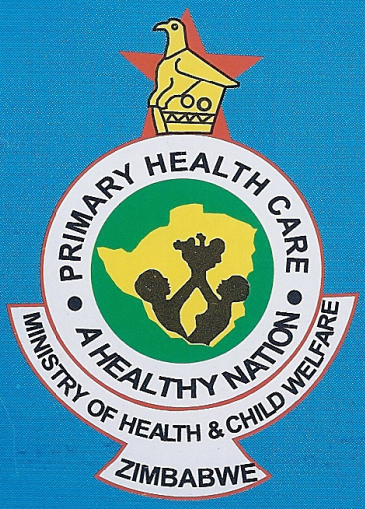
# THE ZIMBABWE NATIONAL MEDICINES POLICY

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Ministry of Health and Child Welfare

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# The National Medicines Policy Of Zimbabwe


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## DEFINITIONS

**Essential Medicines**: Essential medicines are those medicines, which are of the greatest importance, are basic, indispensable and needed to satisfy the health needs of the majority of the population.

**Brand Name:** A Brand name is the proprietary name given by the manufacturer to distinguish its products from those of competitors.

**Generic name**: The generic name is the official name of a medicine, regardless of the manufacturer. The generic or “medical” name is generally the International Non-proprietary Name (INN) established by the World Health Organisation and relates to its chemical structure or therapeutic use. Generic medicines are not covered by patent protection.

**Government Institutions:** includes health facilities of the Ministry of Health and Child Welfare, Missions and Local Government Authorities.

**Medicines:** The Policy covers both medicines and medical supplies, and where the term “medicine” is used in this text it should be understood as relating to both classes of products.

**Quality Assurance:** Quality assurance is a wide-ranging concept covering all matters that directly or indirectly influence the quality of a product It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use. Quality assurance therefore incorporates legislation, registration, inspection, licensing, pre and post marketing surveillance, elements of medicine procurement, distribution and storage, cGMP and other factors

# FOREWORD

The Zimbabwe National Medicines Policy (ZNMP) is an integral part of the National Health Policy, the strategy of which is based on Health Sector Reform, decentralization and conformity with the Primary Health Care approach, to protect, promote and improve health status, consumer satisfaction and equity by increasing the effectiveness, efficiency and quality of services for all the people of Zimbabwe.

Recognizing the important role that medicines play in implementing a National Health Policy and their importance as a component of Primary Health Care, Zimbabwe formulated its first National Medicine Policy in 1987, based on the World Health Organisation concept of essential medicines. Following ten years of successful implementation of the Zimbabwe Essential Drugs Action Programme (ZEDAP) the policy was initially revised in 1995.

The policy aimed to ensure the availability and accessibility of safe, efficacious, cost-effective and affordable pharmaceuticals of good quality for the entire population of the country, and to promote the rational use of medicines in the public and private sectors.

The policy recognised the important role the local manufacturing industry plays in promoting the increased access and availability of quality efficacious generic essential medicines through increased local production.

Following the introduction of health sector reforms, with decentralization resulting in rapid changes, taking the present socio-economic situation into consideration and having seen the importance and necessity of the policy, it is now timely to revise the ZNMP once more and to ensure that its goal and objectives remain realistic and achievable.

The overall objective of the ZNMP is to improve, within the available resources, the health of the majority of the population of Zimbabwe by treating, curing, reducing or preventing diseases and disorders of health through medicine procurement, promotion of local production of essential medicines, management and use, thereby ensuring:

- safety, efficacy and quality of all medicines in use
- equitable availability, accessibility, and affordability of essential medicines, especially to the poorer segments of the population, with a focus on priority health problems and
- appropriate use

Previous statements of medicines policy have served as a guiding light, effectively directing the development of the pharmaceutical sector and of health education, and have provided guidance to health professionals and pharmaceutical providers in both the private and public sectors.

After 20 years of implementation of the National Medicines Policy in Zimbabwe, many of its elements have effectively been achieved These achievements need to be sustained and new and timely strategies developed and implemented in order to reach the goals that have been set.

Zimbabwe, like other countries in the region, is faced with managing the public health impact of HIV/AIDS, malaria and TB which are the major causes of morbidity and mortality in the region.

The previous National Medicine Policies preceded the current challenges to the health systems and the recent financing mechanisms through global initiatives such as the Global Fund To Fight AIDS, Tuberculosis and Malaria (GFATM) and the STOP TB Global Drug Facility. These initiatives, which are responses to the devastating effect of HIV/AIDS, increasing prevalence of TB and the high burden of malaria have created significant pressure on the medicines supplies systems.

On the global level, trade has been affected by globalization of trade and the World Trade Organisation (WTO) TRIPS Agreement which has an impact on health. The re-emergence of regional trading have further confounded the dynamics of health care delivery from the perspective of local production of medicines, Intellectual Property Rights (IPR), pricing and subsequent impact on access to medicines. Zimbabwe is a member of regional economic blocks which include SADC, ECSA, COMESA and the African Union (AU). The Ministry is faced by financial resource constraints and the challenges of sustainability of the level of financing mechanisms channelled through the global initiatives. In this regard the Ministry, like its counterparts in the region, has realised the need to proactively prepare for policy shifts to cope with the situation. The need for harmonization of policies and legislation in the context of the regional economic blocks necessitates the continuous review of existing Medicines Policies.

This newly revised ZNMP will be used as a tool and source of reference in decision-making and strategy development, and it points the way to further development of the pharmaceutical sector.

On behalf of the Ministry of Health and Child Welfare I would like to thank all those who have contributed to the revision of the Policy and have devoted their mental, professional and physical energies to the further evolution of the ZNMP. I would also like to express my sincere gratitude to the European Commission and the World Health Organisation for the financial and technical support. Medicines play an important role in the delivery of health care in Zimbabwe. It is hoped with this renewed Policy, to strengthen and improve the pharmaceutical services throughout the nation so as to render them more efficient and cost effective, for the benefit of everyone in Zimbabwe.

Hon. Dr. Henry Madzorera MP

Minister of Health & Child Welfare, Zimbabwe

Abbreviations

| | |
|---|---|
| ART | Anti-Retroviral Therapy |
| COMESA | Common Market for Eastern and Southern Africa |
| DPS | Directorate of Pharmacy Services |
| ECSA | East, Central and Southern African Health Community |
| EDLIZ | Essential Medicines List for Zimbabwe |
| FDC | Fixed Dose Combination |
| cGMP | current Good Manufacturing Practices |
| HMTC | Hospital Medicine and Therapeutics Committee |
| INN | International Non-Proprietary Name |
| MCAZ | Medicines Control Authority of Zimbabwe |
| MOH &CW | Ministry of Health and Child Welfare |
| NatPharm | National Pharmaceutical Company of Zimbabwe |
| NMTPAC | National Medicine and Therapeutics Policy Advisory Committee |
| PCZ | Pharmacists Council of Zimbabwe |
| SADC | Southern African Development Community |
| STG | Standard Treatment Guidelines |
| TB | Tuberculosis |
| TRIPS | Trade Related Aspects of Intellectual Property Rights |
| WTO | World Trade Organization |
| WHO | World Health Organisation |
| ZEDAP | Zimbabwe Essential Drugs Action Program |
| ZNMP | Zimbabwe National Medicines Policy |
| ZRDCL | Zimbabwe Regional Drug Control Laboratory |

# INTRODUCTION

The revised Zimbabwe National Medicines Policy (ZNMP) is based on:

- The previous Zimbabwe National Drug Policy, Ministry of Health and Child Welfare, December 1995;
- Comments on the Draft Revised ZNMP;
- Comments and proposals from the National Medicine and Therapeutics Policy Advisory Committee (NMTPAC) and the Medicines Control Authority of Zimbabwe (MCAZ).

The ZNMP is intended to serve as a reference guide and directive for the implementation of the essential medicines concept and the management and financing of medicines throughout the country. It provides standards of performance for quality assurance and control, regulation, procurement, production, distribution, sale, import/export, advertising, provision of information and the use of medicines. It extends to the training and development of human resources, advancement of research and development, monitoring and evaluation of services and the promotion of both national and international collaboration. A separate policy has been developed for traditional medicine, and that topic is therefore no longer included in the ZNMP. Finally, the Policy no longer deals with the control of abuse involving alcohol, drugs and allied substances as the MOH&CW has established a separate Department that specifically deals with these issues.

Following the 1995 revision of the National Drug Policy there is now once more a need to revise the content of the Policy, to update various aspects of its components so as to reflect better the current situation and recent developments, and to ensure a more specific policy providing clear, achievable and realistic aims for each component.

The major change in this Policy is the substitution of the word “drug” with “medicine” in line with the amendments in the Medicines and Allied Substances Control Amendment Act [Chapter 15:03], Act Number 1 of 1996.

The classification of medicines in the Essential Medicines List; ABC categorisation and VEN has been made clearer.

The other new area is on promotion of local pharmaceutical production through strategies of the government’s Industrial Development Plan (IDP) and Policy Action Plan.
The Policy also targets bringing coherence between health policy and economic development policy. Its aim is to use common ground between the industrial policy and public health policy to facilitate the growth of the pharmaceutical manufacturing industry.

The other new area is with respect to the globalisation of trade and impact on public health.

# 1. OBJECTIVES OF THE ZIMBABWE NATIONAL MEDICINES POLICY

The Zimbabwe National Medicines Policy is an integral part of the National Health Policy that aims to attain health for all as well as equity and safety in access to health care for all.

The overall objectives of the ZNMP is to improve, within the available resources, the health of the majority of the population of Zimbabwe by treating, curing, reducing or preventing diseases and disorders of health through proper procurement, promotion of local production of essential medicines, management and use of medicines, ensuring:

- Safety, efficacy and quality of all medicines on the market.
- Equitable availability, accessibility and affordability of essential medicines, especially to the vulnerable segments of the population, with a focus on priority health problems and,
- Rational use of medicines by health professionals and consumers.

The Policy recognizes the profession of pharmacy as the authority in matters of medicines and medicines dispensing.

# 2. SPECIFIC AIMS OF THE ZIMBABWE NATIONAL MEDICINES POLICY

2.1 To ensure the highest possible availability of essential medicines throughout the nation, including 100% availability of Vital medicines (as defined in Section 3.3) at all times at the primary care level.

2.2 To ensure successful implementation of the ZNMP through enactment and updating of appropriate legislation and regulation.

2.3 To satisfy the health needs of the majority of the population through a careful selection of medicines and medical supplies according to the Essential Medicines concept of the World Health Organization (WHO).

2.4 To provide safe and effective medicines of acceptable quality at a reasonable price to the public through procurement of generic pharmaceutical products and promotion of their use.

2.5 To ensure that medicines entering or remaining on the market are of acceptable quality, safety and efficacy.

2.6 To promote cost effective production of medicines within Zimbabwe in accordance with the standards of current Good Manufacturing Practices (cGMP).

2.7 To improve rational use of medicines through adherence to ethical criteria for medicines advertisement and promotion and to ensure that both health workers and the general public have access to accurate, up-to-date unbiased and relevant information on medicines and their use, and that commercially based information, advertising and promotion of medicines is consistent with this standard.

2.8 To promote the rational prescribing, dispensing and use of medicines both in the public and private sectors in order to maximise the therapeutic benefit to the patient and to reduce loss, wastage and hazards arising from irrational practices.

2.9 To procure and distribute safe and effective medicines of acceptable quality, in the necessary quantities, at the lowest possible cost, and to ensure that these medicines are maintained in good condition throughout the supply chain in order to minimize wastage and loss.

2.10 To ensure sufficient funding to implement the ZNMP and establish a programme of work to this end, and the allocation of funds to the public sector for the procurement of medicines.

2.11 To develop further the organization and management of the ZNMP, and to monitor and evaluate regularly the impact of this policy.

2.12 To maintain high standards and efficiency in all medicine handling activities by ensuring the training, retention and recruitment of well-trained health workers at all levels of the health system in Zimbabwe.

2.13 To promote the development of operational research and of technical research and development activities in the medicinal and pharmaceutical fields in Zimbabwe.

2.14 To enhance the roles played by the National Medicine and Therapeutics Policy Advisory Committee (NMTPAC) and Hospital Medicine and Therapeutics Committees (HMTC).

2.15 To involve, through national, regional and international co-operation and collaboration, all those forms of authority, experience and knowledge that can contribute towards the successful implementation of the ZNMP and to be well informed on international developments and trends.

# 3. THE COMPONENTS OF THE ZIMBABWE NATIONAL MEDICINES POLICY

## 3.1 AVAILABILITY

**AIM To ensure the highest possible availability of essential medicines throughout the nation, including 100% availability of Vital medicines at all times at the primary healthcare level.**

3.1.1 The Ministry of Health and Child Welfare (MOH&CW) will ensure maximal availability of essential medicines by optimising the processes of selection, financing, local production, procurement, distribution, stores management and quality assurance.

3.1.2 The MOH&CW will ensure the provision and dissemination of information on current needs for medicines and the supply situation to enable the Ministry's institutions, local manufacturers and other suppliers to take timely action to ensure uninterrupted supply of medicines.

## 3.2 LEGISLATION AND REGULATION ON MEDICINES AND MEDICAL SUPPLIES

**AIM: To ensure successful implementation of the ZNMP through enactment and updating of appropriate legislation and regulations.**

3.2.1To ensure that only authorized medicinal products of adequate quality, safety and efficacy circulate in Zimbabwe, the MOH&CW will ensure the enforcement of the Medicines and Allied Substances Control Act [Chapter 15:03] (MASCA) and Regulations.

3.2.2The MOH&CW will work in close consultation with all the stakeholders to facilitate the review, updating and implementation of the relevant legislation, regulations and the amendments thereto.

3.2.3 The MOH&CW will make all necessary efforts to ensure that the autonomous Medicines Control Authority of Zimbabwe (MCAZ) is a viable organisation and functions effectively in implementing and enforcing medicines legislation and regulations.

3.2.4The MCAZ will establish procedures and policies for sampling, testing and evaluating medicines and registration of those that conform to the prescribed standards. In all matters, priority will be accorded to those medicines that meet priority needs and those that are included in Essential Medicines List for Zimbabwe (EDLIZ).

3.2.5 Enforcement of the provisions of medicines legislation and regulations will be monitored at all levels.

3.2.6 Amendment of the relevant laws to take advantage of the flexibilities offered under the World Trade Organisation (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) in order to promote local production of essential medicines. [See also 3.16]

## 3.3 MEDICINES SELECTION

**AIM: To satisfy the health needs of the majority of the population through a careful selection of medicines and medical supplies according to the Essential Medicines concept of the WHO.**

3.3.1 The selection of those medicines, which merit inclusion in the Essential Medicines List, and the choice of medicines to be included in the Standard Treatment Guidelines (STG) will be compatible with one another. Both functions will be entrusted to the National Medicine and Therapeutics Policy Advisory Committee (NMTPAC).

3.3.2 The selection of essential medicines will take account of:

- The pattern of disease prevalence;
- The established need for a given medicine;
- Efficacy;
- Safety;
- Quality;
- Therapeutic benefit as compared with available alternatives;
- The intended level of care as defined under subsection (6) below;
- The cost, in particular the cost of a full course of treatment as compared with available alternatives;

3.3.3 The selection of medicines will be continuously reviewed and revised as necessary in the light of the latest scientific information on medicines and medicinal treatment.

3.3.4 The Policy will seek to keep within reasonable limits the number of medicines circulating on the market and the lesser number included in Essential Medicines List. Fixed Dose Combinations (FDC) and new medicines will only be introduced if they offer proven advantages over existing medicines.

3.3.5 The Essential Medicines List with STG will be disseminated to all health facilities and health workers as well as training institutions for health workers, relevant non-governmental organisations and others who have need of it.

3.3.6 The medicines on the Essential Medicines List are suitable for use at all levels of health care, some requiring a particular degree of specialized skill in their use or special facilities, thus the medicines on the list will be sub-classified as follows:

- C: Medicines for Primary Health Care level and should be available at all levels of health care;
- B: Medicines for secondary and higher levels of care ;
- A: Medicines for Provincial and Central hospital levels;
- S: Medicines for Specialist use only;

3.3.7 Based on economic considerations, medicines listed in the Essential Medicines List are further sub-classified according to their priority in health care as a whole:

V: Vital medicines: These are medicines considered life saving or unavailability would cause serious harm;

E: Essential Medicines: These are medicines normally considered indispensable in basic care and are given second priority;

N: Necessary medicines: These are the remaining medicines included in Essential Medicines List but are lower in priority than V and E medicines.

3.3.8 Medicines used in the public sector will normally be exclusively those listed in the Essential Medicines List. The MOH&CW will ensure that suitable provision is made to allow medicines outside the Essential Medicines List to be prescribed exceptionally in the public sector where special needs arise.

## 3.4 POLICY ON GENERIC MEDICINES

**AIM** **To provide safe and effective medicines of acceptable quality at a reasonable price to the public through the procurement of generic pharmaceutical products and the promotion of their use.**

3.4.1 The selection of medicines shall be carried out exclusively on the basis of their generic names (International Non-Proprietary Name: INN).

3.4.2 All medicines will be registered by their generic name and the generic name of each medicinal product must be indicated prominently on its label. Where the registration holder intends to market a product under a brand name this name may also be indicated on the label but not accorded greater prominence than the generic name.

3.4.3 The MOH&CW will promote awareness among health workers and the public of generic names and of the fact that for many branded medicines fully identical generic equivalents are available at a lower price.

3.4.4 Where branded products are prescribed, the MOH&CW will encourage dispensing pharmacies to substitute with their generic equivalents.

## 3.5 ASSURING THE QUALITY, SAFETY AND EFFICACY OF MEDICINES

**AIM** **To ensure that medicines entering or remaining on the market are of acceptable quality, safety and efficacy,**

**General provisions: quality, safety and efficacy**

3.5.1 The MOH&CW will ensure effective quality assurance and the appropriate legal basis is in place to ensure that only medicines of acceptable quality; safety and efficacy are allowed to be produced, imported, distributed and used in Zimbabwe.

3.5.2Only medicines registered or authorised by the MCAZ following evaluation and against payment of a fee will ordinarily be permitted to be imported,

manufactured, sold by way of wholesale or retail, prescribed, dispensed or otherwise supplied in Zimbabwe.

3.5.3 The MCAZ may itself make provision and set criteria for exemption from registration fees when approving medicines considered to be essential but not used in sufficient quantities to cover the ordinary costs of registration.

3.5.4 The MCAZ will, without compromising its own standards, collaborate with authorities in other countries in the region to attain harmonisation of control procedures and registration requirements, exchange of information and ratification of international conventions and technical agreements.

3.5.5 Medicines already registered in Zimbabwe, which are subsequently found to be unsafe, ineffective, or of insufficient quality shall be withdrawn from the market and their registration cancelled by the MCAZ. Where a medicine is withdrawn in other countries, its regulatory status in Zimbabwe will be re-assessed by the MCAZ.

3.5.6 The MCAZ will maintain a computerised system for medicines registration and licensing.

3.5.7 The MCAZ will issue a bulletin providing information on newly registered medicines, current information on medicines, and their appropriate use, significant findings of quality control and other matters of relevance to the supply and utilization of medicines.

3.5.8 The MCAZ will maintain and further develop its monitoring of Adverse Medicine Reactions, both independently and in collaboration with analogous systems in other countries; findings emerging from these activities shall contribute to the MCAZ's assessment and re-evaluation of medicines.

3.5.9 Experimental use in human subjects of any medicine not registered in Zimbabwe shall be permitted only where specific permission for such use has been granted by the MCAZ following submission and assessment of data required by the Authority to evaluate the purpose and risks of such use; permission may be subject to conditions set by the Authority and the results of the experiment shall be submitted to the Authority in full. The Government will update guidelines to be followed during clinical trials and any related research on medicines and will ensure the enforcement of relevant legal provisions and regulations.

**Specific provisions regarding quality of medicines**

3.5.10 The MOH&CW will ensure that effective procedures and institutions are in place to provide an assurance of the quality of all medicines available in Zimbabwe. The national system of quality assurance will be in full conformity with internationally accepted standards and procedures, as reflected in the MASCA and the regulations made pursuant to that Act.

3.5.11 The Medicines Inspectorate of the MCAZ, shall with the full support and authorization of the MOH&CW, ensure effective surveillance of the medicine supply system at all levels to ensure the maintenance of quality. **Appropriate standards will be applied at all levels, including the processes of registration, post-marketing surveillance, testing, inspection and the licensing of pharmaceutical establishments of all types.**

3.5.12 The laboratory under the MCAZ shall undertake analysis of medicines and medical supplies. The MOH&CW will ensure that the laboratory is appropriately staffed, funded and equipped to undertake this task.

3.5.13 The WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce shall be applied both to the importing and exporting of medicines.

## 3.6 PRODUCTION OF MEDICINES WITHIN ZIMBABWE

**AIM** **To promote cost effective production of medicines within Zimbabwe in accordance with the standards of current Good Manufacturing Practices (cGMP).**

3.6.1 The Government will encourage and support the production of medicines within Zimbabwe, both within its own institutions or by others, provided such production is cost-effective and the standards of cGMP are attained and maintained at all times.

3.6.2 The Government will promote the local production of essential medicines by implementing programs contained in the Industrial Development Plan (IDP) and Policy Action Plan that promote the growth and development of the local pharmaceutical industry to ensure the production of efficacious, safe and quality medicines in order to increase the accessibility and availability of essential medicines to Zimbabweans and economic contribution.

3.6.3 Government will work towards finding common ground between the industrial policy and public health policy to facilitate the growth of the pharmaceutical manufacturing industry

3.6.4 Appropriate structures and communication channels shall be put in place to disseminate information that will enable both local manufacturers and suppliers to take early action and prevent shortage.

## 3.7 INFORMATION, ADVERTISING AND PROMOTION

**AIM** **To improve rational use of medicines through adherence to ethical criteria for medicines advertisement and promotion and to ensure that both health workers and the general public have access to accurate, up-to-date unbiased and relevant information on medicines and their use.**

### General

3.7.1 The MOH&CW will ensure that information on medicines reaching the health services providers and the public provides a sufficient, balanced and reliable basis for prescribing decisions and the use of medicines.

3.7.2 The MOH&CW will through its institutions ensure that complementary information is provided through official channels to ensure balance and completeness.

### Advertising, promotion and information of commercial origin

3.7.3 The MCAZ, will take measures to ensure that the promotion of medicines and

related products is based on scientific evidence and is consistent with the WHO Criteria for Medicine Promotion and the conditions under which such products have been registered for marketing by the Authority.

3.7.4 Advertisements and other forms of promotion directed to the general public shall be permitted only for medicines that have been licensed for sale as "over the counter" products without prescription; such advertisements and communications shall be of a technical nature and attuned to the public's needs and level of understanding.

3.7.5 The MCAZ will approve all printed or electronic advertising and promotional materials, as well as labelling and packaging materials, in advance.

3.7.6 Advertising and promotional materials and related activities of all types will be monitored by the Authority to ensure their consistency with the conditions applicable to the products concerned and the approvals granted.

3.7.7 The MCAZ will support the development and enforcement of national ethical criteria for the promotion of medicines and related products in Zimbabwe; such criteria will be consistent with the WHO Criteria for Medicine Promotion but will take full account of national needs and circumstances.

3.7.8 The MOH&CW will encourage and support the development and use of methods to evaluate the knowledge, attitudes and practices of the community in general and health workers in particular where medicines are concerned and their needs as regards the provision of information so it can design and implement suitable and effective Information, Education and Communication intervention strategies.

3.7.9 Monitoring of adverse medicine reactions by MCAZ will be strengthened, relevant information disseminated and any action deemed necessary co-ordinated through the NMTPAC.

## 3.8 RATIONAL USE OF MEDICINES

**AIM** **To promote the rational prescribing, dispensing and use of medicines both in the public and private sectors in order to maximise the therapeutic benefit to the patient and to reduce loss, wastage and hazards arising from irrational practices.**

### Information

3.8.1 The MOH&CW will seek to identify the information needs of both health workers and the public where medicines are concerned and will ensure that the flow of information on these matters is conducive to a proper understanding of medicines, their properties, benefits and risks, and thereby to their rational use.

### Education and Training

3.8.2 The curricula of the courses provided at all levels to health workers in diagnosis, prescribing or dispensing will be continuously revised and updated as required to include the essential medicines concept, the national medicines policy, principles of medicines management, the rational use of medicines, pharmaceutical production, research and development and the

principles of good communication. The Essential Medicines List with the STG will be actively used in the training.

3.8.3 A comprehensive programme will be developed for the continuous training at all levels of health workers involved in diagnosis, prescribing or dispensing of medicines in collaboration with all health programmes and institutions.

3.8.4 The MOH&CW through the Directorate of Pharmacy Services (DPS) will maintain and develop peripheral level training regarding the essential medicines concept, the financial management of medicine supply and the rational use of medicines. Such activities will involve the training of Medicine Management Supervisors as well as the training of trainers, and will be progressively extended to health workers at the higher levels of the health system.

3.8.5 The Essential Medicines List, as well as modules developed within DPS will provide the basis for training activities. The materials will be updated and supplemented as necessary in the light of new information and feedback from the health workers concerned.

3.8.6 Continuing Education for all health professionals including dispensing doctors will be further developed and will continue to be a requirement for the maintenance of professional registration.

3.8.7 The quality of all training and education will be audited by the MOH&CW through the Health Professionals Council and representatives of the professional bodies concerned.

3.8.8 Health workers who have received their basic training abroad will be required to pass through a more formalized process of supplementary training and introduction. Such training will include the essential medicines concept the ZNMP, principles of medicines management, the rational use of medicines and principles of good communication. The Essential Medicines List and the Standard Treatment Guidelines will be actively used in the course of this training.

3.8.9 There will be further development of information provided to the general public on the correct use of medicines. Emphasis will be placed on the proper handling and storage of medicines, compliance with medicinal treatment, the proper place of self-medication and the safe disposal of medicines.

3.8.10 The MOH&CW will collect and collate relevant data in order to assess the extent to which medicines are being rationally used in both the private and public sector. The information obtained will be made widely available and will be used both to advance management of the medicines supply system and to identify and correct the causes of irrational use and the situations in which this occurs.

**Prescribing and dispensing**

3.8.11 The MOH&CW will continue to advocate the use of generic names and Essential Medicines List with STG in the private sector. In the public sector, medicines will be prescribed and dispensed exclusively under their generic

names and in accordance with the STG contained in Essential Medicines List.

3.8.12 The regulations with respect to dispensing, as formulated in the Medicines and Allied Substances Control Regulations, will be enforced by the MCAZ. The DPS in consultation with the Pharmacists Council of Zimbabwe (PCZ) shall develop guidelines with respect to Pharmacy Practice, appropriate to the Zimbabwean situation.

3.8.13 In view of the ever-present need to contain and reduce the costs for the nation as a whole of medicinal treatment, the MOH&CW will collaborate with the professional associations, the Medical Aid Societies, general practitioners, the consumer movement and other stakeholders to identify and exploit opportunities that increase efficiency and reduce wastage, including the greater use of generic medicines.

## 3.9 MEDICINES SUPPLY: PROCUREMENT, DISTRIBUTION AND STORAGE

**AIM** **To procure and distribute safe and effective medicines of acceptable quality, in the necessary quantities, at the lowest possible cost, and to ensure that these medicines are maintained in good condition throughout the chain of supply so as to minimize wastage and loss.**

### Procurement

3.9.1 The ZNMP will ensure the procurement of both medicines and raw materials of consistently good quality, at the lowest possible price and in appropriate quantities, taking full advantage of the possibilities offered by bulk purchasing and by critical selection of suppliers, including non-commercial sources.

3.9.2 Only medicines, which have been registered or otherwise approved by the MCAZ, shall ordinarily be eligible for procurement for the public or private sectors. The MOH&CW may ensure that in exceptional circumstance provision is made to allow unregistered medicines to be made available.

3.9.3 An approved autonomous non-profit procurement agency, currently NatPharm, will undertake public sector procurement. NatPharm will be free to use the means of purchase most appropriate to the fulfilment of its aims and duties as defined above (general tender, closed tender, negotiated procurement, exceptionally direct procurement).

3.9.4 Medicines shall be procured exclusively under their generic names.

3.9.5 The Government will support the status and viability of the procurement agency and will provide a sufficient financial basis for its operation.

3.9.6 All donations of medicines and medical supplies from any source will be handled through NatPharm and will be subject to the rules applicable to the normal procurement process as well as to the National Medicine Donation Guidelines. These procedures are essential in order to prevent dumping of unwanted or expired medicines and to avoid establishment of parallel procurement and distribution systems.

3.9.7 The procurement agency shall accord priority to locally produced products and suppliers subject to their meeting overall requirements with respect to cost, quality, and the envisaged reliability of supply as per current Procurement Regulations.

3.9.8 Having regard to the obligation assumed by the Government to respect patent law, NatPharm will not knowingly make purchases of goods known to be produced or supplied in breach of patent. Should the legality of the goods in this respect be the subject of a dispute between the proposed supplier and the patent holder, the MOH&CW will source the goods to the best national advantage and will not be a party to such a dispute.

3.9.9 The procurement agency will establish and maintain a system of information on suppliers as regards to quality, performance, reliability and other information deemed of importance to ensure procurement of quality products.

**Distribution**

3.9.10 The Policy aims to ensure the safe, cost-effective and efficient distribution of medicines and medical supplies to the entire country so as to ensure their availability and accessibility to all in need at all times.

3.9.11 NatPharm will ensure the provision of adequate, efficient, cost-effective and appropriate transportation, as well as the necessary systems of communication, maintenance and personnel necessary for distribution of medicines and medical supplies to the public sector and to all levels of health care.

3.9.12 The MOH&CW will co-ordinate its various programmes to make optimal use of existing distribution and storage facilities, avoiding parallel systems and optimise redistribution when deemed necessary.

**Storage**

3.9.13 The Policy will ensure that the quality of medicines is maintained during storage at all levels of the supply chain.

3.9.14 The MOH&CW will ensure that medicines are stored and managed throughout the country according to established guidelines and procedures.

3.9.15 The MOH&CW will provide and maintain appropriate, adequate, secure and well-equipped storage facilities for Government health facilities.

3.9.16 The DPS will devise and ensure implementation of a national stock management system throughout the distribution chain for the public sector. This management system will be included in the curriculum for all relevant health professionals. The monitoring and maintenance of the management system will be the responsibility of health managers at each level.

3.9.17 The Government procurement agency, NatPharm will further ensure that:

- Computerisation of the stock management system at the Regional and Branch Stores is maintained and sustained;
- Management information is collected, effectively utilised and disseminated;

3.9.18 The MOH&CW will support the computerisation of medicine management at

hospital level starting with the central hospitals.

3.9.19 The MOH&CW will ensure that sufficient numbers of personnel, adequately trained in pharmacy and stores management, are deployed in its facilities at all levels.

3.9.20 The MOH&CW will ensure that sufficient resources are available for the effective supervision of all health facilities by provincial pharmacists and trained supervisors.

3.9.21 Each institution in the supply chain is responsible for enforcing its own security, and must lay down guidelines to be reviewed at regular intervals. Proper documentation should be maintained in line with Treasury Instructions and the Stores Manual.

## 3.10 ECONOMIC STRATEGIES

**AIM** **To ensure sufficient funding to implement the ZNMP and establish a programme of work to this end, including the allocation of funds to the public sector for the procurement of medicines.**

3.10.1 The ZNMP aims to make medicines affordable and available to all who need them. It shall therefore be the responsibility of the Government to provide adequate funding to meet the documented needs of the public sector. To this end the Government, through the MOH&CW and relevant ministries, will explore, co-ordinate, regulate and utilise all relevant strategies and resources for health financing.

3.10.2 The Government will plan, budget and secure sufficient funding for the implementation of the various components of the ZNMP.

3.10.3 The MOH&CW will quantify the annual national needs for medicines and medical supplies, both in the public and private sectors. Estimates of need will be based on generally accepted principles of quantification in this field and will form the basis for the continuous adjustment of budgetary requirements. In calculating the latter, due regard will be paid to the need for cost containment and cost-effective operation throughout the procurement and supply chain. Adequate monitoring will be carried out and the findings made available throughout the health system.

3.10.4 Government cost recovery systems will ensure that the fee structure is based on the real cost of services rendered and can therefore fairly be perceived by the consumer as reasonable and equitable. The structure will stipulate the conditions under complete or partial exemption from payment can be granted.

3.10.5 Government will support and strengthen the development and implementation of insurance systems by medical aid societies and the National Health Insurance Scheme to facilitate access to the health system by the consumer.

3.10.6 In the event of epidemics and other emergencies the Government will make special budgetary provisions to meet the need to augment the supply of appropriate medicines.

## 3.11 ORGANISATION, MANAGEMENT AND CO-ORDINATION OF THE ZNMP

**AIM** **To develop further the organization and management of the ZNMP, and to monitor and evaluate regularly the impact of this policy.**

3.11.1 To keep track of the implementation of each of the components of the ZNMP, the MOH&CW will monitor and evaluate implementation and carry out regular surveys. The DPS will support the establishment of a pharmaceutical management information system.

3.11.2 The MOH&CW will progressively adapt the recognized WHO indicators for monitoring national medicine policies so that they are fully appropriate to the needs of Zimbabwe and can be used to track and evaluate the implementation of the various components of the ZNMP.

3.11.3 Through the DPS will co-ordinate the overall monitoring and evaluation of the policy as a component of National Health Policy.

## 3.12 DEVELOPMENT OF HUMAN RESOURCES

**AIM** **To maintain high standards and efficiency in all medicine handling activities by ensuring the training, retention and recruitment of well-trained health workers at all levels of the health system in Zimbabwe.**

3.12.1 The Government will continuously review and update the existing Human Resources Development plan to serve the aims of the ZNMP.

3.12.2 The Government, working both through the MOH&CW, the Health Service Board and the Ministry of Public Service, will develop an establishment and career structure for all categories of health workers to enable the full implementation of the ZNMP.

3.12.3 The Government will take the necessary steps to ensure that sufficient numbers of pharmacy personnel are trained, recruited and retained in the health system, in order to ensure the continued provision and further development of the required pharmacy services.

3.12.4 The Government will undertake to ensure the continuous upgrading and development of human resources and will make every effort to retain adequate level of pharmacy services within the public sector.

3.12.5 The Government will actively support the pharmacy training institutions with the aim of increasing the output of appropriate personnel from the School(s) of Pharmacy and pharmacy technician training schools and improving the standard of education.

3.12.6 The MOH&CW will strengthen hospital pharmacy practice and other pharmacy disciplines.

3.12.7 The MOH&CW will strengthen its pharmaceutical arm by creating new posts and filling vacant positions within the DPS the provincial and district pharmacist as a means of advancing the implementation of the ZNMP and the supervision of medicines management.

## 3.13 Operational and Technical Research

**AIM** **The Policy will promote the development of operational research and of technical research and development activities in the medicinal field in Zimbabwe.**

3.13.1 The MOH&CW will support operational research evaluating the extent to which the ZNMP is achieving its aims and objectives, identifying problem areas and strengthening further the implementation of the policy.

3.13.2 The Government will promote and support co-operation and collaboration between national and international institutions involved in medicine research.

## 3.14 The National Medicine and Therapeutics Policy Advisory Committee

**AIM** **In view of the proven significance of the role played by the National Medicine and Therapeutics Policy Advisory Committee (NMTPAC) and institutional Medicine and Therapeutics Committees, the Policy will aim to continue and enhance these roles.**

3.14.1 The MOH&CW will support the NMTPAC by providing appropriate terms of reference and a working budget. The Committee will assist with the development of policies in the field of medicines generally, advancement of medicinal treatment, rational use of medicines and the implementation of the ZNMP.

3.14.2 The NMTPAC will be composed of experts from the principal areas of medicine and pharmacy and representing different levels of the health care system. The committee will be entitled to co-opt other members as and when required and will consult widely with interested groups including those in the private sector and at consumer level.

3.14.3 Recognizing the need for Medicine and Therapeutics Committees in order to promote the rational use of medicines in health care institutions, the MOH&CW will work towards the establishment of such committees in district, provincial and central hospitals. The committees will be composed of senior administrative staff, pharmacy personnel, doctors, nurses, laboratory staff and co-opted members when required.

3.14.4 The MOH&CW will issue guidelines for the formation and functioning of Hospital Medicine and Therapeutic Committees. The NMTPAC will co-ordinate and advise on the work of the committees. Among their other duties, these committees will be responsible for determining the number, the range and quantity of Essential Medicines List medicines to be available in the health facility and for guiding health workers in the rational use of medicines and the use of the STG. The committees will further monitor the use of medicines in their institutions and draw up hospital formularies. The MOH&CW, acting through the NMTPAC, will be responsible for monitoring and evaluating their activities.

3.14.5 Institutional health workers will be encouraged to participate in the collaborative management of medicine use in their institutions and in

developing rational practices.

## 3.15 National, Regional and International Collaboration

**AIM To involve through national, regional and international co-operation and collaboration, all those forms of authority, experience and knowledge that can contribute towards the successful implementation of the ZNMP and to be well informed on international developments and trends.**

3.15.1 The MOH&CW will actively involve inter alia the Ministries of Finance, Industry and Commerce, Education and Local Government and the Reserve Bank of Zimbabwe in implementation of the relevant parts of the ZNMP.

3.15.2 The Pharmaceutical, Medical and Nursing Associations, the Zimbabwe Association of Church Related Hospitals, Medical Aid Societies, Consumer Organisations, Universities, the Medical Schools, Uniformed Forces Medical Services and the Pharmaceutical Industry will be routinely consulted on the form and implementation of relevant aspects of ZNMP.

3.15.3 The MOH&CW will encourage technical co-operation in this field within the African Region, especially within Preferential Trade Areas, COMESA and SADC as well as among ECSA Health Ministries.

3.15.4 The MOH&CW will encourage and facilitate co-operation offered through multilateral and bilateral agencies and international organisations.

## 3.16 Trade and Public Health

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is one of the agreements of the World Trade Organisation (WTO) that has a significant impact on the health sector. The TRIPS agreement introduces global minimum standards for protecting and enforcing intellectual property rights, including pharmaceutical products and processes. The TRIPS agreement raises concerns about the major impact of this agreement on people's access to medicines and public health. Governments are required to bring their legislation on intellectual property rights to conform to the TRIPS agreement.

**AIM: To ensure that legislation and regulations developed maintain a balance between the minimum standard of Intellectual Property Rights protection and the public health good.**

3.16.1 In implementing regulations related to intellectual property rights, Government shall take advantage of all the safeguards within the TRIPS Agreement for the promotion of public health and ensuring access to pharmaceuticals.

3.16.2 Government shall not enact legislation and regulations more stringent than the TRIPS requirement.

3.16.3 The MOH&CW shall actively collaborate with the Ministries of Justice, Trade and Industry, and other relevant agencies in the area of intellectual property rights in developing consistent legal framework that enhances access to essential medicines.

3.16.4 Parallel importation shall be permitted for pharmaceuticals when the protection of the health of the public is concerned.

3.16.5 The government shall grant compulsory licences to promote access to medicines when the health of the public is at stake.

3.16.6 Regarding the exploitation of the rights conferred by patents on pharmaceuticals, the government shall design laws that prescribes a limited period immediately preceding the expiry of the patent for its agency or a third party to conduct tests on the product required for regulatory approval in the country.

3.16.7 The limited period in section 3.16.6 should also allow the agency or third party to manufacture and store the product, so that when the patent expires, a generic product can enter the market immediately.

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