



*Government of Samoa*

## **SAMOA NATIONAL MEDICINES POLICY 2008**



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## INTRODUCTION

Medicines are an important part of protecting and maintaining the health of all Samoans. Medicines are required for prevention, management and control of illness, and most of all is to offer remedy in terms of treatment of illnesses.

When a medicine is required, its rational use demand 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.

The World Health Organization states that the formulation by governments of a National Medicines Policy is fundamental in ensuring rational medicines use.

This document has been developed 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 illness process.

Medicines may be over prescribed, or prescribed in ways that are not consistent with accepted management guidelines. Such inappropriate use of medicines can lead to shortages, even when a sufficient quantity has been made available by the government and will also have serious effects if the practice is not monitored and regulated properly.

Having a National Medicines Policy in place is an essential tool of ensuring that strategies and guidelines are in place for administering such aspects and protocols for safety.

The National Medicines Policy document has been developed collaboratively within the Ministry of Health, through various consultations with all the relevant Health Sector Stakeholders. This is to ensure that there is common understanding and feedback from those who are involved in administering the operational aspects of this policy. This policy is also a review of the existing policy so that it is line with existing government reforms and changes in the health sector.

Our National Medicines Policy Review 2008 is therefore a consensus document agreed to by all relevant stakeholders in the pharmaceutical sector. It covers a wide range of activities and includes medicines procurement, medicine storage, distribution and prescribing, cost recovery, legislation, quality assurance and herbal medicine.

With this philosophy in place we will be able to consistently address the many challenges which arise in relation to medicine therapy in general, and to ensure careful management of medicines at all levels.

## **A. NATIONAL MEDICINES POLICY VISION**

### **The overall vision of the National Medicines Policy is:**

*'To promote a commitment to a goal and a guide for action. It expresses and prioritizes the medium to long term goals set by government for the pharmaceutical sector and identifies the main strategies for attaining them. This National Medicines Policy provides a framework within which the activities of the pharmaceuticals sector can be coordinated. It covers both the public and private sectors and involves all the main actors in the pharmaceutical field, in particular Medical, Nursing, Pharmacists and Dentist'.*

## **B. GOALS AND OBJECTIVES**

The general objectives of this National Medicine Policy are

1. Access: Equitable availability and affordability of essential medicines
2. Quality: The quality, safety and efficacy of all medicines
3. Rational Use: The promotion of the therapeutically sound and cost effective use of medicines by health professionals and consumers.

## **C. KEY STRATEGIC AREAS**

1. Pharmaceutical Sector – Key Areas to Consider
2. Selection of Essential Medicines
3. Affordability
4. Medicine Financing
5. Supply Systems
6. Storage of Medicines
7. Distribution of Medicines
8. Control of Stock
9. Regulations and Quality Assurance
10. Rational Use
11. Research
12. Human Development
13. Monitoring and Evaluation
14. Alternative Therapy
15. National Medicines & Therapeutics Advisory Committee
16. Complementary & Alternative Therapy
17. Governing Legislations

## **D. POLICY LEGISLATIVE FRAMEWORK**

The Ministry of Health, through its mandated Monitoring and Regulatory role stipulated in the MOH Act 2006 shall ensure compliance and conformity with all the laws related to medicine handling and use in Samoa.

The Professional Bodies who have a direct role to play in administering this policy have a commitment in ensuring that professional standards and codes of practice are adhered to.

The functioning of the current pharmaceutical legislations, Narcotics Act 1967 with amendments 2008, Food and Drugs Act 1967, Poisons Act 1968 with amendments in 2006 and its compatibility with Professional Acts and other legislations affecting implementation of the National Medicine's Policy under the responsibility of other Government ministries and departments, shall be closely monitored and adhered to unless otherwise amended. (Refer to Appendix 1 for List of Governing Legislations)

## **The Pharmaceutical Sector**

The Pharmaceutical Sector shall be supported in the facilitation and implementation of this policy and possible expansion of the sector to enable it to effectively undertake its functions. These functions will not be limited to but will include provision of:

- Essential Medicine Program Management
- Narcotic Drugs Administration and Reporting
- Narcotics Licensing and Registration
- Medicine Registration
- Poison Licensing
- Medicine Inspectorate Services
- Pharmaceutical Personnel Training
- Training of Health Professionals on Rational use of Medications and Narcotics
- Medicine Information Services
- Adverse Medicine Reaction Monitoring
- Poisons Information Service
- Clinical Pharmacy Services
- Therapeutic Medicine Monitoring Service

### ***Key Strategic Area 1: Selection of Essential Medicines***

*The selection of medicinal products for the public and private sector must be in accordance with the essential medicines concept as defined by the World Health Organization. Essential medicines are those, which are of the utmost importance, and necessary to satisfy the health needs of the majority of the population.*

- 1.1 Selection of essential medicines will be made by the National Medicines & Therapeutic Committee. This committee shall be made up of experts in all the medical and pharmaceutical fields from the private and public sector, necessary to enable informed decisions to be taken. As and when necessary, additional members may be co-opted and consultations may be undertaken with interested parties including representatives of professional bodies and any other relevant organizations. However, selection should reflect broad policy objectives and the process of selection by the committee should be carried out independently.
- 1.2 The National Medicine Committee will meet at least once every six months and extra ordinary meetings shall be called on matters requiring urgent attention and decisions in line with relevant legislations.

- 1.3 Selection of medicines is based on a number of criteria but not limited to the following:
- Pattern of disease prevalence
  - Safety and efficacy based on evaluations obtained in controlled clinical trials and/or epidemiological studies
  - Adherence to recognized and adequate quality control standards including stability and where necessary, bioavailability
  - Cost taking into account the following elements; the cost of the treatment rather than that of the dosage form, the cost of treatment in relation to savings made: For example, reduction in the need for surgery or hospitalization, different rates of treatment success achieved as a result of improved patient compliance; reduced loss or waste through the use of more stable products.
  - Therapeutic advantage and Disadvantages
- 1.4 Where several medicines are available for a given indication, or two or more drugs are therapeutically equivalent, the product with the most favorable benefit/risk ratio will be selected. Preference will be given to;
- The medicines which have been most thoroughly investigated
  - The medicines with the most favorable pharmacokinetic properties e.g. Those which improve compliance or minimize risk in various disease states
  - The medicines and dosage form with the greatest stability or for which suitable storage facilities exist.
- 1.5 Fixed ratio combinations will only be selected if one or more of the following criteria are met:
- The clinical condition requires the use of more than one medicine
  - The therapeutic effect of the combination is greater than the sum of the effects of each medicine
  - The cost of the combination is less than the total cost of the individual products
  - Sufficient combinations are provided to allow for dosage adjustment to meet the needs of the majority of the population
  - Compliance is improved
- 1.6 New medicines will only be introduced if they offer distinct advantages over existing medicines. If information on existing medicines shows they no longer have a favorable benefit/risk ratio, they will be deleted and replaced with safer alternatives.
- 1.7 Selection of medicines is by generic name or International Non-proprietary Name (INN) only.

- 1.8 EML containing all the medicines selected for use in the public sector will be produced and distributed to relevant organizations and institutions, District Hospitals and MTII
- 1.9 Suggestions for amendments to the EML should be made in writing to the National Medicine Committee, through the secretary of the committee. Full justification for each suggested amendment must be provided.
- 1.10 Non-standard items (not appearing in the EML) may be requested for specific patients in exceptional circumstances by the consultant physician completing a standard form used for this purpose, which is then sent for consideration by the Hospital Medicine Committee. If there is a funding implication the request is then referred by the Hospital Medicine Committee to the National Medicine Committee for consideration against completing claims for funding.

### ***Key Strategic Area 2- Affordability***

*Affordability is an essential component and Strategy of this policy to ensure that sufficient funding is made available to provide adequate quantities of quality essential medicines at the lowest possible cost. Affordable prices are an important prerequisite for ensuring access to essential medicines in the public and private sectors*

- 2.1 Mark up of medicine prices in the private sector should be done in a way that is not too restrictive for the general public to access in terms of affordability.
- 2.2 Within the total health budget, suitable provision will be made for the implementation of the national medicine policy strategies.
- 2.3 Because of the emphasis on primary health care and the control of endemic diseases, priority consideration will be given to the provision of medicines for these activities.
- 2.4 Cost recovery will be introduced to fund certain activities of the pharmaceutical services administration e.g. Registration of medicines, inspection of premises.
- 2.5 Government commitments shall include looking at reduction of medicine taxes, continuation of the duty free on the importation of medicines and distribution margins through pricing policies so that general and essential medications are affordable and not too restrictive.

### ***Key Strategic Area 3: Financing***

*Drug financing is a vital component for this policy to improve access to essential medicines. There is a need to ensure sustainable financing throughout for procurement of essential drugs.*

- 3.1 There shall be commitment to measures to improve efficiency and reduction of waste. Various measures can be taken to increase value for money and to contain

- costs at each stage. Proof that the resources made available are used wisely and efficiently is a strong argument to justify requests for increased funding.
- 3.2 Government's commitment to ensure adequate financing for essential medicine supply
  - 3.3 Development Aids from various organizations such as but not limited to WHO, shall be inclusive of both the public and private sector financing developments.
  - 3.4 Developing Aids from organizations such as but not limited to WHO shall also be used for implementing this National Medicine Policy or aspects of this National Medicine Policy or to pay for high priority commodities such as vaccines or essential medicines for the neediest groups or for treating diseases with a large public health impact.

### ***Key Strategic Area 4 - Procurement Systems***

*Procurement system is an essential component of this National Medicines Policy for increased access to essential medicines. It is also important to ensure that there is available stock for use in case of an emergency or disaster thus the need to efficient and effective supply systems in place*

#### ***For the public sector***

- 4.1 An Effective and Efficient Medicines Supply System in the Public Sector must be in place for the procurement of Medicines.
- 4.2 Medicines are procured by generic name (INN).
- 4.3 Medicines are procured according to the EML.
- 4.4 Donated medicines must comply with all the following criteria
  - registered for use in Samoa
  - included in the EDL
  - within the expiry date
  - labeled in English
  - follow WHO guidelines for donated medicines
- 4.5 Procurement will also be directed towards manufacturers in preference to wholesalers, distributors and trading houses.
- 4.6 However, notwithstanding these preferences in order to make the best possible use of available funds, procurement will continue to be aimed at securing the lowest available price for a product of acceptable quality.
- 4.7 Procurement of all medicines including essential medicines shall comply but not limited to the following criteria's set out by WHO, UNICEF, UNFPA and World Bank.
  - Procure the most cost effective medicines in the right quantities



- Pre-qualify reliable suppliers of high quality products
- Ensure timely delivery
- Achieve the lowest best possible total cost.

***For both the public and private sector***

4.8 Procurement of medicines, including donations, will be limited to items registered for use in Samoa, unless otherwise approved by the Director General of Health. (CEO of Ministry of Health)

***Key Strategic Area 5- Storage of Medicines***

*Storage of Medicines is an important component of this policy to maintain quality of products before it reaches the end users.*

- 5.1 The National Health Service, being the largest provider of pharmaceuticals in the sector will ensure that there is a provision and regular maintenance of adequately sized, suitably constructed and equipped storage facilities at every level in the public sector medicine distribution system. Where necessary, new stores will be constructed or existing stores modernized or refurbished in order to ensure that medicines are stored in a systematic, secure and safe way so that losses due to deterioration, expiry or theft are minimized as much as possible. When appropriate, storage facilities will include air conditioning and/or properly maintained refrigerator to protect heat sensitive products during the period of their storage. The Ministry of Health in collaboration with the Pharmaceutical sector shall regularly do spot checks on the quality of stored medicines at all levels to ensure that they have not deteriorated under the storage conditions prevailing at each location.
- 5.2 The professional skills of pharmacists, pharmacy assistants and store managers are vital to the efficient and successful operation of a medicine storage and distribution system. The government will therefore ensure that adequate numbers of suitably trained pharmaceutical and stores management personnel are recruited to run and maintain public and if possible the inclusion of the private sector facilities.
- 5.3 Regular checks on private sector medicine storage facilities and conditions, in order to ascertain their adequacy and suitability, will be performed by medicine inspection personnel authorized under the Pharmacy Act 2007, Poisons Act 1968 and the Ministry of Health Act 2006.
- 5.4 In order to encourage the correct maintenance and organization of medicine stores throughout the country the Ministry of Health in collaboration with the Pharmaceutical sector must ensure that a stores procedures manual containing practical guidelines on the required procedures for all medicine storekeepers be developed.

***Key Strategic Area 6- Licensing and Distribution of Medicines***

*Efficient and Effective Distribution systems are important to ensure the prompt and safe distribution of medicines to end-users, so that the quality of the products is maintained throughout the process.*

- 6.1 Only medicines registered in Samoa, or internationally recognized by authorities such as TGA and FDA shall be distributed in the country. Any outstanding or new medicines to be brought into the country must be in accordance with the Food and Drugs Act 1967.
- 6.2 Medicines will be distributed through the Government Pharmacy for the public health sector or another system approved for by government in the future if deemed necessary.
- 6.2 Those who prefer to use the private pharmacy system have the option of buying from the private sector.
- 6.3 The Government will endeavor through the Ministry of Health and the National Health Service to maximize coordination between the different sectors in the transportation and distribution of essential medicines, particularly to less accessible areas of the country.
- 6.4 The National Health Service will ensure the provision of adequate and appropriate transportation, maintenance and communication facilities and the personnel necessary to maintain the efficient operation of the public sector distribution system.
- 6.5 The Ministry of Health will ensure that the decentralization for the public sector distribution system for medicines is rationally and efficiently implemented.
- 6.6 The National Health Service, in coordination with relevant pharmaceutical partners will institute an efficient and practical clearing house system for the identification, collection and redistribution of excess stocks of medicines and medical supplies.
- 6.7 Importers and users of restricted medicines should comply with provisions and regulations as stipulated under the Narcotics Act 1967 and Amendments to the said Act in relation to precursor chemicals.

### ***Key Strategic Area 7- Control of Stock***

*Control of Stock is an important component of this policy to ensure that occurrences of shortages are avoided and that a continued availability of sufficient quantities of required essential medicines at all levels of the health system through accurate and systematic recording, monitoring and reporting of stock levels of all items.*

### ***For the Public Sector***

- 7.1 The National Health Service in collaboration with relevant stakeholders will strive to improve and standardize inventory control procedures at all levels of the public medicine supply system. Minimum and maximum stock levels will be introduced, systematic stock rotation ensure, dead stocks and expired stocks will be identified and either disposed of or, in the case of non-expired unseable items, redistributed.
- 7.2 Regular stock taking must be done to support and facilitate effective and efficient procurement procedures.

### ***For the Private Sector***

- 7.3 The Private Sector is also encouraged to do regular stock taking in case an emergency or disaster strikes the country and warrants the need to mobilize supplies.

## ***Key Strategic Area 8- Rational Use of Medicines***

*Rational Use of Medicines is an essential component of this policy to ensure that medicines are prescribed, dispensed, and used rationally in order to maximize the therapeutic benefit to the patient and reduce loss, wastage and hazards arising from irrational practices, including theft and misappropriation.*

### ***8.1 Training***

Trainings must be in place for all personnel involved at different levels of the process of diagnosis, prescribing, dispensing and adherence

- 8.1.1 Suitable training materials on rational medicine use will be developed in consultation with health workers and distributed at all levels for use both in initial and continuing education activities.
- 8.1.2 It is the responsibility of the Ministry of Health to ensure that trainings or required competencies are in place for personnel involved in operationalising this National Medicines Policy given their role as the Regulatory and Monitoring Authority for the Health Sector as stipulated under the Ministry of Health Act 2006.

### ***8.2 Medicine Information***

Medicine information is crucial to update knowledge on the most practical, unbiased information on the correct handling and rational use of medicines to health workers at all levels as well as community leaders, women's committees, retailers, patients and the general public.

- 8.2.1 Where appropriate, the Ministry of Health will organize training programs, symposia, workshops, and lectures in order to aid the dissemination and understanding of medicine information for the various groups of health personnel including end users and the community at large through media and any other appropriate form of communication.

8.2.2 The Medicines and Therapeutics Committee in collaboration with the Ministry of Health must ensure that recent and current information regarding rational use of medicines is made available to all personnel that are involved in the administering of this National Medicine Policy.

8.2.3 A Medicine Bulletin shall be produced and distributed at monthly intervals in order to provide a forum for dissemination and discussion of all matters related to provision of pharmaceutical services and rational medicine use in the country. Funding of the bulletin will support distribution to all levels of health services in Samoa.

8.2.4 The Ministry of Health will endeavor to continuously collect accurate and useful information and data on medicines and medicine utilization, which will be evaluated and disseminated to health professionals.

### **8.3 PRESCRIBING**

Prescribing is an important aspect of rational medicine use to ensure that the right and most efficient medication is given to patients and must be done in a controlled manner and shall not in any way be the responsibility of end- users to request the type of medication they need. This is also solely to ensure that

8.3.1 In the public sector, all medicines will be prescribed by generic name (INN) and inclusive of the brand if and when necessary. In the private sector medicines will also be prescribed by generic name, however a required brand name of the medicine may be included in brackets after the generic name.

8.3.2 The Ministry of Health will strive to constantly monitor and assess prescribing practices in the country in order to ensure appropriate, efficient, and cost effective prescribing.

### **8.4 DISPENSING**

Dispensing is an important component of Rational Medicine Use to ensure that medicines are dispensed efficiently and correctly according to essential medicines concepts and recommended dispensing practices.

8.4.1 In the public and private sector all medicines (including combination products) will be dispensed and labeled using generic names. Both the Public and Private Sector are expected (a must) to have the following on all dispensed medication before it reaches the patients. It must also be noted that adhering to these criteria's will also ensure proper and easy monitoring of usage and spacing of medications given to patients. The criteria's are as follow:

- ❖ *The generic name of the medicine*
- ❖ *The strength of the active ingredient*
- ❖ *The complete dose regime in written and/or graphic form*
- ❖ *the patient's name*
- ❖ *the date of dispensing*
- ❖ *the quantity of medicine dispensed*

8.4.2 In the private sector medicines may only be dispensed by holders of a valid dispensing license. All medicines will be dispensed and labeled using generic names, but the trade name of a medicine product may appear on the dispensing label after the generic name.

8.4.3 Authorized inspectors appointed under the Pharmacy and Poisons Act will make regular inspections of premises where dispensing operations are performed to ensure that the provisions of the Act in relation to the granting and renewal of dispensing licenses are being satisfied in all respects.

8.4.4 In the private sector and public sector, a specified brand of a prescribed medicine is not available, and the prescriber cannot be readily contacted, a pharmacist may substitute an equivalent generic form or an alternative brand of the medicine. The pharmacist should inform the prescriber at the earliest opportunity when such a substitution has been made. The patient must be advised of the substitution has been made. The patient must be advised of the substitution at the time of dispensing.

8.4.5 All medicines labeled as Prescription Only Medications can only be dispensed upon receipt of a medical prescription from a Registered Medical Practitioner.

## ***8.5 PATIENT COMPLIANCE AND SELF MEDICATION***

Patient compliance is an important component of rational medicine use to ensure that compliance with prescribed treatments is maximized through the implementation of rational prescribing and dispensing practices by health professionals and the provision of adequate information on rational medicine use to patients and the general public.

8.5.1 The Ministry of Health will promote research on the social and cultural factors, which affect the use of medicines and will endeavor through health education and provision of relevant medicine information to assist in behavioral changes such as attitudes and beliefs, which are found to contribute to irrational medicine use of non-use.

8.5.2 The Pharmaceutical sector shall endeavor to ensure that adequate counseling on the use of prescribed medicines is given as part of the prescribing and dispensing process. Training curricular and continuing education programs for all health professionals should be continuously revised where necessary to include a component on patient counseling or information awareness for patients and all end-users.

8.5.3 Health education for the public on subjects including disease prevention, limited self-diagnosis on what constitutes appropriate and inappropriate self-medication, and on suitable alternative non medicine treatments will be promoted through the use of all available forms of mass communication media. This education should be commenced in schools as part of the family health curriculum with the proviso that information on medicines be given only by people who are suitably trained for the task.

## **8.6 DISPOSING OF UNWANTED ITEMS**

*It is important to ensure that all unwanted medicines and associated health care waste are disposed of promptly, efficiently and correctly.*

8.6.1 The disposal (in the case of expired stocks) or redistribution (in the case of expired re-usable items) of expired or otherwise unwanted items or medicine. Medicine inspectors authorized under the Pharmacy and Poisons Act will carry out regular and unannounced visits to all pharmaceutical establishments in order to ensure that suitable methods of disposal and unwanted or waste pharmaceutical, medical and surgical items are in operation.

8.6.2 The Ministry of Health shall promote education of patients in the correct and safe disposal of unwanted medicines.

## **Key Strategic Area 9- Quality Assurance**

*The aim of the policy is to ensure that medicines reaching the patient are safe effective and meet approved specifications and standards. The quality assurance system will include managerial, technical and legal aspects.*

- 9.1 It is the mandated responsibility of the Ministry of Health to ensure that quality assurance procurement measures are in place for the Pharmaceutical Services in the health sector. Such systems and processes must be transparent and done in collaboration with all those who are involved in the administering of this National Medicines Policy.
- 9.2 Only medicines registered in Samoa will be permitted to be procured and distributed in the country. Any new medicines to be introduced in the country must be in line with the Food and Medicines Act 1967 and other overarching legislations. The Ministry of Health will endeavor to work closely with Ministry of Revenue and other necessary Ministries ensure quality control and quality assurance of medications that are brought into the country.
- 9.3 Upon receipt of Medicine supplies, relevant documentation, including certificates of analysis, will be carefully checked to ensure that the quality of the medicine is of the required standard and in line with BP WHO Guidelines.
- 9.4 The Private and Public sector are encouraged to look into the possibility of setting up a mini laboratory that can assist both entities in regular testing of quality of medicines.
- 9.5 The Ministry of Health will institute a system for withdrawal of medicine products from circulation, which have been shown by testing or demonstrated otherwise to be of unacceptable quality and as stipulated under the Food and Medicines Act 1967.

- 9.6 Due to questionable efficacy and the potential for harm the use of expired medicines will not be permitted unless authorized by the pharmaceutical services and experts.
- 9.8 All new medicines introduced into the country must satisfy all the requirements stipulated in the Food and Drugs Act 1967.

### ***Key Strategic Area 10: Controlled Advertising and Promotion***

*Advertising and promotion of medicines must ensure a degree of high professional standard and conform to the requirements of the Pharmacy Act 2007, Poisons Act 2006 and Food and Drugs Act 1967.*

- 10.1 Ethical criteria for medicine promotion and advertising will be established and published for distribution to all interested parties.
- 10.2 The Ministry of Health in its regulatory and monitoring mandated function under the MOH Act 2006 will carefully monitor medicine advertising and promotional activities to ensure that they conform to the relevant ethical criteria and existing governing legislations.
- 10.3 In general, labeling and advertising for medicines must be based on scientifically established evidence. Advertising must also be objective, educational in purpose and in the case of public advertising, restricted to over the counter medicines.
- 10.4 Children shall not be use as a mean of advertising medicine.
- 10.5 Medicine promotional activities will be in line with the national medicine policy objectives. In the respect, whenever the brand name of a medicine is used in any form of promotional or educational material, including radio advertising, the generic name of the medicine must be given due prominence. In the case of printed materials such as advertisements, billboards, posters, etc. the generic name must be at least one third the size and positioned adjacent to the brand name.
- 10.6 Promotion and advertising of pharmacy-only and prescription-only medicines will be restricted to professional medical, pharmaceutical, dental, veterinary or nursing publication.

### ***Key Strategic Area 11- Development & Research***

*It is an essential element of this National Medicine Policy to support research and development activities, which will facilitate further developments and strengthen the work of the pharmaceutical services in the country. In all “Operational Research facilitates the implementation, monitoring and evaluation of different aspects of medicine policy. It is an essential tool in assessing the medicine policy’s impact on national health service systems and delivery, in studying the economics of medicine supply, in identifying problems related to prescribing and dispensing and in understanding the socio-cultural aspects of medicine use”. WHO Report*

- 11.1 Medicine research will be aimed at developing new essential medicines or formulations, improving existing ones, and achieving more rational use of medicines.
- 11.2 Medicine research and development may be carried out by a variety of institutions, including research sections of ministries, government research facilities, universities and other higher educational institutions. The Regional and Local universities should be prioritized in this respect.
- 11.3 Medicine research is a multidisciplinary activity involving medicine, pharmacy, pharmacology and medicinal chemistry. The Government will encourage the development of research in these disciplines, and the training of research personnel in the relevant areas of interest. Training in Herbal medicines and the science of photochemical should not be overlooked as Samoa is abundant in natural flora.
- 11.5 The Ministry of Health through the Health Research Committee will support important areas of health research which have a bearing on National Medicine Policy.

***These include:***

- ❖ Health systems research to measure the impact of the National Medicine Policy and its main components
  - ❖ Behavioral research on prescribing and dispensing problems at different levels of the health system
  - ❖ Research into the economics of medicine supply and utilization
  - ❖ Research into the social and cultural aspects of medicine use, self medication, acceptability and utilization of medicine supply systems, and attitudes of medicine consumers.
  - ❖ Herbal Medicines and Samoan Traditional Healers.
- 11.6 The Ministry of Health will make use of the research findings in making any necessary adjustments in its strategies to ensure achievement of the objectives of the National Medicine Policy in close collaboration with the necessary health sector stakeholders. .
  - 11.7 As herbal and other traditional remedies are extensively used in Samoa and are widely regarded as efficacious, the government shall encourage and support research into these remedies with a view of identifying the most useful remedies for treatment of common endemic diseases, determination of the composition of these, their formulation into standardized products of reliable quality, and rationalization of their use. Such research shall be undertaken in association with



- the University of the South Pacific and any other appropriate University in the Region with information to share.
- 11.8 As problems of medicine supply and utilization affect many countries, the Government will promote the exchange of research findings with other countries and with international agencies such as the WHO and will encourage and support the participation of local drug researchers and research institutions in international medicine research activities.
- 11.9 Transparency/Increase for Mass Drug Campaign (e.g Filariasis and EPI).
- 11.10 National medicine Therapeutic Committee (NDTC) to approve/advice MOH on the approval of any medicines use in mass campaign.

### ***Key Strategic Area 12: Human Resource Base***

*Human Resource is an essential component of this National Medicines Policy to ensure that an appropriate number of adequately trained personnel are available to meet the needs of the National Medicine Policy.*

- 12.1 A strategic workforce plan (Human Resource for Health Policy and Plan of Action) shall be developed by the Ministry of Health in collaboration with relevant health sector partners to take into account this place
- 12.2 The Private and Public entities are to ensure that career paths structures are in place for all personnel that come under their jurisdiction so that opportunities are identified for ways forward
- 12.3 The Ministry of Health will strive to improve the career prospects of all pharmaceutical personnel in the public and private sector and will encourage and support opportunities for the undertaking of upgrading and refresher courses for personnel in the private and public sector.

### ***Key Strategic Area 13: Monitoring and Evaluation***

*Monitoring and Evaluations is an essential component of this policy to ensure the successful implementation of the National Medicines Policy in all its aspects by the establishment of mechanisms for monitoring and evaluating performance under the policy.*

- 13.1 The Ministry of Health will establish and maintain a monitoring and evaluation capability with the function of following the implementation of the National Medicine Policy and Plan of Action and defining indicators for measurement of progress towards achieving policy objectives.
- 13.2 As the Essential Medicine Program is the cornerstone for implementation of much of the medicine policy, this program will be regularly evaluated to determine progress towards achievement of its stated objectives.

- 13.3 Performance of medicines registered for use in the country will be monitored for efficacy, safety and quality, as new information may come to light during widespread use which was not available at registration, and which may require changes in the conditions of medicine registration or even withdrawal of a medicine from the market.
- 13.4 As no medicine is entirely free of adverse reactions, and since these may vary between different countries and under different conditions of an adverse Medicine Reaction Monitoring system, including suitable Adverse Medicine Reporting procedures will be established and maintained by the Ministry of Health. In establishing such a service the experience of other countries will be carefully considered. A committee of experts will also be set up to regularly review reported adverse reactions and advise the government on what action to take. The government will cooperate with other agencies such as the WHO in the compilation and exchange of information on adverse medicine reactions.
- 13.5 Monitoring of rational medicine use will be carried out and recorded, by a variety of methods including prescribing, dispensing and patient compliance surveys, and the comparison of epidemiological data with data on medicine consumption and utilization.

### ***Key Strategic Area 14: Technical Cooperation***

*It is important that Technical Cooperation is sought in terms of funding of various Key Strategic Areas Identified in this National Medicines Policy.*

- 15.1 Technical cooperation will be encouraged and supported in various areas including the following:
- ❖ Evaluation of medicines
  - ❖ Application of the WHO Certification Scheme
  - ❖ Regional procurement schemes and exchange of information on pharmaceutical suppliers
  - ❖ Quality assurance and collaboration with regional and other quality control laboratories
  - ❖ Computerization of inventory control and medicine registration
  - ❖ Transfer of appropriate technology
  - ❖ Research and development
  - ❖ Training and staff development
  - ❖ Studies on medicine utilization
  - ❖ Exchange of medicine information
  - ❖ Emergency situations e.g. epidemics, disasters
  - ❖ Misuse of medicines
  - ❖ Short term work attachments and/or familiarization program with overseas countries.

## ***Key Strategic Area 15: National Medicines and Therapeutics Advisory Committee***

*The National Medicines and Therapeutics Goods Advisory Committee is an important aspect of this National Medicines Policy to ensure correct, efficient, and cost-effective handling and use of Medicines within the country.*

15.1 The National Medicines and Therapeutics Committee shall be made up of representative of those in the private and public sector. Membership should also include those who have direct affiliation with administering of medicines. Community representation is strongly encouraged so that a view of the community is present in future and existing developments with regards to the works of the Pharmaceutical sector.

15.2 The Committee's responsibilities should include the following core functions. Functions of the Committee shall be reviewed if major changes occur in the health sector and in particular the pharmaceutical sector.

- ❖ *Review the essential Medicines List if and when necessary*
- ❖ *Collective Collaboration on issues pertaining to Financing of the Pharmaceutical Sector.*
- ❖ *Monitoring of the use of standard treatment guidelines and overall medicine utilization and make appropriate recommendations to the Ministry of Health on ways forward.*
- ❖ *Provision of relevant and up to date medicine utilization information for prescribers, dispensers, nurses, institutions and to the community at large if and when necessary.*
- ❖ *Maintenance of adequate medicine storage conditions and inventory control procedures*
- ❖ *Ensure appropriate measures for the prompt, safe and efficient disposal of expired medicines and other items of medical waste in line with the Health Care Waste Policy.*
- ❖ *Implementation of dangerous medicines control regulations*
- ❖ *Any other matters relating to the rational use of medicines and overall management of issues in the pharmaceutical sector.*
- ❖ *Assist the Ministry of Health to ensure full implementation of this National Medicines Policy and Plan of Action.*
- ❖ *Make recommendations to boards, councils and Ministry of Health on how the further develop aspects of this National Medicines Policy.*
- ❖ *Assist the Ministry of Health in ensuring that the Policy Plan of Action is implemented.*

15.3 It is the mandated responsibility of the Ministry of Health to ensure that this committee is in operation to ensure efficient and effective quality assurance in the health sector, in particular the pharmaceutical sector.

15.4 An allowance for this committee shall be established taking into account the roles and responsibilities stipulated in this Policy document. It is the responsibility of the Ministry of Health to ensure that this is seen through.

### ***Key Strategic Area 16: Complementary & Alternative Therapy***

*Complementary & Alternative Therapy is an essential component of this National Drugs Policy to ensure collaboration between Western Medications and those in the field of alternative medications.*

16.1 This policy encourages the need to work collaboratively with those in Complementary & Alternative Therapy to ensure there is safety and quality in the services delivered to the population.

16.2 It is the responsibility of the Ministry of Health through the Health Services Performance and Quality Assurance; Medical and Allied Health Division & Nursing and Midwifery Division.

### ***Key Strategic Area 17: Governing Legislations***

*This policy goes hand in hand with existing governing legislations which will be reviewed if and when the need arises to reflect changes occurring in the health sector and the pharmaceutical services.*

17.1 The following existing legislations provides an overarching legal framework for this crucial policy document.

1. **Food and Drugs Act 1967** – “The Food and Drugs Act sets out matters relating to the sale food and drugs. Drugs are broadly defines and includes soap, disinfectant, cosmetic and chemical contraceptives and in certain cases, this Act applies to tobacco to the terms sale and adulteration.

Certain offences are created such as adulteration of food or drugs without fully informing the purchasers of such adulteration, or where such food or drug contains an illegal substance or does not comply with standards or contains a greater proportion of any substance that is legally permitted. It is also an offence to sell food or drugs with a misleading label or statement or to sell them with more than 3% alcohol or where they are unsound or unfit for consumption.

The Act also stipulates conditions relating to the introduction of the new drugs. In relation to drugs there are special duties which relate to the manufacturer or importer of drugs. Importers and Manufacturers are required to inform the CEO of any proposed importation into or manufacture in Samoa new drugs. They are also required to notify the CEO of any material change to a drug and also to inform the CEO where they have reason to believe that a drug has a **substantial outward effect**.

2. **Narcotics Act 1967** – “The Narcotics Act regulates the issuing of narcotics which are listed in the schedule of the act. The CEO and the Ministry of Health under the control of the Minister of Health is responsible for administering the Act. The

Act covers matter relating to the use, importation and exportation of narcotics. It provides for a power of the CEO to supply medicinal opium to registered persons as well as the power to authorize certain narcotics to be carried on a ship or plane for medical reasons. Special provisions relate to the licensing of persons to deal in narcotics. Dealing in importing and or exporting or narcotics is illegal without a license from the Minister of Health. The Act also addresses the issue of search warrants and powers of authorized persons to inspect books and stocks of narcotics” *Samoa Health Legislation Handbook, 2008*

- 3. Ministry of Health Act 2006** – “The Ministry of Health Act provides the basic structure for the administration of the Ministry of Health. The appointment functions and powers of the CEO of Health is also set out. IT makes provision also for the appointing and working arrangements of the Ministry personnel. It allows for certain advisory bodies to be established by the Minister and makes provision for remuneration of advisory bodies”. *Samoa Health Legislation Handbook, 2008*

The Act also established the Ministry of Health as the Monitoring & Regulatory Ministry for the whole Health Sector.

- 4. National Health Services Act 2006** – “The Act provided for certain Ministerial and CEO directions to be made. Certain reports are required to be kept. Advisory bodies may be established by the Minister , the Act sets out how these advisory bodies are to be remunerated and also sets out the status and authority of advisory bodies. Operational arrangements with the Ministry of Health are also set out in the Act as well as matters relating to the transfer of personnel, resources and assets of the Ministry of Health” *Samoa Health Legislation Handbook, 2008*

- 5. Poisons Act 1968-** “The poisons Act regulate the importation, sale and custody of poisons. Poison is defined to be any substance declared by a regulation to be a poison. The Act allows for certain advisory committees to be appointed by the Minister. A person cannot import, sell, pack or label poison for sale unless they are holders of a requisite license or is authorized to do so under the Act, these include chemists, doctors, dentists, veterinary surgeons and Government employees whose duties involve the importation of poison.

***Applications for license to import, pack or retail poison should be made to the CEO of MOH.*** Poisons are also not to be stored in a place where children or unauthorized persons can have ready access to them. The ACT requires that the CEO be informed of any intention to import or manufacture toxic substances. Where poisons are to be imported, they are required to be securely packed. A pilot or a master of a ship must inform Customs and inspections officers that they are carrying poison when they arrive. **Doctors in charge** of a hospital are required to inform the CEO if a person is suffering from poisoning. The Act also provides for special provisions relating to the Control of Advertisements and certain powers relating to contaminated premises”. *Samoa Health Legislation Handbook, 2008*

## *Acknowledgement*

It is with greatest gratitude that we would like to thank all those who contributed immensely in the development of this crucial Policy Document. Your endless support and valuable feedback have enabled this Policy process to come this far.

May we continue to work in sincere and genuine partnership to ensure that the best we can do is given to our people to attain quality and healthy lives.



**Stakeholders at the last Consultation of the Policy Document at the Development Bank of Samoa Conference Room.**

### *Stakeholders.*

1. National Health Services ( Pharmacy Division in particular Tavita Reupena and Lepaitai Hansell for always making their time available for clarifications and technical assistance)
2. Ministry of Finance
3. Ministry of Commerce, Industry & Labour
4. Office of the Attorney General
5. National Council of Churches
6. Ministry of Women Community and Social Development
7. Statistics Bureau
8. Ministry of Revenue (Customs)
9. The Donor Community (World Bank, Aus AID, NZAid, JICA)
10. The Med-Cen Hospital
11. Samoa Nurses Association
12. General Practitioners Association
13. METI Sleep Apnoea
14. Apia Pharmacy
15. Samoa Pharmacy
16. Multipharm Laboratory Ltd
17. Niu Pharmacy
18. Ministry of Police, Prisons and Fire
19. Marias Healthcare
20. National Kidney Foundation
21. Tavana- Nurses on Wheels

22. Samoa Family Health Association
23. National University of Samoa
24. Oceania University of Medicine Samoa
25. Roseberg Clinic
26. Natural Health Care Products
27. Red Cross
28. SUNGO

Last but not the least, the **World Health Organization** through the Pharmacy Project (4<sup>th</sup> Phase) have assisted immensely in financing the Policy Development process for this document and also other Pharmacy Developments in the Health Sector over the years. May we continue to work collaboratively in ensuring health and well being is attained for everyone.

May the Lord bless everyone and their work in abundance.

## NATIONAL DRUGS POLICY PLAN OF ACTION 2008-2014

### *Key Strategic Area 1: Selection of Essential Medicines*

Activity Number	Activities	Indicators	Responsibility	Funding Sources	Training Required	Timeline
1.1	Ensure availability of essential drugs at all times in adequate amounts and appropriate dosage form	<ul style="list-style-type: none"> <li>• Availability of Stocks</li> <li>• No Complaints</li> </ul>	NHS, Med-Cen, Private Pharmacies	Government, Private Finding, Donors		Ongoing
1.2	Develop criteria's and mechanisms for the selection, promotion and maintenance of Samoa's essential medicines list (EML)	<ul style="list-style-type: none"> <li>• Criteria's and mechanisms developed</li> </ul>	MOH, NDTC, All Partners, Consultant	Government, Private Finding, Donors		Within the Timeframe of the POA
1.3	Ensure constant and uninterrupted availability of items on the EML in all public health facilities	<ul style="list-style-type: none"> <li>• Suitable stock level maintained at central medical stores in all health public facilities.</li> </ul>	NHS	Government, Donors		Ongoing
1.4	Categorise and distribute items in SEML according to level of prescription and distribution	<ul style="list-style-type: none"> <li>• Items in SEDL categorised and distributed</li> </ul>	NHS, Private Practises, Private Pharmacies, NDTC	Not Applicable		Within the Timeframe of the POA
1.5	Conduct Information & Awareness Sessions for Public & Workforce regarding EML/Standard & Treatment Guidelines.	<ul style="list-style-type: none"> <li>• Increase awareness of the public and the workforce regarding EML and STG</li> </ul>	MOH, NDTC, All necessary partners	Government, Private Finding, Donors		2008-2009 FY



***Key Strategic Area 2: Affordability***

<b>Activity Number</b>	<b>Activities</b>	<b>Indicators</b>	<b>Responsibility</b>	<b>Funding Sources</b>	<b>Training Required</b>	<b>Timeline</b>
2.1	Discuss with relevant Ministries options for affordability of the public	<ul style="list-style-type: none"> <li>Discussions with relevant Ministries such as MCIL taking place</li> </ul>	MOH	Normal FY Budget	None	Within Timeframe of POA
2.2	Utilise NHA to determine ways forward for affordability of medicines	<ul style="list-style-type: none"> <li>NHA is used</li> </ul>	MOH			

**Key Strategic Area 3: Financing**

Activity Number	Activities	Indicators	Responsibility	Funding Sources	Training Required	Timeline
3.1	Systems and process in place to ensure efficient use of resources from various sources	<ul style="list-style-type: none"> <li>• System in Place</li> <li>• Less Wastage (as minimal as possible)</li> <li>•</li> </ul>	Everyone	Government, Donors	Any relevant training that may be available from and when necessary.	Within the Timeframe of POA
3.2	Accountable & Transparent, effective and efficient Financing System in Place	<ul style="list-style-type: none"> <li>• Minimal wastage</li> <li>• Secure funding</li> <li>• Positive audit reports</li> </ul>	NHS,			

**Key Strategic Area 4: Procurement Systems**

Activity Number	Activities	Indicators	Responsibility	Funding Sources	Training Required	Timeline
4.1	Ensure sufficient funding for adequate supplies of quality drugs to patients	<ul style="list-style-type: none"> <li>Budget for drug supplies developed and approved every FY based on proper estimates of quantification in accordance with accurate data</li> </ul>	NHS, Private Pharmacies, Med Cen	Government		Ongoing
4.2	Review user fees structures and pharmaceutical costs	<ul style="list-style-type: none"> <li>Feasible recommendation regarding user fees in line with necessary policies and laws.</li> </ul>	MOH, MOH, MOF, MOR, MCIL	MOH SNHS		Ongoing

### ***Key Strategic Area 5: Storage of Medicines***

<b>Activity Number</b>	<b>Activities</b>	<b>Indicators</b>	<b>Responsibility</b>	<b>Resources Required/ From Who</b>	<b>Training Required</b>	<b>Timeline</b>
5.1	Construct a Warehouse to be independently run for function of Supplying and Storage of Medicines to be supplied to both public and private Pharmacies. .	<ul style="list-style-type: none"> <li>• Construction of the Warehouse</li> <li>• Efficient Management of Storage of Medicines</li> <li>• Less waste</li> </ul>	Government of Samoa.	Donor Funding, Government of Samoa		
5.2	Conduct Regular Spot Checks for the quality of stored medicines in the pharmaceutical services.	<ul style="list-style-type: none"> <li>• No complaints reported on quality of medications</li> <li>• 'Regular reports of Spot checks to be carried out</li> <li>• Table recommendations with Management and necessary health councils and committees for ways forward.</li> </ul>	Ministry of Health	Government of Samoa		
5.3	Develop Standard Operating for central medical stores (Public)	<ul style="list-style-type: none"> <li>• Standards are in place and implemented</li> </ul>	MOH, NMTAC	Donor Funding , Govt	When necessary	ASAP

### ***Key Strategic Area 6: Distribution of Medicines***

<b>Activity Number</b>	<b>Activities</b>	<b>Indicators</b>	<b>Responsibility</b>	<b>Resources Required/ From Who</b>	<b>Training Required</b>	<b>Timeline</b>
6.1	Develop and Implement Mechanisms to ensure prompt, efficient and timely distribution of essential medicines, vaccines and medical supplies to all health care facilities.	<ul style="list-style-type: none"> <li>• System in place is efficient.</li> <li>• Prompt distribution and disseminations of medicines</li> <li>• Less Complaints from Public and Workforce</li> <li>• Regular mini surveys to assess situation</li> </ul>	NHS, Med-Cen and other private Pharmacies	Government, Donor Funding,		Ongoing
6.2	Provide adequate and appropriate transportation, communication and personnel necessary to maintain an efficient medicines distribution system	<ul style="list-style-type: none"> <li>• Sufficient number of vehicles procured based on demand from public and daily operations.</li> </ul>	National Health Service MOH Donors	Government of Samoa, Donors		Within the timeframe of the Policy and Plan of Action
6.3	Peripheral hospitals and sub-centers to provide medical stores with consumption data to aid in the quantification for orders to ensure constant and uninterrupted supplies as well as decreasing overstocking and expired stocks	<ul style="list-style-type: none"> <li>• System is efficient</li> <li>• No overstocking and less expired drugs</li> </ul>	NHS	Govt	When necessary	ASAP/ongoing

***Key Strategic Area 7: Control of Stock***

<b>Activity Number</b>	<b>Activities</b>	<b>Indicators</b>	<b>Responsibility</b>	<b>Resources Required/ From Who</b>	<b>Training Required</b>	<b>Timeline</b>
7.1	Improve or Develop an efficient Stock Control System in the Public Pharmacy	<ul style="list-style-type: none"> <li>Less Stock Outage</li> </ul>	NHS	Government of Samoa		Ongoing
7.2	Regular Stock Taking in both private and public pharmacies	<ul style="list-style-type: none"> <li>Sufficient supplies available in country for the public</li> </ul>	Private Pharmacies, Med-Cen, NHS			Ongoing

### ***Key Strategic Area 8: Rational Use of Medicines***

<b>Activity Number</b>	<b>Activities</b>	<b>Indicators</b>	<b>Responsibility</b>	<b>Resources Required/ From Who</b>	<b>Training Required</b>	<b>Timeline</b>
8.1	Promote and support education of patients and the general public in the rational use of medicines and its inclusion into school curricula	<ul style="list-style-type: none"> <li>• Clients and stakeholders awareness workshops and consultations conducted</li> <li>• Brochures, pamphlets produced and distributed to general public and clients</li> </ul>	MOH, NHS, Med-Cen, Private Pharmacists, NDTC.	Government, Donors	Training of trainers	
8.2	Establish medicines information services for health care professional involved in the prescribing and dispensing of medicines	<ul style="list-style-type: none"> <li>• Fully equipped and manned Medicines information services established</li> </ul>	MOH and all sectors partners	Government	Drug information management	
8.3	Define and circulate standard treatment guidelines to all health care professionals	<ul style="list-style-type: none"> <li>• Consultations on development of Standard Guidelines.</li> <li>• Standard treatment guidelines defined and circulated</li> </ul>	All relevant health care professionals	NHS in collaboration with all relevant pharmaceutical services	Use of treatment guidelines training for all healthcare professionals involved in the diagnosis, prescribing and dispensing of drugs	
8.4	Develop and circulate guideline information on promoting rational medicines use, disease prevention, healthy lifestyle and nutrition.	<ul style="list-style-type: none"> <li>• Guideline information developed and circulated to all relevant health providers</li> <li>• Information and awareness session conducted</li> </ul>	MOH and all relevant partners.	NHS, Donor		
8.5	Develop and circulate guidelines on self-diagnosis and self-medication to the public	<ul style="list-style-type: none"> <li>• Guidelines developed and circulated to the public</li> <li>• Information and</li> </ul>	Pharmacy division, TTM Management Team, Upolu & Savaii ICHS, CEO	NHS, donor agencies		

		Awareness session conducted				
8.6	Develop measures to ensure all medicines are prescribed & dispensed rationally using their generic names	<ul style="list-style-type: none"> <li>Measures developed in accordance with the essential medicines concepts and the recommendations in the National Medicines Formulary</li> <li>Improvement reflected in measures</li> </ul>	All relevant partners, MOH			
8.7	Constantly monitor and assess prescribing & dispensing practices in the country in order to ensure efficient and cost-effective prescribing as well as the protection of the public.	<ul style="list-style-type: none"> <li>Ongoing monitoring and assessments conducted</li> </ul>	MOH to lead. NHS, Private Pharmacies, Med-Cen Hospital,			
8.8	Develop guidelines for the control of distribution and administration of habit-forming medicines for all public & private health providers	<ul style="list-style-type: none"> <li>Guidelines developed, distributed and adhered to by all health providers</li> </ul>	ACEO Pharmacy, CEO, MCA	SNHS, donor agencies		



**Key Strategic Area 9: Quality Assurance**

Activity Number	Activities	Indicators	Responsibility	Resources Required/ From Who	Training Required	Timeline
9.1	Establish a Medicines Registration System	<ul style="list-style-type: none"> <li>All Medicines are registered</li> </ul>	MOH and all sector partners	Government, Donor	Quality Management	As soon as possible
9.2	Establish and conduct a National Pharmaco-vigilance programme to monitor and prevent adverse medicines reactions in Samoa	<ul style="list-style-type: none"> <li>Pharmaco-vigilance programme planned and implemented</li> </ul>	MOH, NHS, Med-cen, Private Hospital	Government, Donor		
9.3	Routine Testing of Suspected Medications	<ul style="list-style-type: none"> <li>Testing implemented</li> </ul>				
9.4	Establish a System that ensures the highest quality of medications procured and imported into the country.					

***Key Strategic Area 10: Controlled Advertising and Promotion***

<b>Activity Number</b>	<b>Activities</b>	<b>Indicators</b>	<b>Responsibility</b>	<b>Resources Required/ From Who</b>	<b>Training Required</b>	<b>Timeline</b>
10.1	Develop ethical criteria's for medicines promotion and advertising	<ul style="list-style-type: none"> <li>Ethical criteria's in place</li> <li>Information and Awareness Sessions on these Ethical Criteria's</li> </ul>	All relevant health sector partners, MOH	Government, Donors		As soon as possible
10.2	Regular monitoring of medicines advertisements including Alternative		MOH			As soon as possible

**Key Strategic Area 11: Research and Development**

Activity Number	Activities	Indicators	Responsibility	Resources Required/ From Who	Training Required	Timeline
11.1	In future, to carry out research on efficacy of essential medications	<ul style="list-style-type: none"> <li>More information to assist in strengthening and further developing the Pharmaceutical services</li> </ul>	Any relevant Health sector partner or outsider.		When needed and necessary	Within timeframe of POA and when needed
11.2	Research into the Rational Use of Drugs in the Country	<ul style="list-style-type: none"> <li>Research informs further developments to improve existing systems.</li> </ul>	Outsiders and MOH	Government, Donors or private		
11.3	Survey and Research on Financing of Pharmaceutical Services	<ul style="list-style-type: none"> <li>Research is able to capture gaps to be addressed</li> </ul>	WHO or MOH	Government, Donors		
11.4	Review of Pharmaceutical Expenditures	<ul style="list-style-type: none"> <li>Review identifies issues to be addressed and feasible.</li> </ul>	Donor Partners, MOH, Pharmaceutical Services, Private Hospital.	Government, Donors		Ongoing and done when warranted.

### **Key Strategic Area 12: Human Resource Base**

<b>Activity Number</b>	<b>Activities</b>	<b>Indicators</b>	<b>Responsibility</b>	<b>Resources Required/ From Who</b>	<b>Training Required</b>	<b>Timeline</b>
12.1	Develop a Human Resource for Health Policy and Plan of Action that is inclusive of Pharmacy Human Resource Issues and Needs	<ul style="list-style-type: none"> <li>• Policy developed</li> <li>• Policy is inclusive of issues in the pharmacy service</li> </ul>	MOH in collaboration with all relevant stakeholders	Government, Donors	N/A	Within time frame of POA
12.2	Careers paths identified for all those in the Pharmacy Service	<ul style="list-style-type: none"> <li>• Career paths in place</li> <li>• Clear sense of direction for employees</li> <li>• Increase collaboration among stakeholders</li> </ul>	ALL	Government, Donors and Private Sector	When needed and necessary	Within time frame of POA
12.3	Ministry of Health to ensure a holistic approach in identifying issues of human resource deficiencies in the health sector overall	<ul style="list-style-type: none"> <li>• As part of the HRH Policy and Plan of Action</li> </ul>	MOH and All relevant stakeholders		When necessary	Within time frame of POA
12.4	Train adequate pharmaceutical personnel	<ul style="list-style-type: none"> <li>• Sufficient number of personnel are trained to meet the demand of the sector</li> </ul>	ALL	Government, Donors	When necessary and needed	Within timeframe of POA
12.5	On-going training of Medical and Health professionals in the use of Standard Treatment Guidelines	<ul style="list-style-type: none"> <li>• Trainings are reflected in work plans</li> </ul>	NHS, MOH, Private and NMTAC	Government, Donors		Within timeframe of POA
12.6	Attachment for Store personnel to other Central Medical Stores to observe how their distribution system works and how their day-to day activities are run	<ul style="list-style-type: none"> <li>• Attachment has a positive impact on Services</li> <li>•</li> </ul>	NHS, ALL, MOH	Government, Donors		Within timeframe of POA
12.7	Attachment for pharmacy technicians to observe other hospital pharmacies	<ul style="list-style-type: none"> <li>• Attachment is done</li> <li>• Attachment has a positive impact on Services</li> </ul>	ALL	Donors and Government		Within timeframe of POA
12.8	On-going training for pharmacy staff as well as other health professionals on medicines, their uses, side-effects, interactions etc to. This will ensure that health professionals counseling patients are given the most up-to date	<ul style="list-style-type: none"> <li>• Reflected in work plans</li> <li>• Impact on services</li> <li>• Efficiency and effectiveness</li> </ul>	ALL /MOH	Donors and Government		Ongoing

	information					
12.9	<p>To ensure the sustainability, capacity building and consistent improvement for the pharmaceutical sector, the following human resource needs to be addressed through participating donors:</p> <ul style="list-style-type: none"> <li>• on-going training for pharmacy technicians</li> <li>• opportunities for undergraduate studies in Bachelor of Pharmacy</li> <li>• 2 opportunities for postgraduate studies in Clinical Pharmacy</li> <li>• 1 opportunity for postgraduate studies in Clinical Pharmacology</li> <li>• 1 opportunity for postgraduate studies in the area of Quality Assurance</li> </ul>	<ul style="list-style-type: none"> <li>• Reflected in the Workplans</li> <li>• Positive impact of trainings (skills and knowledge attained in the trainings) on the services</li> <li>• Capacity Building</li> </ul>	ALL /MOH	Donors and Government		Within timeframe of POA

### ***Key Strategic Area 13: Monitoring and Evaluation***

<b>Activity Number</b>	<b>Activities</b>	<b>Indicators</b>	<b>Responsibility</b>	<b>Resources Required/ From Who</b>	<b>Training Required</b>	<b>Timeline</b>
13.1	Develop a monitoring and evaluation framework for the National Medicines Policy	<ul style="list-style-type: none"> <li>Monitoring and Evaluation Framework developed</li> <li>Implementation of Plan of Action of the Policy is carried out</li> </ul>	MOH	SNHS, donor agencies		ASAP
13.2	Carry out a full evaluation of the National Medicines Policy	<ul style="list-style-type: none"> <li>Evaluation report completed and distributed to Executive Management, Minister of Health, and relevant parties</li> </ul>	MOH in collaboration with all Pharmaceutical services and relevant health sector partners	Government	None	Biennium basis.
13.3	National Medicines & Therapeutics Committee meets on a quarterly basis	<ul style="list-style-type: none"> <li>Meetings discuss progress of implementation of Policy.</li> </ul>				

**Key Strategic Area 14: Technical Cooperation**

Activity Number	Activities	Indicators	Responsibility	Resources Required/ From Who	Training Required	Timeline
14.1	Revive and Review the Medicines and Therapeutics Committee to ensure technical collaboration is maintained and expertise shared in the area of pharmaceuticals	<ul style="list-style-type: none"> <li>• Committee is multi-sectoral in representation</li> <li>• Meetings every 3 months</li> <li>• Well attended</li> </ul>	MOH	Government, Donors	As proposed	Meeting every three months
14.2	Ongoing sharing of information among colleagues in the profession and other health colleagues	<ul style="list-style-type: none"> <li>• Update on information to be circulated in the pharmaceutical services (Bulletin)</li> </ul>	NMTC, MOH, NHS and all Pharmaceutical services.	Government, Donors		A network (email shall be established for circulation of information on developments in the Pharmaceutical Industry in the region and world wide.

***Key Strategic Area 15: National Medicines and Therapeutics Advisory Committee***

Activity Number	Activities	Indicators	Responsibility	Resources Required/ From Who	Training Required	Timeline
15.1	Quarterly meetings of the NMTC	<ul style="list-style-type: none"> <li>Reports are tabled through office of CEO</li> </ul>	MOH –SDPD to be secretary		None	Every three months
15.2	Enforce registration of alternative medicines practitioners with a recognized professional body	<ul style="list-style-type: none"> <li>Registration of alternative Health Care professionals</li> </ul>	MOH (Medical and Allied Health Quality Assurance)	Government, Donors		
15.3	Investigate alternative medicines for efficacy, safety and quality	<ul style="list-style-type: none"> <li>Ongoing investigations completed and register of expired drugs kept</li> </ul>	MOH (Medical and Allied Health Quality Assurance) NHS Board, NDTC	Government, Donors		



**Key Strategic Area 16: Alternative Therapy**

Activity Number	Activities	Indicators	Responsibility	Resources Required/ From Who	Training Required	Timeline
15.1	Encourage cooperation between the alternative medicines practitioners and workers in the formal health sector particularly in programmes where these can be involved to promote good health for the people	<ul style="list-style-type: none"> <li>Regular meetings and ongoing promotion programs conducted</li> </ul>	NMTC (MOH) in collaboration with all relevant partners to ensure partnership and collaboration	Government, Donors	N/A	Ongoing
15.2	Enforce registration of alternative medicines practitioners with a recognized professional body	<ul style="list-style-type: none"> <li>Registration of alternative Health Care professionals</li> </ul>	MOH (Medical and Allied Health Quality Assurance)	Government, Donors	Consultations with Alternative Therapy	ASAP
15.3	Investigate alternative medicines for efficacy, safety and quality	<ul style="list-style-type: none"> <li>Ongoing investigations completed and register of expired drugs kept</li> </ul>	MOH (Medical and Allied Health Quality Assurance) NHS Board, NDTC	Government, Donors	N/A	
15.4	Control and regulate advertising of alternative medicines	<ul style="list-style-type: none"> <li>Regulation developed</li> </ul>	AG's Office, NDTC, CEO, Media	Government, Donors		ASAP
15.5	Encourage research into alternative medicines	<ul style="list-style-type: none"> <li>Acceptance of research Proposals into this area</li> <li>Local research encouraged</li> </ul>	MOH	MOH, donor agencies	Research methodologies	Ongoing

***Key Strategic Area 17: Legislation and Policies***

<b>Activity Number</b>	<b>Activities</b>	<b>Indicators</b>	<b>Responsibility</b>	<b>Resources Required/ From Who</b>	<b>Training Required</b>	<b>Timeline</b>
16.1	Review the Food and Drugs Act 1967 to reflect new changes in the Health Sector and current developments/arrangements	<ul style="list-style-type: none"> <li>• Food and Drugs Act reviewed</li> </ul>	MOH/Office of the Attorney General	Government, Donors	N/A	As soon as possible
16.2	Review the Narcotics Act 1967 to reflect current changes and arrangements	Narcotics Act is reviewed	MOH/Office of the Attorney General	Government (Budget) and Donors if any.	N/A	
16.3	Ensure that operations both in the private and public sector are in line with current and future legislations	<ul style="list-style-type: none"> <li>• No complaint received</li> <li>• Positive report</li> </ul>	MOH.	Government (Budget	Whne necessary	Within timeframe of POA

***PATENT : To ensure that the protection of patents for pharmaceutical products or processes does not infringe upon the availability of safe, effective and affordable essential medicines in Samoa.***

Activity number	Activities	Indicators	Responsibility	Resources Required/ From Who	Training Required	Timeline
	Develop strategies to ensure that public health interest rather than commercial interest are weighed appropriately when trade and health intersect	<ul style="list-style-type: none"> <li>Strategies developed and implemented</li> </ul>	MOH and all Health Sector Partners	Government, Donors		
	Secure coordination between the different government sectors particularly health, justice, and trade ministries to ensure that public health interests are taken into account during international trade negotiations	<ul style="list-style-type: none"> <li>No. of trade meetings and negotiations attended</li> </ul>	CEO, Relevant Health sector Partners, Cabinet, Minister of Health,	MOH, NHS and all relevant	nil	
	Utilize and enforce existing mechanisms provided in the international agreements to protect public health, in particular the access to affordable, good quality essential drugs	Existing mechanisms utilized and international agreements adhere to	MOH, SNHS, Private Health Providers and Pharmaceutical Industry, CEO, Minister of Health.	MOH, SNHS, & respective organisations concerned	nil	