

Uganda National Drug Policy

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Foreword

The publication of this document marks a very important and timely step in the development of the national health sector in general and the pharmaceutical sector in particular.

Although Uganda has had a National Drug Policy since 1993, this was not detailed or comprehensive nor did it have any strategies to guide implementation. Moreover the policy was enshrined within the National Drug Policy and Authority Statute which although expedient at the time had become increasingly inadequate to deal with the many issues affecting the pharmaceutical sector. Also having the policy tied into legislation creates difficulties for revising what should be a dynamic document and therefore subject to constant review and updating as required.

In order to ensure maximum credibility, relevance and completeness and also to ensure widespread ownership of the document, the development of the new NDP has taken account of all the main issues affecting the sector and has followed a carefully planned consultative process involving all the stakeholders. This culminated in a National Consensus Workshop held in Kampala in April 2000 at which a wide

representation of all interested parties had an opportunity to review and contribute to the advanced working draft.

The final NDP is therefore not only highly relevant, comprehensive and complete but forms a vital and realistic foundation for the continuing development of the pharmaceutical sector in Uganda and for substantive improvements in national pharmaceutical service provision. The NDP is a clear and detailed statement of the commitment of the Government of Uganda to the systematic and co-ordinated development of the national pharmaceutical sector and is an integral part of the overall National Health Policy. The NDP will now be used as a basis for the preparation of 5-year NDP Implementation Plans and associated yearly Priority Action Plans.

The Ministry of Health Task Force on Drug Management which has guided the process of development of the NDP must therefore be congratulated on a job well done and the Task Force Secretariat must be thanked for the hard work they have put in to organising and co-ordinating this process.

Successful implementation of the NDP will require the sustained involvement and inputs of many partners, and I appeal to all of them to study the document carefully and identify the most practical ways in which they may collaborate together in contributing towards achieving this goal.

Finally as was stated earlier a policy should be dynamic and responsive to changing circumstances. I therefore invite all the stakeholders to become actively involved in the monitoring and evaluation of the implementation of the NDP and any future revision of the policy.

In considering the impact of interventions carried out under the NDP, the bottom line should always be – has the patient received the required level and quality of pharmaceutical care? Put more simply – has the patient received the required medicine of good quality with the correct dose regime and with all the necessary information and advice?



Brig. Jim K. Muhwezi **MP**
MINISTER OF HEALTH

Kampala, October 2002

Preface

The publication of this first comprehensive and detailed Uganda National Drug Policy marks a significant step forward in the overall development of national health services in general and national pharmaceutical services in particular.

Now for the first time we have available a vital reference point and a basis for the planning of appropriate interventions necessary to make a significant positive impact on the extent and quality of pharmaceutical service provision.

Although the regular and reliable provision of essential medicines and health supplies is not the sole requirement for the provision of adequate health services to the public, it is nevertheless the most visible and obvious sign that the health system is working.

Nothing damages so dramatically the credibility of the national health service than the lack of these essential supplies. This lack has been particularly problematic at the lower level health units where the majority of Primary Health Care services are needed.

Thus it is essential for all concerned that pharmaceutical service provision should be of the highest standard possible within the limitations of the available resources and that such services should be available and accessible at all levels of the health system.

The chronic shortage of pharmaceutical human resources means that inevitably certain pharmaceutical services such as medicines ordering, dispensing and storage may sometimes have to be undertaken by non-pharmaceutical health staff like nurses and clinicians. This is expected to continue for the foreseeable future until sufficient trained pharmacists and pharmacy technicians are in place to take over these functions.

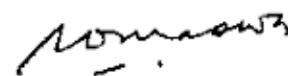
However, these substitute staff should operate under clear guidelines for good pharmaceutical practice and should be provided with adequate support supervision to enable them to operate effectively and to an acceptable standard.

The Ministry of Health is fully committed to the development of a good standard of comprehensive pharmaceuticals services guided by the goals and strategies of the NDP. As a sign of this commitment, the coordination and supervision of implementation of activities under the NDP will be strengthened by the establishment of a Department of Pharmaceutical Services and Health Supplies at the MoH headquarters.

It is expected that overall monitoring and evaluation of NDP implementation and provision of guidance on future review and revision of the NDP will be the responsibility of the Drug Procurement and Management Working Group of the Health Sector Joint Review Mission.

I commend the Task Force on Drug Management for their excellent work in coming up with such a detailed, comprehensive and appropriate drug policy for Uganda. I would also like to express our gratitude to the Task Force Secretariat for all the long hours they put in to preparing the final document. The end result was certainly worth the time and effort put in.

Now it is up to us as health professionals and stakeholders in the health sector to ensure that we facilitate the effective implementation of the NDP by offering our full cooperation and support to the various activities and initiatives which will be undertaken to achieve this aim.



Professor Francis Omaswa
Director General of Health Services
Kampala, October 2002

Introduction

For some considerable time problems affecting national pharmaceutical services provision have been recognised. Those in the area of drug supplies management, particularly in the districts, have featured prominently in various reviews and reports relating to the pharmaceutical sector.

Specific problems noted include drug leakages, absence of proper stock management information and poor storage conditions.

Drug management training was an element of the Uganda Essential Drugs Support Programme 1991–1996 but adequate drug management systems are still not consistently in place.

Although such problems can be assumed to have existed prior to 1993, the introduction of local government reforms with the resulting decentralisation of health service delivery have exacerbated the situation because of uncertainty regarding roles and responsibilities in the area of drug management. However these reforms also provide an opportunity for improving drug management in the districts.

The **Health Sector Strategic Plan 2000** defines procurement and management of drugs, medical supplies, and logistics as a key component of the integrated support systems element of the Plan. Major outputs identified are:

- an efficient and integrated procurement, distribution and storage system
- appropriate and adequate logistics
- efficient and effective drugs and medical supplies management system

The Joint Government/Development Partners Mission of November 1999 reviewed drug management and procurement from the perspective of the SWAp approach and observed that:

- despite efforts to establish an appropriate institutional framework for drug management the current system had weaknesses at all levels
- despite a reasonable per capita expenditure on drugs, the poorer segment of the population do not have adequate access to essential drugs
- the National Drug Policy had not been updated to take account of changing circumstances in the health sector
- decentralisation reforms had not taken into account the need to redesign the drug management system
- despite efforts to improve rational use of drugs, problems still persist with poly-pharmacy, over-prescribing and inappropriate self-medication
- despite an attempt to harmonise planning, procurement, storage and distribution of pharmaceuticals, this still remains a major problem in drug management

Key recommendations of the Joint Mission were

- the establishment of a Task Force on Drug Management with the responsibility of managing the transition and development towards a state of adequate functioning of the sector
- the establishment of a Commissioner for Pharmaceutical Services with adequate supporting human and other resources

The Task Force on Drug Management was subsequently established in late 1999 and functioned up to 2001. Its members included representatives of MoH Headquarters, MoH Districts, National Drug Authority, National Medical Stores, Pharmaceutical Society, Joint Medical Stores, the pharmaceutical private sector, the general public and health sector development partners. It was chaired by the Director of Health Services (Clinical and Community Health).

Its two main objectives were:

- to guide the process of reforming the pharmaceutical sector in general
- to establish a new system which can effectively secure access to essential drugs by the population within the concept of the new National Health Policy

Outputs expected from this Task Force were:

- a revised National Drug Policy
- an updated regulatory framework
- an adequate institutional framework for future drug management and a clear plan implementing necessary changes
- a proposal for the establishment of a Department of Pharmaceutical Services in the MoH with adequate technical and support staff
- a consolidated drug needs assessment

- a plan for essential resources for drug management
- a costed plan for the promotion of rational use of drugs
- a plan of action to address the drug leakage problem
- a plan for financing drug supply including the role of community schemes and cost recovery schemes
- a plan for harmonisation of drug procurement

A key activity related to the National Drug Policy output was to review the current National Drug Policy in a consultative process with relevant stakeholders.

According to WHO, a National Drug Policy is both a commitment to a goal and a guide for action. It expresses and prioritises the goals set by Government for the pharmaceutical sector and identifies the main strategies for attaining them. It provides a framework within which the activities of the pharmaceutical sector can be co-ordinated. It should include both the public and private sectors and the main actors in the pharmaceutical area.

The basis of any policy is a body of values, norms, standards and principles that guide decisions, strategies and actions. A drug policy is a global orientation with objectives and strategies to be undertaken to improve the national pharmaceutical sector and in particular the availability, accessibility and rational use of good quality essential drugs at affordable cost.

Following extensive planning the Task Force held a one-week National Drug Policy workshop in Jinja at the end of January 2000. The workshop was supported and assisted by WHO which sent three professional advisors (one from the AFRO Regional Office in Harare and two from the HQ in Geneva). One advisor participated with the Task Force secretariat in a week-long pre-workshop fact-finding and situation analysis exercise which included consultations with many of the key stakeholders and visits to 4 districts. Following extensive briefing the other two advisors participated in the workshop giving clear WHO guidance as to the most suitable approach for correct National Drug Policy formulation.

The workshop had presentations and intensive discussions on all areas of national pharmaceutical services and covered in detail all the main drug sector management issues which had been identified in the various reviews and reports. The successful outcome of the workshop was a working draft of the National Drug Policy. The Task Force further refined this in line with initial comments received from key stakeholders. The document was subsequently circulated to all stakeholders for further review and finalisation during a National Drug Policy Consensus Workshop which was held in Kampala in April 2000 as the final stage of the consultative process.

Following this workshop the agreed amendments and additions were incorporated into the final form of the document.

A peculiar feature of the previous National Drug Policy was that it was contained within the National Drug Policy and Authority Statute of 1993. This established the National Drug Authority as the national drug regulatory body with one of its functions the implementation of the Policy.

This proved to be a very difficult and impractical arrangement as:

- the policy was not comprehensive, simply consisting of a series of brief statements of intent
- no strategies were identified for implementation of the policy
- it was beyond the capacity of NDA to satisfactorily implement the policy in addition to its primary and increasingly demanding drug regulatory role
- the fact that the policy was enshrined in the statute meant that any amendment required would have to go through the complex and prolonged legal process involving ultimate approval by parliament. As policies are supposed to be dynamic management tools under constant review and capable of suitable amendment to respond to changing circumstances,

this was obviously a major obstacle to implementation.

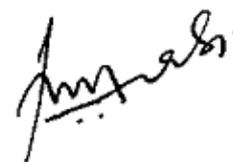
Thus one of the main recommendations of the Task Force workshop was that the National Drug Policy should be separated from the statute so that it can be used, implemented and amended as required.

This step will also represent the first stage in the preparation of a revised statute which is another key output expected of the Task Force. Considerable work has already been done on proposed revisions of other elements of the statute. It is expected that the end result of these changes will be a much improved and updated statute which will greatly strengthen the ability of the NDA to effectively implement the necessary regulatory controls for the pharmaceutical sector in Uganda.

The formal Ministry of Health adoption of this new NDP was followed by the development of a comprehensive, detailed 5-year National Drug Policy Implementation Plan (or National Pharmaceutical Master Plan).

The successful implementation of this will require major commitment and support of MoH and stakeholders in the pharmaceutical sector and significant and sustained financial and technical assistance from our development partners.

It is our sincere hope and expectation that the outcome will be significantly improved national pharmaceutical service provision and pharmaceutical care for each individual patient.



Dr Sam Zaramba
Director of Health Services (Clinical and Community Health)
Chairman, Task Force on Drug Management
Kampala, October 2002

Members of the MoH Task Force on Drug Management

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Mr Chris Forshaw	Danida/Uganda Health Sector Support Programme Pharmaceutical Advisor, NDA Editor, NDP

National Drug Policy

Overall goal

The National Drug Policy (NDP) aims to contribute to the attainment of a good standard of health by the population of Uganda, through ensuring the availability, accessibility and affordability at all times of essential drugs of appropriate quality, safety and efficacy, and by promoting their rational use.

Main objectives

1. **Access:** to make essential drugs accessible to all those who need them by ensuring that they are affordable and always available in all parts of the country.
2. **Quality:** to ensure that all drugs available to the public are of appropriate quality, safety, and efficacy.
3. **Rational Drug Use:** to actively and continuously promote the rational use of drugs and to provide objective, relevant and practical information to health workers, patients and the general public.
4. To institute and sustain suitable drug financing mechanisms which will ensure the continuous availability of adequate quantities of the required essential drugs.
5. To ensure the availability of sufficient suitably trained pharmaceutical and other relevant staff to enable effective implementation of NDP.
6. To optimize use of available resources, knowledge and expertise in implementation of NDP through the establishment of an active partnership between the community, government bodies and private providers (profit and non-profit) involved in the pharmaceutical sector and through cooperation with regional and international agencies.

Note: the terms 'drug' and 'medicine' are used synonymously throughout the document and, unless otherwise specified, apply to human, veterinary and commercial traditional medicines.

Policy Areas of the NDP

1. Pharmaceutical legislation and regulation
2. Drug selection
3. Drug supply:

- 3.1 Quantification
- 3.2 Procurement (including donations)
- 3.3 Storage and inventory control
- 3.4 Distribution
- 3.5 Local production
- 3.6 Quality assurance
- 3.7 Disposal of expired or otherwise unwanted drugs and medical supplies

4. Rational drug use and drug information:

- 4.1 Prescribing
- 4.2 Dispensing
- 4.3 Patient use
- 4.4 Drug information

5. Drug financing and pricing

- 5.1 Drug financing
- 5.2 Drug pricing

6. Traditional medicines

7. Human resource development

8. Research and development

9. Technical co-operation

10. Monitoring and evaluation

1. Pharmaceutical legislation and regulation

Goal: to provide a comprehensive, appropriate legislative framework for effective implementation of the NDP.

Objectives:

- 1. To improve the efficiency and effectiveness of the drug regulatory agency in ensuring the required control of human, veterinary and commercial traditional medicines
- 2. To ensure that all forms of drug handling are appropriately regulated, duly authorised and licensed
- 3. To ensure that all persons involved in drug handling are appropriately licensed
- 4. To ensure that pharmaceutical professional practices are effectively monitored and controlled by the relevant professional bodies according to the applicable statutes
- 5. To ensure that all premises where drugs are handled (eg. manufacturing, wholesale, retail) are regularly inspected, appropriately regulated and duly authorised and licensed
- 6. To facilitate efficient and reliable human and veterinary drug registration according to strictly defined criteria
- 7. To promote a strong awareness in the public of the need for appropriate controls on the handling and use of drugs, and on substances of abuse.

8. To develop appropriate terms of reference and financial mechanisms to ensure the sustainable and effective functioning of the drug regulatory agency.

Strategies:

1. Update existing pharmaceutical legislation to take account of the changing environment (eg. health policy, decentralization, professional laws) and to generally improve Government regulation and control of all aspects of drug handling and use, including drug manufacture, import, export, marketing, storage, sale and supply
2. Strengthen and streamline the regulations, processes and procedures and ensure the human resource, technical, financial and logistical capacity necessary for the effective application of legislation, including in particular those required for enforcement
3. Improve the reliability, efficiency and effectiveness of the drug registration process
4. Enhance the capacity of the drug regulatory agency to effectively implement controls on veterinary and commercial traditional medicines
5. Improve the inspection and licensing of pharmaceutical premises (eg. factories, stores, pharmacies, drug shops, etc)
6. Improve procedures for the evaluation, monitoring, control and support supervision of all pharmaceutical personnel
7. Establish a reliable and well-functioning national drug quality control laboratory which is administratively independent but functionally linked to the drug regulatory agency
8. Collaborate with other national, regional and international agencies in efforts to combat drug and substance abuse, illicit drug sales and counterfeit drugs and to ensure adequate control of the handling and use of all drugs and chemicals in circulation
9. Build capacity both at the centre and district to enable and maintain effective decentralisation of drug regulatory activities
10. Use appropriate communication strategies to sensitize the public on hazards associated with all forms of unauthorised drug handling and use and the need to have effective enforcement and strengthening of regulatory controls.

2. Drug selection

Goal: to ensure that drugs selected are both affordable and appropriate for the needs of the human and animal population of Uganda according to Essential Drugs concepts.

Objectives:

1. To ensure that drugs selected for use in both the public and private health sectors at all levels of the health system are the most appropriate to meet the currently recognised needs of the majority of the population
2. To improve the understanding by health workers, patients and the public of essential drugs concepts as they relate to the drug selection process
3. To maximise the use of the Essential Drugs List of Uganda (EDLU) as the primary tool for drug selection at all levels of the health system
4. To strengthen and harmonise the essential drugs selection process at national and district levels for both public and private sectors.

Strategies:

1. Carry out regular review and revision of the EDLU (at least every 3 years) using the current WHO model list as a basis and taking into account available resources and currently applicable clinical practices
2. Ensure that all involved in drug selection understand established selection criteria and the need to apply these in the context of public health needs
3. Ensure the use of the EDLU as a basis for procurement, prescribing and dispensing in the public health system and promote its use in the private (profit and non-profit) sector.

3. Drug supply system (quantification, procurement, storage, distribution)

Goal: to establish and maintain a secure, cost-effective drug supply system in order to ensure that required essential drugs are available and accessible to the population and that quality is maintained up to the point of use.

3.1 Quantification

Goal: to establish and maintain a reliable system with appropriate mechanisms for regular and accurate quantification of essential drug needs at all levels of the health system.

Objectives:

1. To improve the availability and reliability of required quantification data
2. To enhance the capacity to carry out quantification at each level of the health system
3. To improve the ability to correctly utilise the data
4. To avoid wastage and drug expiry caused by over-estimation of requirements

Strategies:

1. Promote collaboration with relevant partners (eg. members of the district health team, national drug procurement agency, national drug regulatory agency) to establish and maintain a reliable drug management information system (DMIS) and health management information system (HMIS) which will ensure the ready availability of accurate morbidity and drug consumption data required for drug quantification purposes and the regular and timely feedback of useful information to the partners
2. Develop and distribute quantification guidelines for each level.
3. Ensure the necessary quantification capacity at all levels by training sufficient relevant staff in record-keeping and quantification methodology and by providing adequate monitoring and supervision of the processes involved
4. Systematically collect and analyse the relevant data
5. Ensure that periodic and regular quantification is carried out at all levels.

3.2 Procurement (including donations)

Goal: to maintain the constant availability at all levels of adequate quantities of the required essential drugs through the institution and further development of a rational, harmonised, efficient and cost-effective system of procurement

Objectives:

1. To develop procurement capacity, skills and experience at all levels so that a system of drug procurement is established which is:

- appropriate
- timely
- efficient
- cost-effective
- harmonised
- transparent

in order to:

- optimise utilisation of available funding
- guarantee the constant availability of required essential drugs
- gain and maintain the trust of the public, donors and all other interested parties in the credibility and validity of the procurement system

2. To avoid wastage of resources through inefficient drug procurement practices (eg. procurement of low-quality or short shelf-life drugs, procurement delays leading to stock-outs, etc)

3. To ensure procurement of generic drugs in the public sector and encourage this in the private sector.

4. To maximise appropriate procurement of locally produced essential drugs.

Strategies:

1. Develop and implement appropriate procurement guidelines for all levels of the health system

2. Carry out a suitable and continuing programme of training at all levels in procurement procedures and establish a system for monitoring and support supervision

3. MoH to arrange in close collaboration with all key stakeholders to develop, introduce and implement strategies and procedures and guidelines to co-ordinate, harmonise, integrate and monitor public sector drug procurement in whatever form, including:

- routine procurement through the national drug procurement agency
- procurement by the districts
- procurement through development partner-funded programmes
- drug donations

Subsequently MoH to monitor all future public sector procurement activities to ensure strict adherence to the agreed guidelines.

4. Ensure that drug procurement for the public sector is based on the EDLU

5. Collaborate with relevant donor agencies to produce guidelines, and statutory instruments as required, for drug donations (based on the WHO model and appropriately adapted for national use) and institute an audit system to ensure adherence to these and to established procedures

6. Ensure that the national drug procurement agency maintains and further develops its capacity to carry out timely and efficient procurement for the public health system (including procurement of national strategic stocks, eg. vaccines and essential items of low commercial

value)

7. Encourage the private sector to procure drugs so as to complement the public sector procurement system, eg. procurement of *essential* drugs by *generic* name
8. Encourage local pharmaceutical manufacturers to produce essential drugs at competitive prices and encourage procurement agencies to source available essential drugs locally in order to support the local industry
9. Establish a monitoring and evaluation system to ensure adherence to procurement guidelines and procedures and to measure progress towards achievement of procurement objectives

3.3 Storage and inventory control

Goal: to ensure that all drugs are appropriately, cost-effectively, safely and securely stored at all levels in order to maintain quality and minimise storage-related costs and drug losses from whatever cause.

Objectives:

1. To ensure that adequate financial, physical, technical and human resource capacity is available to maintain and develop the required storage and inventory control systems at all levels
2. To ensure adherence to recommended storage and inventory control procedures
3. To minimise wastage and losses arising from poor storage/inventory control practices

Strategies:

1. Produce guidelines on recommended good practices for storage and inventory control procedures for all levels, especially for public sector institutions
2. Train all staff involved in recommended inventory control and storage practices and institute adequate support supervision and monitoring systems to ensure adherence to recommendations
3. Review and improve relevant record-keeping to ensure that required data is accurate and readily available
4. Carry out inspections of existing storage facilities in both public and private sectors and determine additional requirements and improvements
5. Ensure that sufficient and appropriately designed/equipped storage facilities are available and that they are properly maintained

3.4 Distribution

Goal: to establish and maintain a distribution system which ensures equity of access to, and the constant availability of, required essential drugs throughout the country.

Objectives:

1. To increase the capacity (eg. human resources, logistics, information) of the drug distribution system to provide reliable and efficient distribution services
2. To ensure the establishment of and adherence to good distribution practices

3. To ensure equitable distribution (and re–distribution where necessary) of drugs to all parts of the country
4. To harmonise public sector drug distribution
5. To establish appropriate structures and systems at national and district levels which will ensure efficient distribution of essential drugs and secure access to these by the population.

Strategies:

1. Produce guidelines on good pharmaceutical wholesale and distribution practice
2. Train sufficient numbers of staff required for drug distribution operations (in both public and private sector) and ensure the establishment of an appropriate system of monitoring and support supervision
3. Produce guidelines, establish systems and incentives to promote, and introduce statutory controls as required to enforce, the equitable distribution of drug outlets
4. Establish and maintain an efficient mechanism for the identification and redistribution of excess stocks in both government and non–government institutions
5. Collaborate with all relevant parties in order to promote to the greatest extent possible the harmonisation of the public and private sector drug distribution networks

3.5 Local production

Goal: to consider, and support if appropriate, development of efficient local production of essential drugs of good quality, safety and efficacy, relevant to national needs and resources.

Objectives:

1. To create an environment conducive to the establishment of increased national capacity for the production of essential drugs
2. To ensure that local production follows recommended procedures, ie. current Good Manufacturing Practice (cGMP), and statutory requirements

Strategies:

1. Establish a system of incentives for the local manufacture of essential drugs (eg. tax incentives, tender preference, reduced import tariffs, reduced rates for electricity and water consumption)
2. Institute regular and systematic inspection of premises and processes to ensure full adherence to licensing requirements and current Good Manufacturing Practice (cGMP)
3. Improve local pharmaceutical technical capacity by encouraging and assisting in the training of sufficient numbers of staff in pharmaceutical production techniques, quality assurance and cGMP.
4. Institute a system of monitoring and support supervision to ensure maintenance of required standards.

3.6 Quality assurance

Goal: to protect the health of the consumer from harmful effects which may be caused by the use of counterfeit, unsafe, ineffective or poor quality medicines and other medical products.

Objectives:

1. To establish and maintain a comprehensive system of quality assurance which can efficiently detect problem products and ensure that the required safety, effectiveness and quality of medicines and other medical products is maintained throughout the entire medical supply system up to the point of use.
2. To promote a good understanding of the need for effective quality assurance of medicines and other medical products by all those involved in the medical supply process, including the consumer.

Strategies:

1. Establish, adequately support and maintain the effective and efficient operation of a reliable, comprehensive National Drug Quality Control Laboratory (NDQCL).
2. Establish effective working links between the NDQCL and other (local, regional, international) drug/medical supplies quality assurance agencies and promote active collaboration with them.
3. Establish close liaison and effective working procedures with other national bodies involved in import control and drug handling surveillance, eg. Customs, Police Drug Squad, in order to detect and intercept problem items, eg counterfeit or other unregistered medicines.
4. Select medicines on the basis of quality, safety, efficacy and stable dosage forms.
5. Only obtain medical supplies from suppliers with acceptable quality standards and procedures.
6. Ensure that medicines received from commercial suppliers and donors meet specified quality standards at the time of delivery and are registered for use in Uganda.
7. Ensure that medicines packaging meets contract requirements and can effectively withstand handling and storage conditions.
8. Ensure that any re-packaging and dispensing activities maintain quality.
9. Ensure that drug storage and transportation conditions are adequate to maintain quality.
10. Promptly address and resolve medicinal product quality concerns reported by health professionals and consumers.
11. Implement effective and efficient recall procedures to promptly remove from circulation defective medical products which may represent a health hazard to the consumer or user.
12. Provide adequate training in and supervision of drug quality assurance for those involved in the drug supply process at all levels.
13. Establish and maintain an effective drug information system to adequately support drug quality assurance requirements.
14. Design and institute a system of post-marketing surveillance (PMS) effectively to monitor the quality of medical products in circulation.
15. Disseminate relevant practical information on the need for and requirements of quality assurance measures to health professionals, patients and the public in order to help maintain

medicinal product quality.

3.7 Disposal of expired or otherwise unwanted drugs and medical supplies

Goal: to protect the health of the public from potential harm which may result from the unsafe or ineffective disposal of expired or otherwise unwanted medical items including drugs.

Objective:

To institute and maintain a system which will ensure the safe, effective and controlled disposal or destruction of such items

Strategies:

1. Collaborate with all relevant agencies in drawing up and effectively implementing:

- national guidelines for the disposal of these items (preferably within the context of a national health–care waste management plan)
- any necessary supporting legislation and standards

The guidelines and plan will include safe and cost–effective strategies and procedures for:

- identification of drugs and medical supplies waste
- records
- handling
- segregation
- recycling
- collection
- transport
- storage
- disposal/destruction

2. Develop, institute and maintain a training programme for all those who will be involved in the handling and processing of such waste.

3. Systematically monitor and evaluate the implementation of the drugs and medical supplies waste management plan and make any necessary amendments.

4. Ensure adequate investment in the required waste disposal equipment/technology in order to establish adequate national capacity to efficiently dispose of unwanted medical products.

4. Rational drug use and drug information

Goals:

- To promote rational prescribing, dispensing, and administration of drugs by health workers
- To support appropriate and informed use of drugs by individuals and the community
- To improve the capacity for monitoring and evaluation of drug use in the health system and the community as a guide to the formulation of appropriate interventions

4.1 Drug information

Goal: to ensure that appropriate information on the correct use and storage of drugs is readily available, widely disseminated and used accordingly.

Objectives:

1. To ensure the availability of, ready access to and correct application of consistent, appropriate information on drugs and therapeutics for health workers, patients and the public in general
2. To ensure that information used in the promotion and marketing of medicines is unbiased, accurate and not misleading

Strategies:

1. Establish a drug information infrastructure/system, including a National Drug and Poisons Information Centre, to provide on request and actively disseminate objective, relevant, practical and up-to-date information to health workers and consumers
2. Establish a suitable body, representing all agencies involved in production and dissemination of drug and therapeutics and rational drug use information and including relevant consumer bodies to ensure the relevance, appropriateness, harmonisation and co-ordination of the information to be provided and to avoid conflicting messages and duplication of effort and expense
3. Ensure continuous review and regular periodic revision and publication of the:
 - Essential Drug List for Uganda (EDLU)
 - Essential Veterinary Drug List for Uganda (EVDLU)
 - National Standard Clinical Guidelines (NSCG) (including Standard Diagnostic and Standard Treatment Guidelines)
 - Uganda National Formulary (UNF)
4. Train health workers in the appropriate use of drug information sources and institute a system for monitoring and provision of support supervision in this area.
5. Produce and distribute guidelines for drug promotion and marketing (based on WHO recommendations and existing national requirements) and ensure their effective enforcement through appropriate legislation, including controls on advertising.

4.2 Prescribing

Goal: To ensure that maximum therapeutic benefits are obtained from prescribed medicines through the adoption of recommended, rational prescribing practices by all prescribers.

Objectives:

1. To ensure that all prescribing, whether in the public or private sectors, conforms with agreed national standards and recommendations
2. To ensure the provision of appropriate prescribing information and guidelines
3. To introduce a system for the reporting of adverse drug reactions and quality defects

Strategies:

1. Carry out regular revision and periodic production of the NSCG (at least every 3 years) and its efficient distribution of to all relevant health workers
2. Ensure the use of EDLU as a basis for all public sector prescribing of medicines and promote its use in the private sector
3. Promote use of the EDLU and NSCG as a basis for the rational use of drugs through continuous in-service training and support supervision
4. Establish a practical and sustainable system of monitoring and evaluating prescribing practices as a means of identifying and planning necessary interventions
5. Actively support the establishment and functioning of drug and therapeutic committees (DTC) in all hospitals and districts through *inter alia* the preparation and provision of guidelines for their operation and instituting a feedback system to follow-up on key issues
6. Ensure that hospitals develop their own formularies as needed based on the EDLU and NSTG and on DTC recommendations.
7. Encourage teaching hospitals to recruit a clinical pharmacist to advise on good prescribing practice and assist on ward rounds
8. Enforce the statutory requirement that all prescriptions in the public health sector should be written using generic names and actively promote the use of generic names for prescribing in the private sector
9. Ensure that formal training in rational prescribing and rational use of drugs in general is included in the training curricula of all relevant health workers
10. Actively encourage all health workers to report on adverse drug reactions (ADRs) and suspected quality defects and institute a sustainable system for the collation and analysis of such reports and the wide dissemination of practical information/advice on ADRs and drug quality problems to health workers and the public.

4.3 Dispensing

Goal: to ensure the provision of high quality dispensing services throughout the public and private health systems.

Objectives:

1. To ensure that dispensing practices at all levels in both the public and private sectors comply with recommended standards of good dispensing practice
2. To improve the availability and performance of suitably trained dispensing staff
3. To institute generic substitution as a means of improving access to and affordability of drugs

Strategies:

1. Develop and circulate guidelines on good dispensing practice for all dispensing personnel in both the public and private sectors
2. Ensure the training of sufficient numbers of the required dispensing staff and incorporation of essential drugs/rational drug use concepts into formal training curricula

3. Establish a practical and sustainable system for the regular monitoring of dispensing practices
4. Strengthen systems and procedures for the inspection and licensing of dispensing premises and personnel
5. Actively promote the concept and practice of appropriate generic substitution in dispensing following strict criteria and update the relevant legislation accordingly.

4.4 Use of drugs by individuals and the community

Goal: to ensure correct use of medicines by patients and the general public

Objectives:

1. To increase and improve the understanding of the place of drugs in treatment
2. To rationalise the use of drugs by patients and the community, maximising therapeutic benefits and minimising potential hazards

Strategies:

1. Design and implement an effective and sustainable system for producing and disseminating objective, relevant and practical information to the public on drugs, self medication and the treatment of common conditions using all available media
2. Create nation-wide community awareness of issues related to essential drugs, rational drug use and adverse drug reactions
3. Actively encourage all health workers to adopt professional practices in handling drugs and carefully counsel patients on the correct use and storage of prescribed and dispensed medicines
4. Implement suitable measures to ensure that all those involved in over-the-counter drug sales follow ethical procedures in handling drugs and provide clients with practical and relevant information on the correct use and storage of drugs
5. Actively encourage the reporting of adverse drug reactions (ADRs) and suspected drug quality problems by individuals and ensure the prompt and appropriate investigation of such reports, subsequent feedback to the complainant, and the dissemination of information on these issues to health workers, patients and the public in general.

5. Drug financing and pricing

Goal: to ensure the constant availability of adequate quantities of required essential drugs at affordable prices.

5.1 Drug financing

Goal: to ensure that sufficient funds are available to maintain a regular and adequate supply of the required essential drugs and equitable access to these by the population.

Objective:

1. To develop and support suitable and sustainable drug-financing mechanisms at all levels

2. To encourage private sector investment in appropriate pharmaceutical service provision and pharmaceutical manufacturing.

Strategies:

1. Ensure adequate annual MoH budget allocations for procurement of drugs & medical supplies
2. Establish an effective mechanism at national and district levels for the rapid mobilisation of funds for drugs and medical supplies required in the handling of health emergencies (eg. epidemics and disasters)
3. Encourage and support the development and strengthening of national and community schemes which contribute to the sustainable financing of essential drug (eg. user fees, Bamako Initiative type schemes, drug revolving funds, health insurance schemes, etc)
4. Set up a drug financing and pricing committee within MOH (involving all relevant stakeholders) to:
 - actively investigate and make recommendations on available options for funding of public sector supply of drugs and medical supplies (eg. regular budget, user fees, health insurance schemes, donor in-puts, etc)
 - co-ordinate and integrate such funding
 - monitor drug prices (world market, local retail, wholesale and cost)
 - periodically publish drug indicator prices based on currently available price information, eg. WHO, MSH, national drug procurement agency, etc.

Identify and establish incentives to promote private sector involvement and investment in the cost-effective and equitable provision of pharmaceutical services as well as in the local manufacture of essential drugs.

5.2 Drug pricing

Goal: to promote equity of access to essential drugs by ensuring that they are affordable to the country and the population

Objectives:

1. To maintain consumer prices of essential medicines available in the country at the minimum possible using all available options.

Strategies:

1. Design, establish and maintain a system for the monitoring of world market, local retail, wholesale and cost prices of essential drugs, setting of indicator prices and the regular and effective dissemination of these to both suppliers and consumers (see also 5.1 strategy 4)
2. Ensure that prices of drugs purchased for the public sector do not exceed the relevant indicator price through close monitoring of procurement at each level
3. Actively promote the concepts and practice of generic prescribing and appropriate generic substitution as a means of minimising drug costs
4. Ensure that the implications of the World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights (WTO/TRIPS Agreement) are well publicised and understood by the relevant policy-makers.

5. Ensure that national patent legislation is suitably amended to enable advantage to be taken of WTO/TRIPS Agreement exemption provisions related to the importation and manufacture of patented medicines.

6. Ensure appropriate application of the (WTO/TRIPS Agreement) provisions related to the importation and manufacturing of patent medicines (eg. compulsory licences, parallel imports, allowable exceptions).

6. Traditional medicines

Goal: to maximise the benefits and minimise the hazards associated with the use of Traditional Medicines (TM) in both human and animal treatment.

Objectives:

1. To identify, investigate and characterise useful TM
2. To promote understanding of the place of TM in human and animal treatment by both health professionals and the public.
3. To integrate TM into human and veterinary therapeutic practice
4. To regulate the commercial manufacture, distribution, marketing and handling of TM
5. To promote local production of useful and commercially viable TM
6. To collaborate with other countries in the region in exchange of information and experiences with TM

Strategies:

1. Promote research into and standardisation of TM by strengthening national TM research capacity
2. Promote understanding of the potential benefits and hazards of TM through supporting co-ordination and collaboration between TM practitioners and other interested parties, eg. health providers, health institutions, development partners, local communities
3. Establish and maintain a process for the systematic assessment and registration of TMs by the national drug regulatory authority and for subsequent patenting of suitable commercial products
4. Promote the appropriate use of TM as an integrated part of disease management through the dissemination of practical and useful information to health professionals and the public
5. Encourage the development and maintenance of medicinal plant gardens in order to sustain the supply of raw materials required in the local production of essential TM
6. Establish effective working links with TM agencies in the region to facilitate the exchange of useful information and experiences

7. Human resource development

Goal: to develop and maintain an adequate human resource base for NDP implementation at all levels

Objectives:

1. To significantly improve MoH headquarters pharmaceutical capacity to reflect the fundamental importance of pharmaceuticals in health service provision and to provide for the required future development and co-ordination of national pharmaceutical services
2. To ensure that adequate numbers of suitably trained and highly motivated personnel are available throughout the health system (public and private) for the effective implementation of the NDP
3. To ensure the continued motivation and further professional development of pharmaceutical professionals (ie. pharmacists, pharmacy technicians and dispensing assistants) in order to encourage their retention within the public health sector
4. To improve drug supply management capacity and performance in hospitals and the districts
5. To institute and maintain the application of good pharmaceutical practice in all relevant activities

Strategies:

1. Adequately support and strengthen MoH headquarters department of pharmaceutical services in order to provide for core functions including:
 - monitoring and supervision of national pharmaceutical services
 - direction and co-ordination of policy implementation
 - effective policy review and further development
2. Identify pharmaceutical and other relevant human resources required (numbers, experience and skills) at all levels for the implementation of key NDP activities
3. Actively promote the training and recruitment of pharmaceutical professionals at all levels in order to manage the drug supply system and effectively implement the NDP. Ensure their continued motivation and retention through the provision of proper incentives, including:
 - regular in-service training
 - continuing professional education/development activities
 - post-graduate training courses, etc.
4. Ensure the appropriate incorporation and coverage of NDP, PHC, ED/RDU and drug supply management concepts in the training curriculum of all health workers
5. Ensure that the formal curriculum of all pharmacy professionals includes the following elements:
 - public health
 - health policy
 - drug supply management
 - drug policy issues
6. Identify and develop mechanisms for the appropriate deployment of all pharmacy professionals which will ensure equitable distribution and provision of pharmaceutical services.
7. Identify and introduce a system of incentives to encourage health workers suitably trained in drug supply management to work in under-served areas
8. Increase the capacity of the districts and hospitals (referral, regional and district) to carry out effective drug supply management and to effectively implement relevant NDP activities,

both in terms of numbers of staff and required skills

9. Establish posts for district pharmacists to be responsible for overall direction of pharmaceutical services in each district
10. Ensure that all those involved in dispensing activities in retail drug outlets have at least a basic training in good dispensing practice (see also 4.3)
11. Institute a system of continuing in-service training in NDP concepts and their practical application for all relevant health workers
12. All health professional councils should continue to set and refine standards of practice and training and should introduce a requirement for continuing competence/continuing professional development as a basis for the renewal of practice licenses and professional registration
13. Continuously monitor the pharmaceutical human resource situation, identify gaps, deficiencies and suitable solutions, and provide adequate support supervision in order to sustain effective implementation of the NDP
14. Identify centres of excellence and institute suitable arrangements to facilitate their effective collaboration in national pharmaceutical human resource development.

8. Research and development

Goal: to promote all forms of research relevant to identified needs and especially research which will contribute to the effective implementation of NDP.

Objectives:

1. To enhance overall and specific research capacity in order to support relevant drug-related research
2. To identify key areas of NDP where research will be required
3. To provide health professionals with encouragement and support to enable them to undertake useful research
4. To ensure widespread dissemination and appropriate utilisation and application of research findings in the further development of health policy and practice

Strategies:

1. Support and develop strong working links with relevant existing research institutions
2. Encourage health professionals into drug-related research through continuing professional education and postgraduate studies and sensitise the pharmacy council to provide appropriate guidance and support
3. Identify and support operational research in key areas of NDP implementation and facilitate use of the findings as part of routine monitoring, evaluation and planning exercises
4. Assist the drug regulatory authority to produce guidelines for conducting drug-related clinical trials and ensure that they are correctly applied in line with good clinical practice
5. Promote and support relevant research into all aspects of herbal/traditional medicine in order to characterise and standardise their use, maximise benefits and minimise potential hazards

6. Encourage appropriate research and development of essential pharmaceutical products
7. Provide support and encouragement for districts to carry out problem-solving research into important issues, eg. key aspects of drug management and utilisation
8. Ensure the sensitisation and active participation of the community in all relevant research activities
9. Establish a system to facilitate dissemination of useful research findings to all interested parties (including, where appropriate, the community) and sensitise health policy-makers to the practical utilisation of these in the further development of health services.

9. Technical co-operation

Goal: to establish, maintain and effectively utilise all available forms of technical co-operation which will support the successful implementation of NDP.

Objectives:

1. To establish and actively maintain a framework for technical cooperation which maximises the exchange of required information, skills and experience
2. To harmonise procedures and standards in key areas
3. To encourage the establishment and appropriate utilisation of national and regional centres of technical excellence

Strategies:

1. Identify, establish contact and maintain regular working relationships with international, regional, and national agencies, institutions and bodies to facilitate ongoing technical cooperation and the exchange of required information, skills and experience
2. Utilise such links to facilitate harmonisation of procedures and standards in priority areas (eg. registration and licensing, quality control, drug inspection, training, technical reports)
3. Promote the optimal use of existing resources by identifying and encouraging national and regional specialisation and capacity in priority areas of required competence

10. Monitoring and evaluation

Goal: to ensure that the processes, strategies and outcomes of NDP implementation shall

Objectives:

1. To establish and sustain an effective system of monitoring and evaluation of NDP implementation
2. To ensure that the results of such monitoring and evaluation are appropriately applied to facilitate the further planning and necessary refinement of NDP implementation.

Strategies:

1. Identify priority areas of NDP implementation for monitoring and evaluation, eg. drug availability, accessibility, affordability, quality, efficacy, prices (cost of a basket of the

commonest essential drugs), enforcement of regulations, etc.

2. Develop guidelines and indicators for monitoring and evaluation of the NDP
3. Identify and develop monitoring and evaluation capacity at all levels
4. Utilise, develop and support existing institutions to enable effective monitoring of NDP implementation
5. Institute a sustainable system of on-going monitoring of key components of the NDP, with reference to the implementation plan and relevant indicators
6. Evaluate the progress towards the stated NDP goals and objectives every 2–3 years, ensuring the involvement of both external and internal evaluators
7. Effectively utilise the results of monitoring and evaluation for the improvement of further planning and implementation of NDP.