serving training of health professionals.
- 3.4.4 The MOH shall design and implement a continuous capacity development programme for health professionals with a special focus on rational/responsible use of medicines including anti-microbials in collaboration with academia. This would include mandatory Continuous Professional Development programmes for all health professionals working with medicines.
- 3.4.5 The MOH shall establish and resource a functional drug information programme to provide services to health professionals as well as the general public, leveraging existing technologies and communication platforms including those used during COVID 19 pandemic.
- 3.4.6 Collaboration with the laboratory units to ensure culture and sensitivity test results are shared promptly for effective patient management
- 3.4.7 The Ministry of Health working with relevant stakeholders shall develop and implement protocols for patient safety to be integrated into SOPs at all levels of care, with regular assessments to guide implementation and adherence in both public and private health sectors.
- 3.4.8 Documentation of medication and dispensing errors and evidence of capacity building to ensure patient safety
- 3.4.9 The MOH working with relevant stakeholders shall establish Quality and patient safety programmes in alignment with global patient safety programming

### ***3.5 Disposal of Medicines***

- 3.5.1 Disposal of medicines shall be guided by clear protocols as detailed by Waste management Unit of the MOH in collaboration with relevant stakeholders in a manner that is safe to the environment.

### ***3.6 Disease Specific Strategies***

- 3.6.1 Public health emergencies and pharmaceuticals making provisions for government projects and programs.
- 3.6.2 Key activities on disease specific strategies are to be worked on within the programmatic areas of these disease programmes with the focus on access to medicines.

- 3.6.3 The MOH in collaboration with partners, shall develop and implement national strategies for pharmaceuticals in combating and containing specific prioritized diseases including emergency use authorisations in alignment with existing health systems processes, standards, structures and infrastructure. These shall include but not limited to selected infectious conditions, mental health, neglected diseases, non-communicable diseases, emerging diseases and disease management.

#### **4. *Regulation and Quality Management***

Quality assurance involves systems established to regularly and predictably secure quality medicines for the population. Within the pharmaceutical sector, strong regulation is a critical function which should drive private sector development as well as securing health outcomes from the use of health technologies. Safety is paramount in the regulatory function.

Currently, there's no separation of pharmaceutical regulation and procurement functions and the implementation of regulatory functions is weak. There is limited post-marketing surveillance, with restricted testing capacity based on overseas laboratory quality control (QC) testing and no pharmacovigilance capacity within the systems. No product evaluation, registration or listing system exists at the moment however, Samoa applies reliance in the selection of medicines during procurement. In general, the regulatory framework would require extensive investments to upgrade its regulatory systems. An abbreviated Benchmarking Tools assessment would help identify priority actions. Veterinary medicines are also not regulated. There are no laid down procedures to regulate herbal medicines.

#### **Key Strategic Areas**

##### **4.1 *Product Regulation and Quality Assurance***

- 4.1.1 The regulatory framework for pharmaceuticals is urgently needed. This shall entail the following:
- ✓ Use the abbreviated benchmarking tools to identify priority actions
  - ✓ Review the Drugs Act 1967 and related Acts to provide the appropriate legal context
  - ✓ Strengthening testing capacity through an effective collaboration with SROS
  - ✓ Improvements in HR capacity
  - ✓ Regulate Veterinary medicines to support the AMR Action Plan and the One Health agenda
  - ✓ Collaborations with other regulatory bodies in the Pacific Island Community on testing and standards, capacity building and technical collaboration, among others.
- 4.1.2 The Regulatory Framework shall prioritize pharmacovigilance in order to improve patient safety by collaborating with their respective hospital DTCs on regular basis.
- 4.1.3 Clinical trials to support the developmental program for the Healthy Samoa Agenda

- 4.1.4 Build on the EPI systems to establish an inclusive Pharmacovigilance Program for medicines and vaccines and explore membership to WHO program for International Drug Monitoring
- 4.1.5 Establish a centre for post-market surveillance and adverse drug reactions as part of efforts to strengthen quality assurance for medicines in circulation in the Samoa pharmaceutical market.

## **4.2 *Regulation of Practice, Premises and Standards***

- 4.2.1 Standards for pharmaceutical care and management shall be developed and implemented to guide the practice of pharmacy in Samoa. These standards shall be managed and enforced by the regulating entity for practice and shall be aligned to mandatory continuous professional development in collaboration with academia and professional associations.
- 4.2.2 Pharmacy Technician capacity building, certification and regulation is key to ensure this cadre of pharmaceutical work force supports the medicines policy implementation

## **4.3 *Traditional Medicines***

Herbal medicines have not been properly covered in the NMP 2008. Incorporating infection prevention and control into how traditional healers prepare their medicines to enhance their safety.

One challenge is that there are fewer available resources to enhance the monitoring of traditional medicines to ensure that their safety is not compromised. There is a council for traditional healers under the Allied health professionals, however the products are not regulated.

- 4.3.1 Assessment of the traditional/herbal medicines practice and also for safety and efficacy of products to enable the determination of its use as a primary health care
- 4.3.2 Engage Samoan Health Professionals and traditional practitioners to agree on rules of engagement
- 4.3.3 Step by step integration of the practice
- 4.3.4 Regulation of products linked to the overall regulation of medicines in Samoa

## IMPLEMENTATION PLAN

The policy implementation plan is designed for a period of 5 years with review to guide the subsequent 5-year period. This is to be done in alignment with national health sector planning processes. Thus, the implementation of this policy is through a rolling - 5 year costed implementation plan in line with The Health Sector Strategy. Theory of Change for policy implementation is described fully to inform implementation arrangements.

The implementation plan details specific activities, roles and responsibilities, collaborations, timelines, required resources inputs as well as expected outputs and outcomes; and shall be updated to guide a phased approach to implementation.

### Theory of change

In line with the objectives of the Samoa Medicines Policy and Plan of Action, it is envisaged that the anticipated change which would deliver sustainable and equitable access to medicines could be framed as indicated in the figure below. Progress towards this change would be monitored through the relevant indicators at the Output, Outcome and Impact level per the Monitoring and Evaluation Framework below. Successful and effective implementation is guided by a broad and improved governance mechanism initially established and operational in the pharmaceutical sector.

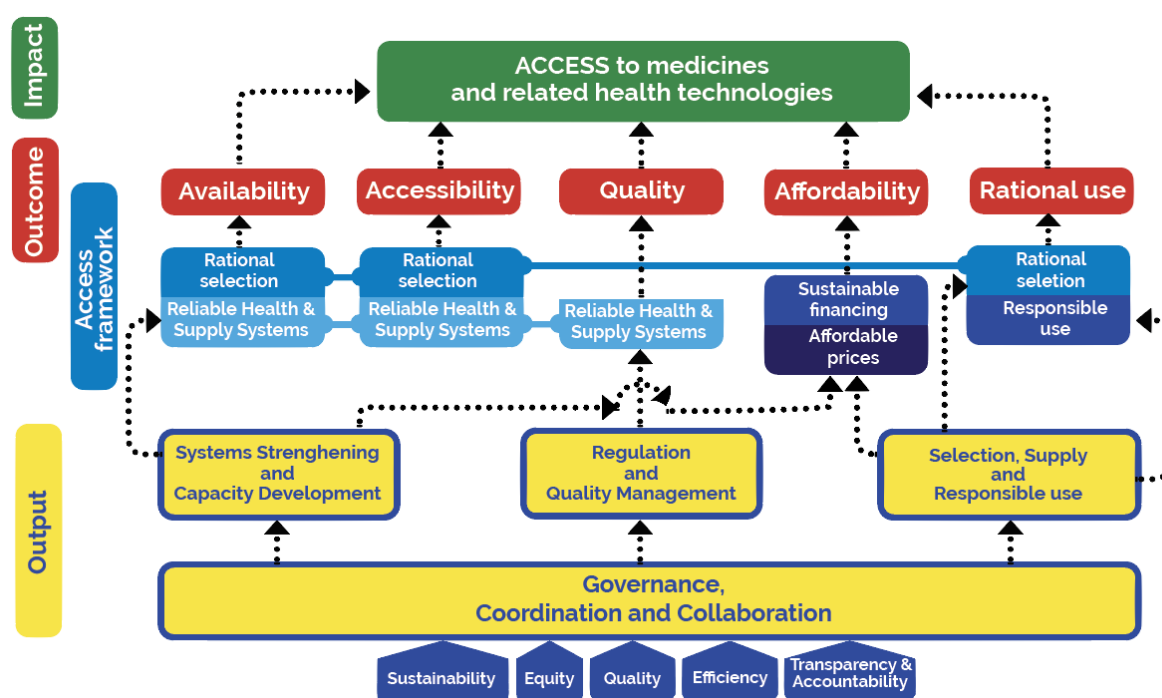


Figure: Theory of Change for Samoa Medicines Policy Implementation

The governance initiatives in the plan would drive the implementation process to the targets and value-for-money. Hence the subsequent successful and effective implementation of the annual workplans (all activities under various thematic areas of the policy and strategic areas of the strategic document) in a timely manner, would ensure that access to medicines is delivered. The improvements in governance evident through the strengthening and operations of National platform for pharmaceutical systems e.g., Steering Committee, the Hospital Drugs and Therapeutic Committees

(which have been framed as governance tool for strengthening RUM at the health facility level). These would be validated through meeting reports, decisions, follow-through action and feedback.

Specifically, capacity building in pharmaceutical Human Resource and the pharmaceutical systems strengthening initiatives would impact on reliable systems and affordable prices, which are drivers of **availability** and **affordability**. The change created through this section of the Plan would be measured through standard pharmaceutical sector indicators: *Availability of Tracer Medicines, Number of days wages required by the lowest paid government worker to afford selected treatments (Affordability of treatment for adults and children under 5 years of age), Stockout duration, Percentage of Expired medicines, Percentage Health facilities with Adequate record keeping (Health Facilities adherence to mSupply data model), Functional Drugs and Therapeutic committees* from the Monitoring and Evaluation framework.

Implementation of the initiatives on regulation and quality management would impact on *reliable systems* to deliver **accessibility** and **quality** services and products offered by certified professionals working with minimum standards in their operations and premises. The change created through this section of the Plan would be measured through pharmaceutical sector indicators: *Number of tests on pharmaceuticals performed by the regulator (including drug registration and post-marketing surveillance, but excluding testing done in conjunction with procurement activities), Percentage of samples tested passing identity and assay (with focus on Samoa Tracer Medicines List), Percentage of samples tested Tracer Medicines passing identity/assay, Percentage of samples tested by STROS control lab, national academic institutions, quality control lap in another country, private sector laboratory, Percentage of the population within one-hour walking distance to facilities have essential medicines available Number of post market surveillance conducted and actions taken, Number of recalls done annually;* per the Monitoring and Evaluation framework. This would be supported by contextual data on adherence to standards for pharmaceutical care.

The costed work plan is shown below using the WHO costing tool for AMR action Plans

Implementation of the initiatives on selection, supply chain and responsible use are directly coupled with **rational selection, sustainable financing, affordable prices, rational use**, and would impact on affordability and rational use. The change created through this section of the Plan would be measured through pharmaceutical sector indicators: *Availability of updated STGs and EML at the point of healthcare delivery, Average number of medicines per prescription, Percentage patients prescribed antibiotics/injections, Percentage prescribed medicines on Essential Medicines List, Percentage medicines prescribed by generic name (INN), Price of key Tracer medicines by Median Price Ratio (MPR); Proportion of health sector budget allocated to pharmaceuticals;* per the Monitoring and Evaluation framework.

The above represents the inter-connections required to create the needed change in access to medicines (to be supported by a panel of outcome indicators per the Monitoring and Evaluation framework) in the pharmaceutical sector in Samoa. It is in recognition of the underpinning assumptions of effective coordination and collaboration, funding and effective partnerships as well as the leadership to cause an efficient effect and impact.

The costed implementation below is based on the following four key strategic areas:

- (i) Governance, coordination and collaboration
- (ii) Pharmaceutical Systems Strengthening
- (iii) Selection, Supply Chain and Responsible Use and
- (iv) Regulation and Quality Management.

This is detailed in the matrix below.

## Key Strategic Area 1: Governance, Coordination and Collaboration

### Objectives:

- (i) To strengthen the governance structures, processes and systems within the pharmaceutical sector for the effective rollout of interventions to promote access, based on strong governance principles
- (ii) To strengthen critical partnerships and collaborations with all stakeholders, including relevant sectors, in order to promote access and address cross-cutting pertinent issues such as research and antimicrobial resistance.

Activity Ref.	Work-track Activities	Deliverables	Lead	Collaborators	Y1	Y2	Y3	Y4	Y5
1	Hold quarterly Steering Committee meetings.	SC meeting reports showing technical collaborations and progress on actions in Medicines Plan	ACEOs Warehouse/ Pharmaceutical Services	SC members, Partners	X	X	X	X	X
2	Appoint Coordinators and Hold quarterly/half yearly Pharmaceutical Stakeholder Platform Meeting	Letters of appointment and Quarterly Pharmaceutical Stakeholder meeting reports showing the collaborations, partnerships etc. and progress on implementation of the Pharmacy Policy and Plan	ACEOs (Warehouse Pharmaceutical Services	MOH (relevant Directorates), Ware Programme Managers, Pharmaceutical sector partners; DFCA; CMS; all relevant stakeholders	X	X	X	X	X
3	Advocate for incremental investments in the pharmaceutical sector from Government, Partners and Private Sector leveraging sector performance data	Quarterly Pharmaceutical Sector Performance Data; Advocacy messages/briefs on investments in the pharmaceutical sector; Reports from advocacy meetings with targeted investors; Technical document on investment	Steering Committee (MOH)	MOH, MOFEP, Private Sector, Partners	X	X	X	X	X



Activity Ref.	Work-track Activities	Deliverables	Lead	Collaborators	Y1	Y2	Y3	Y4	Y5
		opportunities in the sector							
4	Annual 'visibility' fora on the Pharmaceutical Sector (National, Regional/International) meetings	Pharmaceutical agenda in Samoa set within the regional/international space	MOH ACEO Warehouse/Pharmacy	WHO, Partners, Private Sector, Academia, Ministry of Foreign affairs, MOT, MOF	X	X	X	X	X
5	Conduct Annual peer review meetings with award systems	Performance Model and League Table of Indicators for Pharmaceutical Performance at district levels on Performance Model; Incentive and support package for Best and Worst Performing Facilities	ACEO Warehouse	ACEOs, Relevant Donors and, WHO	X	X	X	X	X
6	Develop/deploy Pharmaceutical Information Management Systems to support M and E	Use the IT infrastructure for M Supply program to Pharmacy Information Management System (PIMS) for Samoa; Standard Tools and Templates for Reporting; Training Manual on PIMS; Training Reports on PIMS;	ACEO Warehouse	Partners, WHO	X	X			
7	Conduct key periodic assessments to yield critical data on the pharmaceutical sector	Study reports: (Pharmaceutical Sector Scan; Good governance of medicines; WHO level 2 assessment; Product Quality; Supply chain; Mapping of Medicines Outlets; Pricing; Household surveys; Adherence to treatment guidelines; Policy briefs and Technical Briefs; Reports on Dissemination and Policy Dialogue	ACEOs Warehouse/Pharmacy	PPBR, ICT, M&E , Relevant Donors and, WHO	X		X		X
8	Establish stewardship program for AMR	Functional stewardship program with clear TORs committee (Meeting reports); as per the AMR Action Plan	ACEOS Pharmacy	AMR Working Group and Partners, WHO	X	X	X	X	X
9	Policy for PHE and Global health security and role of pharmaceuticals	Guidance document for PHE and pharmaceuticals	ACEOS Public Health/Pharmacy	Warehouse, Pharmacy and Partners, WHO	X				X

Activity Ref.	Work-track Activities	Deliverables	Lead	Collaborators	Y1	Y2	Y3	Y4	Y5
10	Advocate for legislative Review to support policy implementation	Reports on Advocacy activities; Amendment of relevant Acts	Head of Legal (MOH)	ACEO, Warehouse, Pharmacy MOJ, Academia, Partners, Select Committee on Social Services (Health) of Parliament	X	X	X	X	
11	Establish inter-sectoral Coordination mechanism to support Policy Implementation (The SC could play that role	Meetings reports	PPBR /Warehouse/Pharmacy	PPBR /Warehouse/Pharmacy	X	X	X	X	X

## Key Strategic Area 2: Pharmaceutical Systems Strengthening

### Objective:

To build capacity and strengthen pharmaceutical systems to deliver sustainable and equitable access.

Activity Ref.	Work track Activities	Deliverables	Lead	Collaborators	Y1	Y2	Y3	Y4	Y5
12	Evaluate the Overseas Treatment Abroad program	Evaluation Report	PPBR	Finance, Audit IM&E, Warehouse, Pharmacy, MoF, Partners		X			
13	Evaluate the P4R program as a pilot to step by step health insurance  Develop model for risk protection for investments in the pharmaceutical sector including insurance models	P4R evaluation Report  Risk management plan for pharmaceutical sector	PPBR	Finance, Audit IM&E, Warehouse, Pharmacy, MoF, Partners, Professional bodies					
13	Define pharmaceutical sector needs to inform budgets and funding for the supply of medicines based on the minimum services package	Needs identified and Quantified; Funding gaps identified/budget; Business plan for CMSA; Advocacy plan for pharmaceutical financing; Reports on continuous advocacy for national budget allocation and actual disbursement of the funds	ACEOS Warehouse/Pharmacy (MOH)	PPBR, MOF, Partners/UN Agencies, WHO, Private Sector, Donors, Relevant NGOs and CSOs	X	X	X	X	X
14	Establish mechanism for monitoring medicines prices within the health system, with key focus on private sector supply chain	Routine quarterly reports on prices of selected basket of medicines; Compilation of cumulative data for pricing policy	ACEO Warehouse (MOH)	Procurement and Finance, WHO, Partners					
15	Establish High Level Coordination Mechanism for the MOH and the major donors/partners (roundtable)	Scheduled quarterly meeting with minutes and action points; TORs developed and training for all level	MOH PPBR	UN Agencies and Partners	X	X	X	X	X

Activity Ref.	Work track Activities	Deliverables	Lead	Collaborators	Y1	Y2	Y3	Y4	Y5
		Coordination mechanisms conducted.							
16	Working with Bilateral and multilateral partners for sponsorship training for pharmaceutical work force	number of pharmaceutical workforce trained and certified	PSS, Academia	MOH, ACEOS, Partners, NZ Embassy	X	X	X	X	X
17	Advocate for improved conditions of service	HR needs assessment; Bargaining document on improved conditions of service-including access to continuous capacity building;	MOH HR	MOH-HR, ACEOS, PSS	X		X		X
18	Design, implement, monitor public education campaign on rational use of medicines (RUM)	RUM campaign materials; RUM campaign report	PSS, CSOs, ACEO Pharmacy	MOH, ACEOS, Health promotion, PSS, WHO, Partners	X	X	X	X	X
19	Conduct in-depth assessment of the pharmaceutical private sector market structure (including assessment of economic impact and growth and national manufacturing potential)	Technical reports on the pharmaceutical industry in Samoa	PSS/SROS	MOH, ACEOS, SROS, Private Sector, Partners			X		
20	Develop research agenda and conduct implementation research on policy for the pharmaceutical sector	Research agenda document with clear (framework for resource mobilization to support research); Research reports, publications	ACEO Pharmacy/warehouse	PPBR, SROS, Academia, Private Sector, PSS, WHO, Partners	X	X		X	

## Key Strategic Area 3: Selection, Supply Chain and Responsible Use

### Objective:

To strengthen the selection process and ensure pharmaceutical supply chain delivers efficacious, safe and affordable treatments in sustainable and equitable manner as well as their responsible use for all persons living in Samoa.

Activity Ref.	Work track Activities	Deliverables	Lead	Collaborators	Y1	Y2	Y3	Y4	Y5
21	Update and disseminate Samoa-EML and Samoa-STG with orientation on changes made	Updated EML and STG with list of related health technologies (in both hard and softcopy) disseminated	NMSGC secretariat	Academia, WHO, Private Sector, PSS		X		X	
22	Establish functional committee under the Steering Committee for the Selection of Medicines and Development of Guidelines (National Medicines Selection and Guidelines Sub-committee (NMSGC))	Medicines Selection Sub-Committee Reports (Functional Committee); Committee governance tools and operating norms; Documented National Medicines Selection Process including Conflict of interest	ACEOS Pharmacy & Warehouse	Academia, PPBR Partners, WHO	X	X	X	X	X
22	Identify and support, existing staff/team at MOH, and provide logistics for the STG/EML review process	-STG/EML coordination team/unit identified and supported	ACEO Pharmacy	Academia, Relevant Donors and Partners, WHO	X		X		X
23	Train Coordination Staff on key components of the medicines selection process	Training materials, resources and working tools and templates for managing the selection process; Training reports	ACEO Pharmacy	, Academia, Relevant Donors and Partners, WHO	X	X		X	
24	Document the medicines selection process benchmarking global (including WHO) best practice	National Medicines Selection Process of Samoa	Secretariat-NMSGC,	Academia, Partners, WHO, Private Sector, PSS	X	X			
25	Train prescribers of updated STGs and EML	Training materials, resources and flowcharts; Training reports	ACEO Pharmacy	Academia, Relevant Donors and Partners, WHO, Private Sector, PSS, SMA	X	X			
26	Implement supply chain initiatives to secure access to medicines	Supply chain reports that support decision making			X	X	X	X	X

Activity Ref.	Work track Activities	Deliverables	Lead	Collaborators	Y1	Y2	Y3	Y4	Y5
27	Advocate for Government budgetary allocation and disbursement for financing medicines supply at the Warehouse	Financing model/plan for pharmaceuticals; Funds disbursed for pharmaceutical supply chain operations and procurement of medicines;	MOH ACEO F&P	MOF, Private Sector, PSS, Relevant partners	X	X	X	X	X
28	Mobilize resources to consolidate supplies for Health to unify the procurement systems for efficiency	Reports for Consolidated Supply systems	ACEO PPBR	ACEOs warehouse, Dental, Laboratory MOJ, MOF, Partners, WHO	X	X	X	X	X
29	Develop the business and operational model plan to Samoa Supply chain with defined roles	Warehouse Business and operational model (including chain of custody) approved by Government	ACEO Warehouse	MOH, ACEOS, MOF, Private Sector, Relevant Donors and Partners, WHO	X	X			
30	Organize quantification workshops to forecast country needs, with facilities based on data from LMIS/PIMS; and annual supply chain review meetings	Forecasted quantities of pharmaceuticals; Annual supply chain performance reports	ACEO Warehouse	ACEOS, F&P, ACEO PPBR MOF, Relevant Donors and Partners	X	X	X	X	X
31	Develop and implement change management plan to support current MoH reforms	Change management guidance document available and implemented	ACEO PPBR	ACEO Warehouse, Pharmacy MOF, Relevant partners		X	X	X	X
32	Develop/review and Disseminate National Donations Guidelines, with orientation on new modalities for donations	Updated Donation Guidelines, Dissemination report	ACEO PPBR	ACEO Warehouse, Pharmacy, F&P, MOF, Relevant partners, WHO		X	X		
33	Develop and implement Drug Information Plan for Samoa	Drug Information Plan	ACEO Pharmacy	ACEO Warehouse, NHS managers Academia, Private Sector, PSS, SMA Relevant partners	X	X	X	X	X
34	Setup, Supervise, Support and Monitor DTCs at all Teaching Hospital and Referral Hospitals.	TORs; Operational Manual for Hospitals; Quarterly Reports for SC meetings DTC reports on Adherence to Guidelines	ACEO Pharmacy	MOH, WHO, Relevant partners		X	X	X	X

Activity Ref.	Work track Activities	Deliverables	Lead	Collaborators	Y1	Y2	Y3	Y4	Y5
35	Monitor adherence to STGs in health care public and private sector	Monitoring reports	ACEO Pharmacy	ACEO warehouse MOH, WHO, Relevant partners	X	X	X	X	X
36	Develop and Implement Patient safety protocols and standards at all levels of care	Patient safety protocol for Samoa	MOH	MOH, WHO, Academia, Private Sector, PSS, SSGMC, Relevant partners	X	X	X	X	X
37	Train all health professionals at relevant levels on patient safety protocols	Patient safety training materials and reports	MOH	MOH, WHO, Academia, Private Sector, Health professionals, Relevant partners		X	X	X	X
38	Documentation of Dispensing and medication error as a patient safety measure at all levels of care	Patient safety report	ACEO Pharmacy	MOH, WHO, Academia, Private Sector, Health Professionals, Relevant partners			X	X	X
39	Develop drug disposal protocol for Samoa, with dissemination/orientation for all stakeholders	Drug Disposal protocol developed; Dissemination reports	ACEO Warehouse	Waste management Unit, WHO, Academia, Private Sector, Relevant partners			X		
40	Collaborate with disease specific programmes on pharmaceutical management aspects of programme strategies and their implementation	Pharmaceutical management sub-Plan as part of disease management and emergency response strategies	Programmes/ACEO PPBR	MOH, ACEOS, Partners	X	X	X	X	X
41	Develop a special protocol (including funding mechanism) to facilitate access to medicines under public health emergencies and emerging diseases.	Protocol for promoting access to medicines under public health emergencies	MOH	MOH, ACEOS, WHO, Academia, Private Sector, PSS, SMA, Relevant partners	X	X			

## Key Strategic Area 4: Regulation and Quality Management

### Objective:

To strengthen the regulatory framework and quality management processes within the pharmaceutical sector of the Republic of Samoa

Activity Ref.	Work track Activities	Deliverables	Lead	Collaborators	Y1	Y2	Y3	Y4	Y5
42	Advocate to review the Drugs Act 1967 and other relevant legislations	Amendment bill	Head of Legal	ACEO Quality assurance, Warehouse, PPBR, Pharmacy Parliament, MOH, Private Sector, PSS, WHO, Relevant Donors and Partners	X	X	X		
43	Use abbreviated Global Benchmarking tools (GBT) to identify priority actions	Report of GBT to define next steps	ACEO Pharmacy	ACEO Quality Assurance, Private Sector, PSS, WHO, Relevant Donors and Partners		X	X	X	X
44	Establish a Pharmacovigilance Program for medicines and vaccines	Pharmacovigilance program established with reporting to International Drug Monitoring	ACEO Pharmacy	EPI, ACEO Quality Assurance Private Sector, PSS, WHO, Relevant Donors and Partners	X	X	X		
45	Establish a centre for Post market surveillance	A functional Post market surveillance centre available	ACEO Quality Assurance	ACEO Warehouse, Pharmacy, Private Sector, PSS, WHO, Relevant Donors and Partners	X	X	X	X	X
46	Develop and implement Standard of Practice; including training on Standards through mandatory CPDs for all pharmaceutical cadre including Pharmacy Technicians	Samoa Standards of Pharmaceutical Services, Standards for Pharmacy Technicians; Training reports on Standards of Practice;	ACEO Pharmacy	ACEO Warehouse, Private Sector, PSS, WHO, Relevant Donors and Partners	X	X	X	X	X
47	Assessment of traditional/herbal medicines for safety and quality	Assessment report	ACEO Pharmacy, PPBR, Warehouse	SROS, Traditional healers, Allied Health Professionals, WHO and other related Partners	X				
48	Engage Samoan Health Professionals and traditional healers	Advocacy meeting reports	ACEO PPBR, Pharmacy	Health Professionals, Allied Health Council, SROS	X	X	X	X	X
49	Regulation of herbal products for quality and safety	Some products qualified for primary health care level	ACEO Quality assurance	SROS, Traditional healers, PSS, WHO, Relevant Donors and Partners	X	X	X	X	X



## COST ESTIMATES OF THE IMPLEMENTATION PLAN

The cost estimates for implementation of the Plan over a 5-year period are as detailed below.

Activity Ref.	Work track Activities	Y1	Y2	Y3	Y4	Y5	Activity Cost Category	Budget Y1	Budget Y2	Budget Y3	Budget Y4	Budget Y5	Total
<b>Key Strategic Area 1: Governance, Coordination and Collaboration</b>								<b>2,169,946</b>	<b>665,789</b>	<b>473,011</b>	<b>473,011</b>	<b>989,215</b>	<b>4,770,971</b>
<b>1</b>	Hold quarterly Steering Committee meetings.	X	X	X	X	X	Cost of Governance Setup	17,208	17,208	17,208	17,208	17,208	<b>86,040</b>
<b>2</b>	Appoint Coordinators and Hold quarterly/half yearly Pharmaceutical Stakeholder Platform Meeting	X	X	X	X	X	Cost of HR and Capacity Development Interventions	30,000	30,000	30,000	30,000	30,000	<b>150,000</b>
<b>3</b>	Advocate for incremental investments in the pharmaceutical sector from Government, Partners and Private Sector leveraging sector performance data	X	X	X	X	X	Cost of Advocacy	20,463	17,208	17,208	17,208	17,208	<b>89,295</b>

Activity Ref.	Work track Activities	Y1	Y2	Y3	Y4	Y5	Activity Cost Category	Budget Y1	Budget Y2	Budget Y3	Budget Y4	Budget Y5	Total
4	Annual 'visibility' fora on the Pharmaceutical Sector (National, Regional/International) meetings	X	X	X	X	X	Cost of Multi-Stakeholder process	121,900	121,900	121,900	121,900	121,900	609,500
5	Conduct Annual peer review meetings with award systems	X	X	X	X	X	Cost of Governance Setup	210,562	169,260	169,260	169,260	169,260	887,602
6	Develop/deploy Pharmaceutical Information Management Systems to support M and E	X	X	X	X	X	Cost of Technical Deliverables	125,932	84,630	84,630	84,630	84,630	464,452
7	Conduct key periodic assessments to yield critical data on the pharmaceutical sector	X	X	X	X	X	Cost of Implementation Monitoring	15,597	15,597	15,597	15,597	15,597	77,983
8	Establish stewardship program for AMR	X	X				Cost of Technical Deliverables	259,315	172,315	-	-	-	431,630
9	Policy for PHE and Global health security and role of pharmaceuticals	X	X				Cost of Governance Setup	17,255	3,255	-	-	-	20,510
10	Advocate for legislative Review to support policy	X				X	Cost of Advocacy	1,032,912	-	-	-	533,412	1,566,324

Activity Ref.	Work track Activities	Y1	Y2	Y3	Y4	Y5	Activity Cost Category	Budget Y1	Budget Y2	Budget Y3	Budget Y4	Budget Y5	Total
	implementation												
11	Establish inter-sectoral Coordination mechanism to support Policy Implementation (The SC could play that role)	X	X	X	X		Cost of Governance Setup	159,401	17,208	17,208	17,208	-	211,025
12	Develop policy on Emergency preparedness and response	X	X				Cost of Technical Deliverables	159,401	17,208	-	-		176,609
<b>Key Strategic Area 2 - Pharmaceutical Systems Strengthening</b>								<b>849,311</b>	<b>1,810,615</b>	<b>365,580</b>	<b>253,716</b>	<b>253,716</b>	<b>3,532,937</b>
	<i>Financing and pricing</i>												
12	Evaluate the Overseas Medical Treatment Scheme	X	X	X	X	X	Cost of Implementation Monitoring	119,043	45,043	45,043	45,043	45,043	299,216
13	Evaluate the PfR program as a pilot to step by step health insurance	X	X	X	X	X	Cost of Technical Deliverables	22,802	4,302	4,302	4,302	4,302	40,010
	Develop model for risk protection for investments in the pharmaceutical	X	X	X	X	X	Cost of Technical Deliverables	4,302	4,302	4,302	4,302	4,302	21,510

Activity Ref.	Work track Activities	Y1	Y2	Y3	Y4	Y5	Activity Cost Category	Budget Y1	Budget Y2	Budget Y3	Budget Y4	Budget Y5	Total
	sector including insurance models												
13	Define pharmaceutical sector needs to inform budgets and funding for the supply of medicines based on the minimum services package	X	X	X	X	X	Cost of Technical Deliverables	17,208	1,517,208	17,208	17,208	17,208	1,586,040
14	Establish mechanism for monitoring medicines prices within the health system, with key focus on private sector supply chain	X	X	X	X	X	Cost of Technical Deliverables	18,852	18,852	18,852	18,852	18,852	94,258
15	Establish High Level Coordination Mechanism for the MOH and the major donors/partners (roundtable)	X	X	X	X	X	Cost of Governance Setup	20,463	17,208	17,208	17,208	17,208	89,295

Activity Ref.	Work track Activities	Y1	Y2	Y3	Y4	Y5	Activity Cost Category	Budget Y1	Budget Y2	Budget Y3	Budget Y4	Budget Y5	Total
16	Working with Bilateral and multilateral partners for sponsorship training for pharmaceutical work force	X	X	X	X	X	Cost of HR and Capacity Development Interventions	90,647	53,647	53,647	53,647	53,647	305,236
17	Advocate for improved conditions of service	X	X	X	X	X	Cost of HR and Capacity Development Interventions	148,302	74,302	74,302	74,302	74,302	445,510
18	Design, implement, monitor public education campaign on rational use of medicines (RUM)			X			Cost of Public Education Initiatives	-	-	111,865	-	-	111,865
19	Conduct in-depth assessment of the pharmaceutical private sector market structure (including assessment of economic impact and growth and national manufacturing potential)		X				Cost of Technical Deliverables	-	56,900	-	-	-	56,900

Activity Ref.	Work track Activities	Y1	Y2	Y3	Y4	Y5	Activity Cost Category	Budget Y1	Budget Y2	Budget Y3	Budget Y4	Budget Y5	Total
20	Develop research agenda and conduct implementation research on policy for the pharmaceutical sector	X	X	X	X	X	Cost of Research	407,692	18,852	18,852	18,852	18,852	483,098
<b>Key Strategic Area 3 - Selection, Supply Chain and Responsible Use</b>								<b>1,771,786</b>	<b>2,030,040</b>	<b>1,936,464</b>	<b>1,939,763</b>	<b>2,059,763</b>	<b>9,737,816</b>
	<i>Selection</i>												
21	Update and disseminate Samoa-EML and Samoa-STG with orientation on changes made		X	X	X	X	Cost of Technical Deliverables	-	128,210	17,210	17,210	17,210	179,840
22	Establish functional committee under the Steering Committee for the Selection of Medicines and Development of Guidelines (National Medicines Selection and Guidelines Sub-committee (NMSGC))	X	X	X	X	X	Cost of Technical Deliverables	68,193	31,193	31,193	31,193	31,193	192,966

Activity Ref.	Work track Activities	Y1	Y2	Y3	Y4	Y5	Activity Cost Category	Budget Y1	Budget Y2	Budget Y3	Budget Y4	Budget Y5	Total
22	Identify and support, existing staff/team at MOH, and provide logistics for the STG/EML review process	X	X	X	X	X	Cost of HR and Capacity Development Interventions	28,000	28,000	28,000	28,000	28,000	140,000
23	Train Coordination Staff on key components of the medicines selection process	X	X				Cost of HR and Capacity Development Interventions	15,597	34,097	-	-	-	49,693
24	Document the medicines selection process benchmarking global (including WHO) best practice	X	X				Cost of Technical Deliverables	15,597	44,097	-	-	-	59,693
25	Train prescribers of updated STGs and EML	X	X				Cost of HR and Capacity Development Interventions	121,900	140,400	-	-	-	262,300
26	Implement supply chain initiatives to secure access to medicines	X	X	X	X	X	Cost of Advocacy	4,302	4,302	4,302	4,302	4,302	21,510

Activity Ref.	Work track Activities	Y1	Y2	Y3	Y4	Y5	Activity Cost Category	Budget Y1	Budget Y2	Budget Y3	Budget Y4	Budget Y5	Total
27	Advocate for Government budgetary allocation and disbursement for financing medicines supply at the Warehouse	X	X	X	X	X	Cost of Advocacy	4,302	4,302	4,302	4,302	4,302	21,510
28	Mobilize resources to consolidate supplies for Health to unify the procurement systems for efficiency	X	X	X	X	X	Cost of Advocacy	3,255	3,255	3,255	3,255	3,255	16,275
29	Develop the business and operational model plan to Samoa Supply chain with defined roles	X	X				Cost of Technical Deliverables	56,899	19,899	-	-	-	76,797
30	Organize quantification workshops to forecast country needs, with facilities based on data from LMIS/PIMS; and annual supply chain review meetings	X	X	X	X	X	Cost of Technical Deliverables	4,302	4,302	4,302	4,302	4,302	21,510



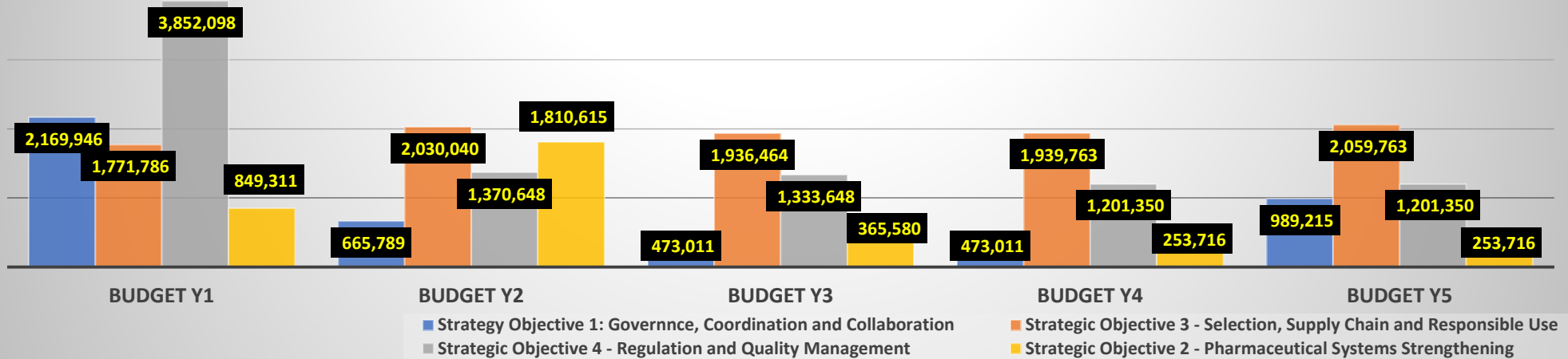
Activity Ref.	Work track Activities	Y1	Y2	Y3	Y4	Y5	Activity Cost Category	Budget Y1	Budget Y2	Budget Y3	Budget Y4	Budget Y5	Total
31	Develop and implement change management plan to support current MoH reforms			X	X	X	Cost of Multi-Stakeholder process	-	-	31,193	31,193	31,193	93,580
32	Develop/review and Disseminate National Donations Guidelines, with orientation on new modalities for donations			X	X	X	Cost of Seed Fund for Procurement of Initial Selected Medicines and Related Health Technologies	1,200,000	1,320,000	1,440,000	1,560,000	1,680,000	7,200,000
33	Develop and implement Drug Information Plan for Samoa		X				Cost of Technical Deliverables	-	45,193	-	-	-	45,193
34	Setup, Supervise, Support and Monitor DTCs at all Teaching Hospital and Referral Hospitals.		X				Cost of Technical Deliverables	-	61,201	-	-	-	61,201
35	Monitor adherence to STGs in health care public and private sector		X	X	X	X	Cost of Governance Setup	29,447	-	29,447	29,447	29,447	117,786
		X	X	X	X	X	Cost of Implementation	82,043	45,043	45,043	45,043	45,043	262,216

Activity Ref.	Work track Activities	Y1	Y2	Y3	Y4	Y5	Activity Cost Category	Budget Y1	Budget Y2	Budget Y3	Budget Y4	Budget Y5	Total
							Monitoring						
36	Develop and Implement Patient safety protocols and standards at all levels of care			X	X	X	Cost of Technical Deliverables	-	-	61,201	24,201	24,201	109,602
37	Train all health professionals at relevant levels on patient safety protocols	X	X	X	X	X	Cost of Technical Deliverables	74,729	37,729	37,729	37,729	37,729	225,645
38	Documentation of Dispensing and medication error as a patient safety measure at all levels of care		X	X	X	X	Cost of HR and Capacity Development Interventions	-	34,097	15,597	15,597	15,597	80,887
39	Develop drug disposal protocol for Samoa, with dissemination/or ientation for all stakeholders			X	X	X	Cost of Research	-	-	96,268	59,268	59,268	214,804
40	Collaborate with disease specific programmes on pharmaceutical management aspects of programme strategies and their implementation			X			Cost of Technical Deliverables	-	-	42,701	-	-	42,701

Activity Ref.	Work track Activities	Y1	Y2	Y3	Y4	Y5	Activity Cost Category	Budget Y1	Budget Y2	Budget Y3	Budget Y4	Budget Y5	Total
41	Develop a special protocol (including funding mechanism) to facilitate access to medicines under public health emergencies and emerging diseases.	X	X	X	X	X	Cost of Multi-Stakeholder process	63,222	44,722	44,722	44,722	44,722	242,108
<b>Strategic Objective 4 - Regulation and Quality Management</b>								<b>3,852,098</b>	<b>1,370,648</b>	<b>1,333,648</b>	<b>1,201,350</b>	<b>1,201,350</b>	<b>8,959,095</b>
<i>Product regulation and Quality assurance</i>													
42	Advocate to review the Drugs Act 1967 and other relevant legislations	X	X	X			Cost of Advocacy	70,196	59,696	59,696	-	-	189,588
43	Use abbreviated Global Benchmarking tools (GBT) to identify priority actions		X	X	X	X	Cost of Technical Deliverables	-	94,949	57,949	57,949	57,949	268,797
44	Establish a Pharmacovigilance Program for medicines and vaccines	X	X	X			Cost of Infrastructure	2,433,602	72,602	72,602	-	-	2,578,806
45	Establish a centre for Post market surveillance	X	X	X	X	X	Cost of Infrastructure	1,055,500	1,000,000	1,000,000	1,000,000	1,000,000	5,055,500

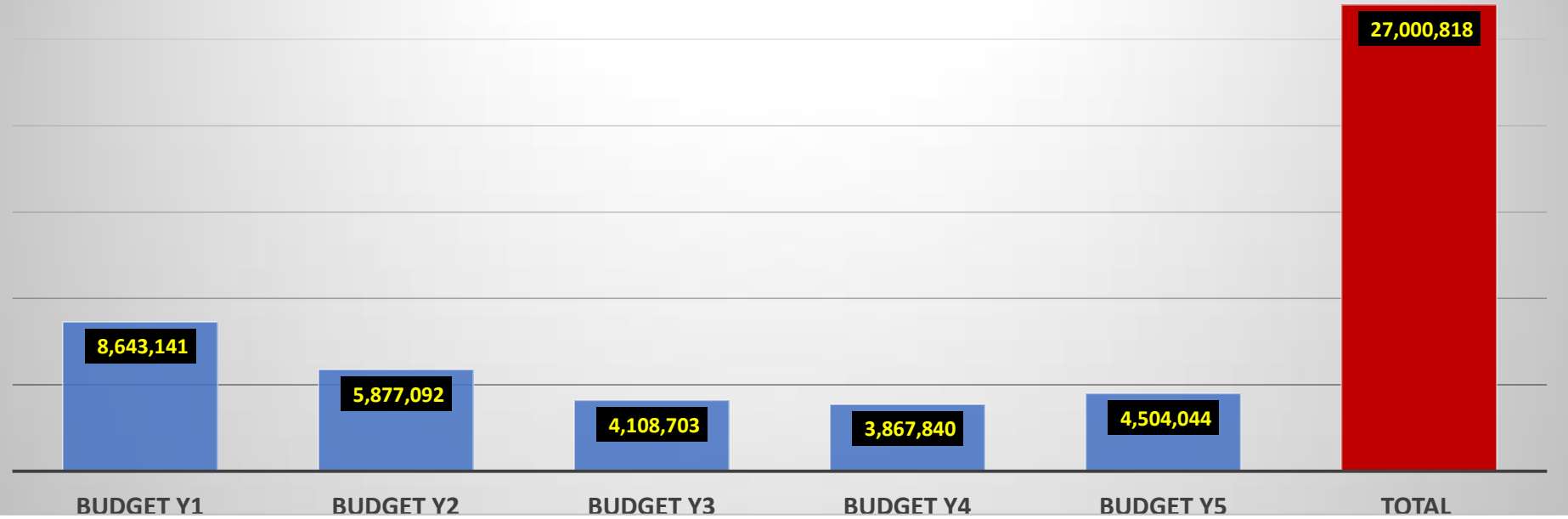
Activity Ref.	Work track Activities	Y1	Y2	Y3	Y4	Y5	Activity Cost Category	Budget Y1	Budget Y2	Budget Y3	Budget Y4	Budget Y5	Total
46	Develop and implement Standard of Practice; including training on Standards through mandatory CPDs for all pharmaceutical cadre including Pharmacy Technicians	X	X	X	X	X	Cost of HR and Capacity Development Interventions	112,000	75,000	75,000	75,000	75,000	412,000
47	Assessment of traditional/herbal medicines for safety and quality	X					Cost of Research	56,899	-	-	-	-	56,899
48	Engage Samoan Health Professionals and traditional healers	X	X	X	X	X	Cost of HR and Capacity Development Interventions	95,297	39,797	39,797	39,797	39,797	254,486
49	Regulation of herbal products for quality and safety	X	X	X	X	X	Cost of Technical Deliverables	28,604	28,604	28,604	28,604	28,604	143,020
								8,643,141	5,877,092	4,108,703	3,867,840	4,504,044	27,000,818

## Budget Analysis (Year 1 to 5 - by Strategic Area)

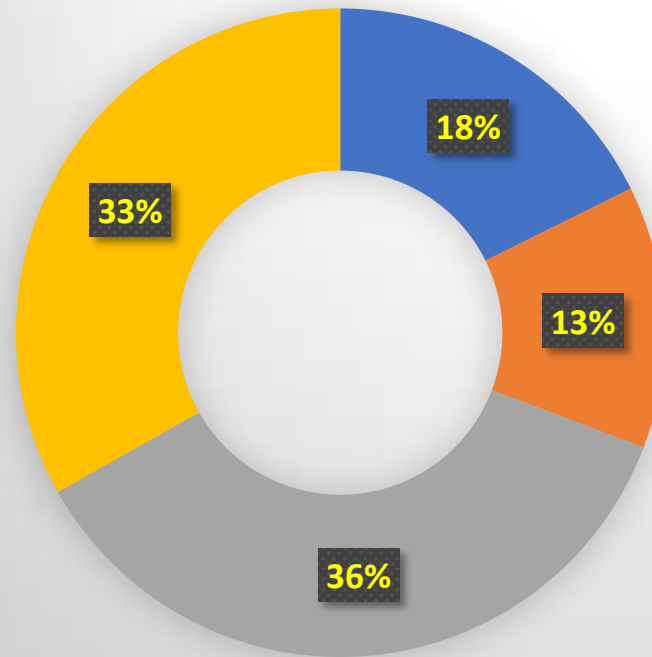


Key Strategic Areas	Budget Y1	Budget Y2	Budget Y3	Budget Y4	Budget Y5	Total
Key Strategic Area 1: Governance, Coordination and Collaboration	2,169,946	665,789	473,011	473,011	989,215	4,770,971
Key Strategic Area 2 - Pharmaceutical Systems Strengthening	849,311	1,810,615	365,580	253,716	253,716	3,532,937
Key Strategic Area 3 - Selection, Supply Chain and Responsible Use	1,771,786	2,030,040	1,936,464	1,939,763	2,059,763	9,737,816
Key Strategic Area 4 - Regulation and Quality Management	3,852,098	1,370,648	1,333,648	1,201,350	1,201,350	8,959,095
Sub Totals	8,643,141	5,877,092	4,108,703	3,867,840	4,504,044	27,000,818

## Annual Budget



## Investments by Strategic Area



■ Strategic Objective 1: Governance, Coordination and Collaboration

■ Strategic Objective 2 - Pharmaceutical Systems Strengthening

■ Strategic Objective 3 - Selection, Supply Chain and Responsible Use

■ Strategic Objective 4 - Regulation and Quality Management

## MONITORING AND EVALUATION

The implementation of this policy would be supported by a Monitoring and Evaluation Framework to guide performance management and progress. This M&E framework is aligned to the MOH overarching M&E framework. The framework is shown below with.

- (i) Clear indicators for monitoring the NMP plan linked to the MOH M&E framework
- (ii) Medicines Policy Indicators to be captured into the IT infrastructure for ease of measurement
- (iii) Mid-term evaluation of policy implementation and independent external evaluation of Policy
- (iv) Medicines Policy implementation indicators to be part of the Sector-wide indicators
- (v) Quarterly and Annual progress reports on policy implementation to the MOH Policy unit

The matrixes below present indicators that will be used to effectively monitor and evaluate the implementation of this policy document.

### Top 10 indicators

Indicator	Policy area	Responsible	Reporting
1. Availability of Samoa Tracer Medicines list	Overall impact (with 9 others below)	MOH	Monthly reporting
2. No. of SC meetings per year	Governance	MOH	Quarterly reporting
3. No. of Sub Committees meetings per year	Governance	MOH	Quarterly reporting
4. Per capita expenditure on pharmaceuticals	Systems Strengthening	MOH	Annual reporting
5. Percentage of Pharmacists working at the public sector	Systems Strengthening	MOH	Annual reporting
6. % Expiry	Selection, Supply, RUM	MOH	Monthly reporting
7. No of days stock-out (per month)	Selection, Supply, RUM	MOH	Monthly reporting
8. Drug consumption (Tracer list)	Selection, Supply, RUM	MOH	Monthly reporting
9. Average number of medicines per prescription	Selection, Supply, RUM	NHS	Monthly reporting
10. Percentage of samples tested passing identity and assay (with focus on Samoa Tracer Medicines List)	Quality Assurance	Quality Assurance	Quarterly reporting



## 17 Indicators

Level	Indicator (routine and non-routine)				Baseline <sup>15</sup> (2024)	Target (year)	Data Source	Frequency/ Reporting	Responsibility
IMPACT	(Access to medicines improved (for Improved health outcomes))								
	Access to medicines (as a Panel of Outcome Indicators below, in addition to availability of tracer medicines)								
Availability	1. Availability of Tracer Medicines	X	X	X	48%	80% (estimate)  Min 90% (2028) (estimate)	– M Supply IT platform / Stock cards – Health Facility Monthly Pharmacy Reports	Measured Routinely: – Monthly: Health Facility level – Quarterly: National level	– Health Facility level: Pharmaceutical staff – ICT staff  – Drug and Therapeutic Committee Chair – National: ACEO Warehouse/ Pharmacy
OUTCOME <sup>16</sup>	(Improved Availability, Accessibility, Quality, Affordability, Improved Rational Use)								
Outcome Area: Governance, collaboration and coordination									
	2. No. of SC meetings per year					– Min 4	– SC meeting reports	– Quarterly	– ACEO Warehouse/Pharmacy
	3. No. of multi-stakeholder pharmaceutical sector meetings per year					– Min 2	– Technical reports	– Bi-annually	– ACEO Warehouse/Pharmacy
Outcome Area: Pharmaceutical systems strengthening and capacity building									
Affordability	4. Number of days wages required by the lowest paid government worker to afford selected treatments.			X	Based on selected conditions	Based on selected conditions	– Commissioned Study	Biennial or 4 yearly	– MOH (with support from partners, WHO)
Accessibility	5. Percentage of the population within one-hour walking				NA	Set based on baseline	– Commissioned Study	Biennial	– MOH (with support from partners, WHO)

<sup>15</sup> Values for Baseline and Targets are sourced from the End of year report of the Health sector for Samoa, 2022

<sup>16</sup> WHO recommend access indicators at the outcome level: Source: WHO Operational package for assessing, monitoring and evaluating country pharmaceutical situations Guide for coordinators and data collectors December 2007

Level	Indicator (routine and non-routine)				Baseline <sup>15</sup> (2024)	Target (year)	Data Source	Frequency/ Reporting	Responsibility
	distance to facilities that have essential medicines available								
Financing	6. Annual public medicines budget				[from 2023 budget value]		– MOH annual budget	Biennial	– MOH
	7. Per capita expenditure on pharmaceuticals				\$ 201	\$ 500	– MOH annual budget	Biennial	– MOH
Price	8. Prices of selected Basket of Tracer Medicines			X	NA	90% Products <2xIRP	– Commissioned Surveys	Biennial	– MOH (with support from WHO)
Human resource	9. No. of new pharmacists trained in Samoa per year				0	10% in 5 years	– Academia	Annual	– MOH/Academia
	10. Percentage of Pharmacists working at the facilities						– MOH	Annual	– MOH/Academia
	11. No. of Training workshops, CPDs etc. held for pharmaceutical cadre per year						– MOH/PSS/Academia	Annual	– MOH/Academia
<b>Outcome Area: Selection, supply and responsible use</b>									
Selection	12. Availability of STG/EML at the point of practice. (Measured for per Health Facility; Aggregate)	X	X	X			– MOH Annual Report	Annual	– MOH
Supply	13. No of stock-out days (Measured per relevant tracer medicines per	X	X		NA <sup>17</sup>	Max days 10	– ICT infrastructure/ Stock cards at health facility level/ – Health Facility Monthly Pharmacy Reports	Measured Routinely: – Monthly: Health Facility level – Quarterly: National	– Health Facility level: Pharmaceutical staff – ICT/ M&E officers – Drug and Therapeutic

<sup>17</sup> Data available with limitations

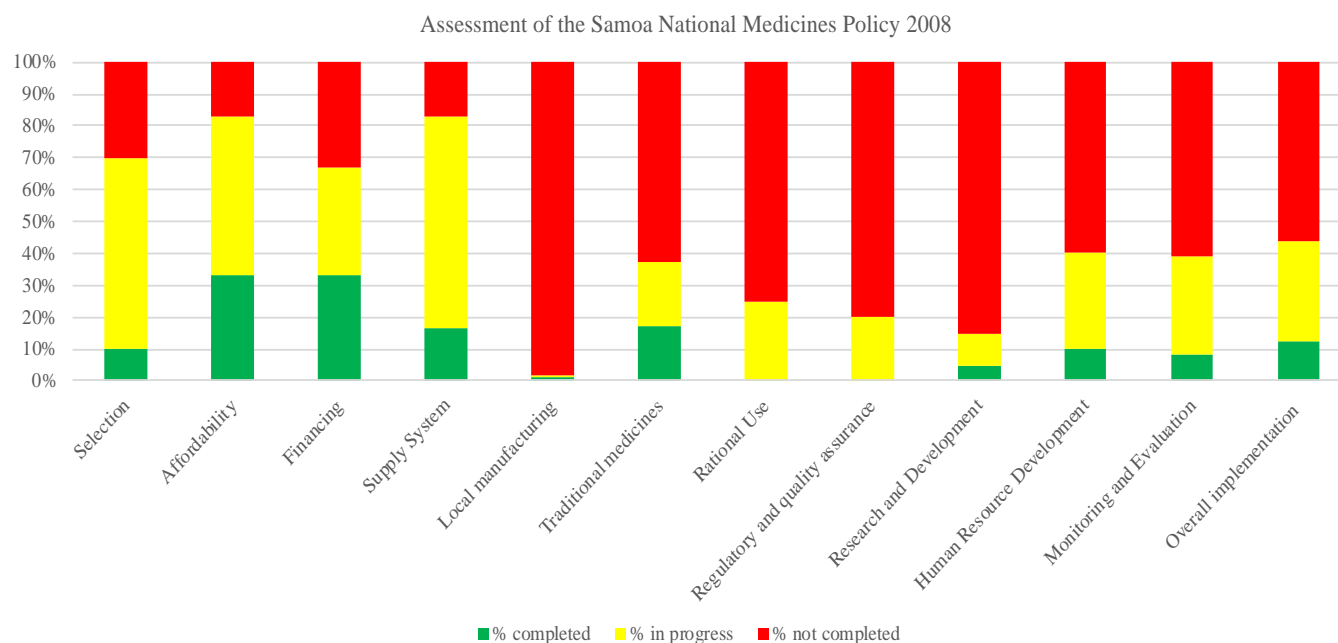
Level	Indicator (routine and non-routine)				Baseline <sup>15</sup> (2024)	Target (year)	Data Source	Frequency/ Reporting	Responsibility
	preceding 6-month period)							level	Committee Chair – ACEO Pharmacy
	14. Percentage of Expired medicines	X	X	X	NA	Max 10%	– Stock cards at health facility level/ – Health Facility Monthly Pharmacy Reports	– Quarterly	– Drug and Therapeutic Committee Chair – ACEO Pharmacy
	15. Percentage of Storage Facilities with adequate Storage Conditions	X	X	X	NA	100%	– Commissioned assessments	Quarterly	– ACEO Pharmaceutical Warehouse
Pharmaceutical information	16. Percentage Health facilities with Adequate record keeping (Health Facilities adherence to LMIS model)					Min 80%	- Health Facility Monthly Pharmacy Reports	Quarterly	- ACEO Pharmaceutical Warehouse
Responsible use	17. Number and Percentage Health facilities with Functional Drugs and Therapeutic committees	X			NA		Hospital DTC report	Monthly	– Hospital DTCs – Drug and Therapeutic Committee Chair

**Notes:**

1. There are several indicators which lack a baseline
2. Availability: Measured per relevant tracer medicines at primary, secondary and tertiary levels at specific reporting dates of the month, to obtain a cross-section
3. Number of multi-stakeholder pharmaceutical meetings held per year: Measured for Peer review / performance review, Information dissemination etc.
4. Public and community education: Number of public education campaign held in RUM in a year
5. Research: Number of publications on research conducted in the pharmaceutical sector in Samoa by authors including Samoa professionals
6. Affordability: Measured in treatment of conditions for adults and children under 5 years
7. Supply chain: Percentage of Storage Facilities with adequate Storage Conditions. Should be broken down into (normal storage and cold chain facilities)
8. Prices: Measured as Median Prices and Median Price Ratios. 90% targeted available products within 2x the IRP adjusted to Samoa
9. Functional DTCs: Measured for each facility; Also, the Number of DTC meetings held by each Hospital per year
10. Number if tests performed by the reliance system: Including drug registration and post-marketing surveillance, but excluding testing done in conjunction with procurement activities. Breakdown by those tested by governance quality control lab, local academic/research institution, quality control lap in another country, or private sector laboratory

## ANNEXES

### Appendix 1: Implementation Status of Samoa National Medicines Policy 2008



The table below summarizes the outcome of the SWOT Analysis of Samoa's Pharmaceutical Sector.

## Appendix 2: SWOT Analysis of the Pharmaceutical sector Situation in Samoa

Internal factors		
Positive	Strengths	Weaknesses
	<ul style="list-style-type: none"> <li>- Structures for regulation exist: MOH Quality Assurance division. The MOH mobilizes resources, budgets, sets policies, coordinates services, and monitors performance. The Quality Assurance is responsible for ensuring the quality, efficacy, and effectiveness of health commodities</li> <li>- ACEOs' for Pharmaceutical services and warehouse exists and these can be leveraged for implementation of Medicines policy and strategy,</li> <li>- STG (2012) and EML (latest 2022) exists</li> <li>- AMR Plan available and yet to be endorsed</li> <li>- Safe disposal of pharmaceutical waste including expired drugs handled by Waste Management Division</li> <li>- Scientific Research Organization for Samoa (SROS) provides leverage for research into plant medicines as well as laboratory support for testing of pharmaceuticals depending on effective collaboration</li> </ul>	<ul style="list-style-type: none"> <li>- Limited publications on the pharmaceutical sector</li> <li>- Challenges with reporting on the actions on pharmaceuticals.</li> <li>- Limited role for the local private sector in the supply chain</li> <li>- Limited integration of supply chain and reporting systems</li> <li>- PUSH supply system or a PUSH: dealing with shortages</li> <li>- Staff numbers and capacity challenges exist especially for supply chain functions</li> <li>- No Samoa university training pharmacists</li> <li>- DTC established; not very functional. Drug use indicators not being measured</li> <li>- Limited dissemination of and non-adherence to STG and EML</li> <li>- Essential devices list does not exist</li> <li>- Plan for Antimicrobial Resistance (AMR) exists. Prescribing of antimicrobials, a challenge even at tertiary facilities.</li> <li>- Limited emphasis on traditional medicines in the supply chain; despite their use at the community level</li> <li>- No standard guidelines for critical regulatory functions</li> <li>- Limited emphasis on quality of practice</li> <li>- Local manufacture of medicines is weak (SROS manufactures sanitizers (affects the access situation)</li> <li>- Governance systems for Regulatory Framework requires some level of reengineering</li> <li>- Pharmacy technicians require some capacity building and regulation.</li> <li>- No essential Health services package exists</li> </ul>
	Opportunities	Threats
	<ul style="list-style-type: none"> <li>- Constitutional provision for access to medicines for all; and a move to secure insurance first for staff then to all – 'A healthy Samoa Agenda'</li> </ul>	<ul style="list-style-type: none"> <li>- Challenging health and economic context - a constraint for Government led capital intensive investments in health systems and infrastructure.</li> <li>- Overseas Treatment Program</li> </ul>
		Negative

	<ul style="list-style-type: none"> <li>– Agenda being set for increase allocation to health</li> <li>– Sector wide emphasis on the need to assure product quality</li> <li>– MOH M&amp;E framework under construction</li> <li>– Active donor community, provides opportunities for partnerships and collaborations to strengthen the pharmaceutical sector. E.g., Donor driven monitoring programs are leveraged to do quarterly monitoring.</li> <li>– SROS collaboration</li> </ul>	<ul style="list-style-type: none"> <li>– shortages for procurement of medicines and health technologies</li> <li>– Limited resources for the current System to perform optimal regulatory functions. Pharmacovigilance (PV) and Post market Surveillance (PMS) not being done. Inspections are not done regularly.</li> <li>– Conditions of service in public sector not motivating for staff retention</li> <li>– significant lack of human resources capacity to support the implementation of components of NMP, including medicine regulation and procurement and supply of medicines</li> </ul>	
	<b>External factors</b>		

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