INTRODUCTION:

Health is a constitutional right of every citizen of India. It is the basic need of individuals irrespective of caste or creed, rich or poor. Health is in the concurrent list and is the purview of the centre and the state. The Government of Mizoram, through the Department of Health and Family Welfare takes several initiatives to improve the health of its people by implementing various central schemes like National Health Mission (NHM), Revised National Tuberculosis Control Programme (RNTCP), Integrated Diseases Surveillance Programme (IDSP), National Vector Borne Diseases Control Programme (NVBDCP), National Iodine Deficiency Control Programme (NIDDCP), National Leprosy Eradication Programme (NLEP), National Programme for Control of Blindness (NPCB), School Health Programme, etc.

However, the success of all the above programmes whether it is a Central Scheme or a State Programme fully depends on the availability of safe, efficacious and quality drugs at an affordable price with strict adherence to Rational use of medicines and rational approach to therapeutics.

Realizing the importance of health care, the State Government has been providing the necessary policy frame work, institutions and resources in the shape of finances, personnel, drugs and equipment for the delivery of public health care services in the State. Over the years, there has been a remarkable expansion of health institutions in the Government sector. A large number of personnels have been and are being recruited. Priority has been given to development of health infrastructure. Considerable volume of equipment is being procured annually. Free medicines are being provided as per availability of the budget. There has been a considerable expansion of the referral transport system. At present, there is availability of a variety of specialized and super specialty services in various disciplines within the State. The result of this has been that the health indicators in the State have improved.

The single most vital component of health care is drugs as they account for substantial part of household expenditure on health. The market for drugs has been growing rapidly in terms of production, trade, investment, employment and consumption. However, the industry is characterized by various features like growth of irrational drug combinations and highly priced branded drugs which wastes a lot of patients' money. The capacity of the Health Services to procure good quality drugs and ensure timely supply also has scope for improvement.

Irrational use of drugs leads to serious problems through adverse drug reactions, drug resistance, increased morbidity and high cost. The Food & Drug Administration also has constraints of capacity in ensuring the required quality standards of the drugs under

the provisions of law.

Although the intention of the Government is to promote equitable, affordable and quality health care, there is a need to provide a clear guide for action. Keeping in view the importance of drugs in the healthcare services, a specific state essential generic drug policy in the State of Mizoram is required not only to reiterate the commitment of the Government to the goal of improved health care services but also to provide clear priorities and strategies. The essential generic drug policy is envisaged to prioritize and express the goals and identify the main strategies for achieving them.

OBJECTIVES:

The Government of Mizoram is committed to promote access to affordable essential medicines of high standard quality to the people of the State. This, in the broadest sense, is the main objective of the essential generic drug policy. In more specific terms, the policy objectives are the following:-

(i) To promote accessibility of medicines. This would mean equitable availability and affordability of essential medicines including traditional medicines.

(ii) To ensure safety, quality and efficacy of medicines.

(iii) To promote prescription of drugs in generic name at public and private sector.

(iv) To promote good prescribing practices , dispensing practices and rational use of drugs in the public and private sectors.

(v) To provide cost effective, efficient procurement and supply management system for drugs.

(vi) Strengthening of Health programme to provide research on all aspects of drug use.

STRATEGIES:

Achieving the objectives of the essential generic drug policy requires adoption of various strategies and policy measures which are explained in the following paragraphs:-

1. SELECTION OF ESSENTIAL MEDICINES:

1.1 Importance of the concept:

The State Government in order to attain rational use of safe and efficacious drugs, convened a meeting of several Stakeholders including Doctor, Specialists from in and outside the state to formulate the Mizoram State Essential Medicine List and the list presents a list of minimum medicines needed for our state's basic health care systems listing the most efficacious, safe and cost-effective medicines for priority conditions. They are selected on the basis of current and estimated future public health relevance and potential safe and cost effective treatment.

1.2 Selection process:

1.2.1 Selection of drugs is a crucial step in ensuring access to essential drugs and in promoting rational use of drugs. Drug selection would be based on the well accepted concepts and principles of essential drugs which have also been recommended by the World Health Organization. The Department of Health & Family Welfare shall appoint an Expert Committee known as the **State Drug Consultative Committee** which will comprise of the following members:-

1.	Secretary, Health & Family Welfare	- Chairman
2.	Principal Director, Health & Family Welfare	- Co-Chairman
3.	Director, Health Services	- Vice Chairman
4.	Director, Hospital & Medical Education	- Vice Chairman
5.	Head of Drug Control Administration	- Member Secy.
6.	Joint Director (P), DHS	- Member
7.	Joint Director (P), DHME	- Member
8.	Medical Superintendent, Civil Hospital, Aizawl	- Member
9.	HOD of every clinical discipline, Civil Hospital, Aizawl	- Member
10.	HOD, Deptt of Pharmacy, RIPANS	- Member

The Committee would be responsible for initially preparing and subsequent updation of the essential drug list every two years for the public sector. A separate Drug Consultative Committee with appropriate composition would be constituted in respect of drugs pertaining to Indian Systems of Medicine.

1.2.2 The selection of essential drugs will be based on the following criteria:

a) Therapeutic need
b) Relevance to State morbidity and Mortality pattern
c) Safety, quality and efficacy
d) Cost effectiveness
e) Ease & safety in administration and dispensing
f) Usefulness in more than one condition
g) Likelihood of patient compliance
h) Training and experience of the prescribers
i) Treatment facilities in the State

1.2.3. The State Drug Consultative Committee would be guided by the following principles while preparing the essential drug list:-

(i) Only medicines with sound and adequate evidence of efficacy and safety in a variety of settings should be selected.

(ii) Relative cost effectiveness would be a major consideration for choosing medicines within the same therapeutic category. While comparing between medicines, not only the unit cost of medicines but the total cost of treatment must also be kept in mind along with its efficacy.

(iii) The drugs selected shall be identified and listed by their generic name or International Non-proprietary Name (INN) only.

(iv) In some cases the choice may be influenced by other factors such as pharmacokinetic properties or by local considerations such as the availability of facilities for storage, effects of local diseases , food habits on drug effectiveness (e.g. malnutrition, liver diseases etc.), local differences in sensitivity and resistance of micro-organisms and differences in climate, topography and other

environmental factors.

(v) Medicines selected must be available in a dosage form in which adequate quality including bioavailability can be ensured. Its stability under the anticipated conditions of storage and use must be determined.

(vi) Attempts shall be made to procure medicines in a single compound. Fixed rational combinations shall be acceptable if one or more of the following criteria, supported by evidence ,are met:-

- The clinical condition justifies the use of more than one drug;
- The therapeutic effects of the combination are greater than the sum of effects of each drug, i.e. the combination must be synergistic and not simply additive;
- The cost of combination product is less than the total cost of the individual products;

1.2.4 The State Essential Drug List will be subsequently categorized according to the levels of health care facilities like primary, secondary and tertiary.

1.2.5 The State Essential Drug List will be revised after every three years so as to reflect therapeutic advances and changes in cost, resistance pattern and public health relevance.

1.2.6 The Government recognizes that there are some drugs which though not listed in the Essential Drug List are required for specific diseases/exceptional cases. Keeping this in view, a supplementary drug list shall be drawn by the State Drug Consultative Committee and procurement of drugs shall be earmarked for purchase of the drugs in the supplementary drug list.

2. QUANTIFICATION OF DRUGS:

Quantification of drugs shall be done cautiously with sense of responsibility and accountability based on reliable quantification methods taking into consideration consumption and morbidity pattern for different levels of facilities (Primary, Secondary and Tertiary levels). The quantification shall be done taking into consideration the following parameters:

2.1 Parameters such as demand, lead time, transportation constraints and emergency needs. There should be a provision for buffer stock keeping in view the State specific constraints particularly the accessibility to remote areas.

2.2 Appropriate inventory management software shall be developed, used and revised whenever necessary to ensure accurate quantification.

3. PROCUREMENT OF ESSENTIAL DRUGS:

3.1 All drugs shall be purchased by the Department of Health & Family Welfare by consulting Principal Director and both Director of Health Services and Director of Hospital & Medical Education. However the distribution shall be done by the Dy. Director, Central Medical Store, Zemabawk to different Hospital stores (warehouses) of the districts.

3.2 All the items shall be purchased by open tender through National Competitive Bidding.

3.3 Open tenders should be called only of drugs listed in Mizoram Essential Drugs List.

3.4 After finalization of the tenders, an "Approved List" shall be drawn up containing the names of the drugs, the names of the supplier and the cost of the drugs.

3.5 All drugs and medical consumables shall be purchased in generic names.

3.6 All drugs and medical consumables and surgical and sutures items will be purchased directly from the manufacturers or authorized distributors.

3.7 Essential drugs shall be procured to ensure cost effectiveness and sustainability while conforming to the principles of transparency, accountability and efficiency.

3.8 Only drugs listed in the Essential Drug List shall be procured centrally. The drugs included in the supplementary drug list would be procured out of the earmarked provision in the budget not exceeding 10% of the allocated budget for drugs at the level of the respective Institutions or districts (in case of PHCs and lower institutions).

3.9 The existing procurement mechanisms of drugs and supplies shall be improved with a view to ensuring timely availability of quality drugs. Efforts shall be made to make the detection of pilferages / wastages / expired stocks easier. For this purpose, an appropriate Management Information System shall be evolved and a web based e-procurement model be developed.

3.10 The objective is to put in place an effective system of procurement of essential drugs by generic names to ensure timely availability, good quality and reasonable cost. The focus would be to minimize stock outs and expired stocks, and ensure availability of essential drugs as per the actual requirement of the health institutions.

4. INVENTORY AND DISTRIBUTION:

4.1 The stores shall be managed by appropriate skilled and qualified personnel i,e. Pharmacist.

4.2 Management Information System for essential drugs will be put in place in the Health Institutions in a phased manner to monitor the availability of drugs.

4.3 In the management of warehouses/stores, the following principles shall apply:- a) The drugs procured shall be stored in appropriate storage conditions as recommended by the manufacturer since improper storage may result in deterioration of drugs.

b) There shall be a proper Inventory Control System to prevent excessive stocking of individual items and also prevent stock outs. Loses due to spoilage or expiry shall be minimized.

c) Appropriate system for accounting shall be developed to attain the objectives of controlling stocks and generate information on expenditure relating to consumption of drugs and medical supplies. This would generate data to facilitate forecasting the quantification of drugs required in the future.

d) Physical verification of stocks shall be undertaken regularly so as to rotate stocks as also to weed out in time expired drugs. Such verification will minimize diversion of stocks and reduce theft and fraud.

e) Uniform system and procedures for stock management would be laid down in the public health facilities. Manuals and guidelines, specific to the needs of the health institutions will be developed to enforce the laid down system. Such manuals and guidelines shall be developed, keeping in mind the capacity of user.

f) The supply of drugs and equipment received under central programmes in kind shall also be monitored centrally and streamlined.

4.4 Drugs shall be distributed under proper transportation conditions ensuring safety and proper delivery. Distribution will be done in an appropriate and timely manner to maintain availability throughout the State.

4.5 Steps shall be taken to ensure that the drugs by generic name are available to the public.

4.6 Proper recall and disposal procedures shall be followed as per standard guidelines.

5. FINANCING:

5.1 The Government will make appropriate allocations for procurement and supply of drugs for all types of health institutions - Primary, Secondary & Tertiary in Govt. Sector.

5.2 The Government will also explore alternate financing sources and develop innovative means and mechanisms for the purpose of availability of drugs listed in the essential drug list.

6. QUALITY ASSURANCE AND REGULATION:

6.1 The Food & Drugs Administration Wing, Department of Health & Family Welfare, Mizoram will be responsible for implementing the legislation and regulations on pharmaceuticals to ensure quality, safety, efficacy of drugs and accuracy of product information. The said organization needs to be strengthened through a capacity building process by augmenting infrastructure, manpower and financial resources. This would include upgrading the competence of the human resources working in the organization through training.

6.2 The Drug Testing Laboratory is very much needed for maintaining quality of the drugs. Efforts should be made to have the Drug Testing Laboratory as per national standard at the earliest.

6.3 Appropriate financial provision would be made available to cover cost of quality assurance and drug testing.

6.4 Surveillance on the quality of drugs available in the market shall be kept by collecting samples and taking further action according to law.

6.5 Appropriate drug information shall be provided and made available to the health professionals as well as public/patients.

6.6 Steps shall be taken to ensure proper implementation of drug regulations especially with regard to offences related to adulterated or spurious drugs.

6.7 The rules relating to cosmetics shall be enforced and laboratories notified for testing purposes.

6.8 Sale, Storage, use of drugs and record keeping specified under Schedule X of the Drugs and Cosmetics Act, 1940 shall be supervised and monitored effectively by the inspectorate working under Food & Drugs Administration Wing, Mizoram. Special checking squads under the leadership of State Drug Controller will be constituted to undertake periodic inspections in this regard;

6.9 Schedule-H & H1 drugs shall be strictly dispensed on the prescription of Registered Medical Practitioners.

6.10 The office of Drug Controller, Food & Drugs Administration, Mizoram shall be computerized to provide better data base system. The computerization will facilitate access of information to the public.

6.11 An Intelligence-cum-Legal Cell shall be established in the office of The Food & Drugs Administration Wing, Mizoram to facilitate busting of spurious drug rackets and their prompt prosecution.

6.12 Efforts shall be made to provide incentives to informers giving information about spurious drugs.

6.13 Efforts shall be made to rationalize number of Drug licenses.

7. DRUG ADVERTISEMENT AND PROMOTION:

In order to prevent risks of misuse and marketing of drugs by quacks, wherever required, laws would be made and strengthened. This would also help in regulating commercial advertisement and marketing of drugs. Any advertisement and promotion of drugs will be required to provide complete drug information.

8. RATIONAL USE OF DRUGS:

8.1 The Government shall promote rational use of drugs in the State so that patients receive medicines appropriate for their clinical needs, in doses that meet the individual requirements for an adequate period of time and at the lowest cost.

8.2 In order to minimize wastage and ensure effective treatment, rational prescribing, dispensing and use of drugs by health professionals/health workers, following strategies would be adopted:-

a) In all the Hospitals of the State, Drugs and Therapeutic Committee shall be established and made effectively functional. These Committee will be responsible for reviewing drug utilization and promoting rational use of drugs. A State and District Level Drugs and Therapeutic Advisory Committee shall also be constituted to monitor the activities of the drugs and Therapeutic Committees of the hospital which shall comprise of the following members:

State Level Drugs & Therapeutic Advisory Committee

1.	Secretary to the Govt of Mizoram Health & Family Welfare	-	Chairman
2.	Principal Director, Health & Family Welfare	-	Sr. Vice Chairman
3.	Joint. Secy/Deputy Secy to the Govt of Mizoram Health & Family Welfare	-	Member
4.	Director, Health Services	-	Vice Chairman
5.	Director, Hospital & Medical Education	-	Vice Chairman
6.	Head of Drug Control Administration	-	Member Secy.
7.	Med. Supdt, Civil Hospital, Aizawl	-	Member
8.	HOD, Medicine, Civil Hospital, Aizawl	-	Member
9.	HOD, Surgery, Civil Hospital, Aizawl	-	Member
10.	HOD, Obstetrics & Gynaecology Civil Hospital, Aizawl	-	Member
11.	HOD, Paediatrics, Civil Hospital,Aizawl	-	Member
12.	Joint Director, DHS (P)	-	Member
13.	Joint Director, DHME (P)	-	Member
14.	HOD, Dept of Pharmacy, RIPANS	-	Member

District Level Drugs & Therapeutic Advisory Committee

1.	Chief Medical Officer	-	Chairman
2.	District Medical Superintendent	-	Vice Chairman
3.	Drug Controlling Officer	-	Member Secy.
4.	Senior Medical Officer	-	Member
5.	Dy. Medical Supdt.	-	Member
6.	4 Specialist of any discipline	-	Member

b) The concepts of essential drugs, rational drug use and generic prescribing shall be an integral part of basic and in service training of health professionals. As such, these shall be incorporated in the curricula of health training institutions.

c) All drugs shall be prescribed and dispensed only by their generic name or International Non-Proprietary Name (INN) in the public sector. Regular Prescription Audits shall be commissioned in public hospitals to measure the compliance in this regard.

d) The present Drug Information Centre should be better equipped.

e) The State would endeavour to conduct training of drug sellers, continuing education of health care providers and consumer education.

f) The State would endeavour to provide financial incentives to promote rational use of drugs apart from regulatory and managerial strategies.

9. PHARMACOVIGILANCE:

9.1 Although medicines are useful to alleviate human illness, all medicines are not completely safe. Therefore, pharmacovigilance is necessary to safeguard the public from the possible adverse drug reactions and prevent the cause of false public alarm and misinterpretation. Pharmacovigilance activities will be funded through the State drug budget.

9.2 Pharmacovigilance centres shall be established to monitor and document adverse drug reactions and events. These centres shall collect data on adverse reactions and events and other drug related problems like substandard drugs, counterfeit drugs, inappropriate use, medication errors etc. from various health professionals/workers.

9.3 All adverse drug reaction reports and other drug related problems shall be properly documented and follow up action including preventive measures shall be taken.

10. EMERGING DISEASES AND PHARMACEUTICALS:

10.1 New diseases are emerging while existing diseases may pose new challenges. Such diseases usually become issues of concern when treatment is very expensive and out of reach of most of the people or the treatment or control is simply difficult or not available at all. In order to address such challenges,

appropriate measures need to be conceived and put in place.

10.2 Efforts will be made to establish a system where both public and private sectors shall be involved to provide drugs needed to adequately treat and control emerging diseases.

11. HUMAN RESOURCES DEVELOPMENT:

11.1 To support the successful implementation of the policy and to promote the concepts of essential drugs and rational use of drugs while ensuring proper management of the limited resources to promote long term sustainability, it is necessary to develop expertise and human resources in the pharmaceutical field.

11.2 Drug management system at all levels shall be managed by appropriately trained and skilled personnel. Necessary steps will be taken, in due course of time, for training of adequate number of pharmacy professionals in the State so as to manage the hospital pharmacies and drug supply system.

11.3 Appropriate in-service training programmes shall be designed and implemented at different levels to enhance the skills and meet the emerging challenges.

11.4 Clinical pharmacy services shall be introduced in all major Hospitals for the benefits of the patients;

12. POLICY IMPLEMENTATION:

The Department of Health & Family Welfare shall take a lead role in implementing this policy. Mechanism for coordination and collaboration shall be developed to facilitate implementation of the policy. The Department shall be the Nodal Agency for promotion of inter and intra-sectoral collaboration and co-operation. The Department shall regularly

review to verify conformity to this policy.

13. DISPOSAL OF EXPIRED DRUGS AND/OR DRUGS NOT OF STANDARD QUALITY:

There shall be a committee on disposal of 'Expired Drug' and drugs declared 'Not of Standard Quality' at the state Capital and District Headquarters comprising of the following members:

Central Drugs Disposal Committee

1.	Dy. Director, Central Medical Store	- Chairman
2.	Superintending Pharmacist, Central Medical Store	- Member Secy
3.	Representative of Director of Health Services	- Member
4.	Representative of Director of Hospital and Med. Education	- Member
5.	Representative of State Drug Controller	- Member

District Drug Disposal Committee

1.	Chief Medical Officer	- Chairman
2.	District Asst. Director (F&D)	- Member Secy
3.	Representative of District Medical Superintendent	- Member

The Committee shall, after due verification of the stock and purchase details pertaining to the 'Expired Drugs' and/or drugs declared 'Not of Standard Quality' shall supervise the destruction of the above drugs and make a list of such drugs along with Name of the Drug with strength, Batch No., Expiry Date, Name and Address of the Manufacturer, Name of the supplier with the total cost in Rupees. The members shall put their signature on the list of the drugs destroyed which shall be deleted from the stock register.

Destruction of the drugs shall be carried out as per the existing procedure for

destruction of drugs laid down by the State Pollution Control Board in order to avoid pollution of the environment.

14. MONITORING AND EVALUATION:

Monitoring and evaluation is an essential component of the State Essential Generic Drug Policy. Monitoring and evaluation shall take place at regular intervals and complete external evaluation will be conducted after every five years. Monitoring system for private sector shall also be developed and implemented by the department. A mechanism for redressal of public grievances shall also be developed and made effective.

15. AMENDMENTS:

This policy document shall be reviewed and revised at appropriate intervals based on the need but at least once every five years.
