

INTRODUCTION:

Access to health care is well recognized as a basic right of the people. The right to protection of life and personal liberty is enshrined in Article 21 of the Constitution of India which includes the right to live with human dignity and all that goes along with it, namely, the bare necessities of life. The Hon'ble Supreme Court has held that it must include the protection of health. Section 24 of the Constitution of Jammu & Kashmir casts a duty upon the State to improve public health. It provides that the State shall make every effort to safeguard and promote health of the people and ensure widespread and efficient medical services through out the State.

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 personnel 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 and are relatively better than the national average.

The single most vital component of health care is drugs as they account for substantial part of household expenditure on health. Research papers reveal that 3.12% of the total household expenditure was expenditure on health in the state in 1999-2000. Out of this the household expenditure on health, 90% was expenditure on drugs. The market for drugs has been growing rapidly in terms of production, trade, investment and employment. However, the industry is characterized by various features like growth of irrational drug combinations and highly priced branded drugs which synergize to waste a lot of patients' money. Even in the public sector, there are problems of access to essential medicines due to availability, cost and inappropriate prescriptions. The capacity of the Health & Medical Education Department 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 Drug & Food Control Organization 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 state specific drug policy in the State of Jammu & Kashmir 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 drug policy is envisaged to prioritize and express the goals and identify the main strategies for achieving them. This is also expected to remove any contradiction between various government measures.

OBJECTIVES:

The Government of Jammu & Kashmir is committed to promote access to affordable essential medicines of adequate quality to the people of the State. This, in the broadest sense, is the main objective of the 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 medicine.
- (ii) To ensure safety, quality and efficacy of medicines.
- (iii) To promote good prescribing practices, dispensing practices and rational use of drugs in the public and private sectors.
- (iv) To provide efficient procurement and supply management system for drugs.

STRATEGIES:

Achieving the objectives of the 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 concept of essential drugs/medicines is central to the State drug policy because it promotes equity and helps in setting priorities for the health care system. It is clear that no public sector can afford to supply or reimburse all medicines that are available in the market. The core of the concept is that use of a limited number of carefully selected medicines based on

Standard Treatment Protocols leads to a better supply of drugs, rational prescribing, reduction in costs and finally to better health outcomes. Essential drugs, which are selected on the basis of safe and cost-effective clinical guidelines, give better quality of care and better value for money. The procurement of fewer items in larger quantities results in more price competition and economies of scale. Quality assurance, procurement, storage, distribution and dispensing are all easier with a reduced number of drugs. Training of health workers and drug information in general can be more focused and prescribers gain more experience with fewer drugs and are more likely to recognize drug interactions and adverse reactions. Although, there may be about 20,000 medicines/ combinations available in the market, with about 300 drugs recommended by the World Health Organization and 268 in the Essential Drugs List of Government of India, it would be possible to tackle almost all disease conditions.

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.

1.2.2. The Department of Health & Medical Education shall appoint an Expert Committee known as the State Drug Committee which would be responsible for initially preparing and subsequently updating at the prescribed intervals the essential drug list for the public sector. The Committee will comprise Clinicians, Pharmacologists, Microbiologists, Pharmacists and independent experts in the field besides senior functionaries of the Department like the Principals of Medical and Dental Colleges, Directors of Health Services, Controller of Drug & Food Control Organization etc. The Committee shall be headed by the senior-most Principal of Government Medical Colleges in the State.

A separate drug committee with appropriate composition would be constituted in respect of drugs pertaining to Indian Systems of Medicine.

1.2.3. The selection of essential drugs will be based on the following criteria:-

- (i) Therapeutic need

- (ii) Relevance to State morbidity and mortality pattern
- (iii) Safety, quality and efficacy
- (iv) Cost effectiveness
- (v) Ease & safety in administration and dispensing
- (vi) Usefulness in more than one condition
- (vii) Likelihood of patient compliance
- (viii) Training and experience of the prescribers
- (ix) Treatment facilities in the State.

1.2.4. The State Drug 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, the total cost on treatment and not the unit cost of medicines only must 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.
- (v) Medicines selected must be available in a form in which adequate quality, including bioavailability, can be ensured. Its stability under the anticipated conditions of storage and use must be determined.
- (vi) Most of the medicines should be formulated as single compounds. Fixed rational combinations shall be acceptable if one or more of the following criteria supported by evidence are met:-
 1. The clinical condition justifies the use of more than one drug
 2. 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.
 3. The cost of combination product is less than the total cost of the individual products.

- 1.2.5. The State essential drug list will be subsequently categorized according to the levels of health care facilities like primary, secondary and tertiary.
- 1.2.6. The essential drug list will be revised after every two years so as to reflect therapeutic advances and changes in cost, resistance pattern and public health relevance.
- 1.2.7. 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 Committee and a provision of grants not exceeding 10% of the allocated budget for procurement of drugs shall be earmarked for purchase of the drugs in the supplementary drug list.

2. QUANTIFICATION OF DRUGS:

- 2.1. Quantification of drugs shall be done consciously with sense of responsibility and accountability based on reliable quantification methods taking into consideration consumption, morbidity pattern for different levels of facilities (Primary, Secondary and Tertiary levels). The quantification shall be done taking into consideration the 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 used and revised whenever necessary to ensure accurate quantification.

3. PROCUREMENT OF ESSENTIAL DRUGS:

- 3.1 Essential drugs shall be procured to ensure cost effectiveness and sustainability while conforming to the principles of transparency, accountability and efficiency.
- 3.2 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).
- 3.3 The drugs included in the essential drug list shall be centrally procured through an autonomous, transparent, accountable and free from constraints mechanism.
- 3.4 Tamil Nadu Medical Supplies Corporation which has achieved unprecedented success in ensuring timely availability of quality drugs has been recommended by the Government of India and the World Health Organization to be adopted for procurement. The advantages of such a system are well known and are as follows:-
 - a). Procurement in a centralized manner of limited number of drugs helps in more price competition and economies of scale leading to lower costs.
 - b). Quality assurance becomes easier with centralized procurement of fewer drugs.
 - c). Procurement, storage and transportation become easier, more transparent and more accountable when it is done through an autonomous Corporation. The Corporation has to compile its accounts annually in which trade activities, profits or losses and inventories have to be reflected in detail and discussed in various Board meetings. Thus, it is easier to detect pilferages/wastage/expired stocks.
 - d). Procurement on centralized basis through autonomous Corporation reduces tendency to invest funds in unutilized and slow moving stock. The Corporation is expected to invest in drugs which have a good off take. An ideal situation would be when the Corporation conducts its business in sync with the consumption pattern in the health institutions of the Health & Medical Education Department. This model thus facilitates to minimize stock outs and expired stocks, and ensure availability of essential drugs as per the actual requirement of the health institutions.
- 3.5 The proposed Corporation will develop an appropriate Management Information System and web-based e-procurement model. Accordingly, the Government would set up Jammu & Kashmir Medical Supplies Corporation on the pattern of TNMSC in a state specific manner. There are certain state specific aspects which will need to be taken

into account while designing the procurement, supply and distribution system relevant to the situation of the State. 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. While the Health and Medical Education Department will advise on Medicines to be procured, the decisions on procurement shall lie with the corporation.

- 3.6 The proposed corporation shall produce an annual report on its activities which shall be submitted to the Government.

4. WARE-HOUSING AND DISTRIBUTION:

4.1. The Government shall establish modern warehouses at Divisional and District levels under the proposed J&K Medical Supplies Corporation keeping in view the State's topography, climatic conditions and issues of accessibility. The capacity of warehouses/stores would be in line with the requirement to ensure constant supply of drugs to the health institutions they are feeding. The warehouses/stores shall be managed by appropriate number of skilled and qualified personnel (which will include pharmacists) in line with the principles of good store management.

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. Losses due to spoilage or time 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 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.

5. FINANCING:

5.1. The Government will provide allocations for procurement and supply of drugs for all types of institutions – Primary, Secondary & Tertiary. The Department of Health & Medical Education shall be responsible for projecting the cost of drugs required from time to time.

5.2. The Government will also explore alternate financing source and develop innovative means and mechanisms to ensure availability of drugs listed in the essential drug list at all times.

6. QUALITY ASSURANCE AND REGULATION:

6.1 Controller, Drugs & Food Control Organization in the State is 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 Laboratories shall be strengthened by providing equipment, qualified analysts, adequate space and other requirements as may be consistent with the workload. The drug testing laboratories would be accredited with national and, where possible, international accreditation bodies to ensure the reliability of tests as per national/international standards.

6.3 Private sector laboratories may also be involved to ensure the quality of drugs in the State. However, these would need to be supervised by the State.

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

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

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

6.7 The office of Controller, Drugs & Food Control Organization shall be computerized to provide better data base system. The computerization will facilitate access of information to the public.

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 advertisements and promotion of drugs will be required to provide complete drug information.

8. LOCAL MANUFACTURE OF PHARMACEUTICALS:

8.1 In order to promote self-sufficiency, the State Government will encourage, promote and support local manufacturers of pharmaceuticals.

8.2 The regulatory agency shall enforce guidelines on manufacture, such as but not restricted to

Good Manufacturing Practices (GMP), and Good Storage Practices (GSP).

8.3 To ensure safety, quality and efficacy of products the regulatory agency shall regulate manufacture of medicinal products and cause periodic inspection of the manufacturing premises within the State.

9. RATIONAL USE OF DRUGS:

9.1 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.

9.2 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). Evidence-based Standard Treatment Protocols (STP) shall be developed as the basis for training, prescribing and drug supply. These shall be revised from time to time and made accessible to health professionals and workers at levels.

b). In all the hospitals of the State, Drugs and Therapeutic Committees shall be established and made effectively functional. These will be responsible for reviewing drug utilization and promoting rational use of drugs. A state level drugs and therapeutic Advisory Committee shall also be constituted to monitor the activities of the drugs and Therapeutic Committees of the hospitals.

c). 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.

d). 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.

e). A Drug Information Centre shall be established preferably in the Government

Medical Colleges to work in collaboration with all the stakeholders in order to provide appropriate drug information. A state level Formulary would be published annually in line with the World Health Organization/National norms and distributed to all qualified prescribers free of cost or on subsidized rate. This will be funded through the available budget for drugs. It is recognized that activities pertaining to drug information are a right charge on the budget for procurement of drugs.

- f). The state would endeavour to conduct training of drug sellers, continuing education of health care providers and consumer education.
- g). The state would endeavour to provide financial incentives to promote rational use of drugs apart from regulatory and managerial strategies.

10. PHARMACOVIGILANCE:

- 10.1 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.
- 10.2 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.
- 10.3 All adverse drug reaction reports and other drug related problems shall be properly documented and follow up action including preventive measures shall be taken.

11. EMERGING DISEASES AND PHARMACEUTICALS:

- 11.1 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.

- 11.2 The Government shall allocate resources and establish a system where both public and private sectors shall be involved to provide drugs needed to adequately treat and control emerging diseases. In case of such emerging diseases, if treatment is available elsewhere, the Government shall make arrangements to procure such drugs and expertise and maintain adequate stock of drugs till such time these diseases are no more a public health concern.

12. HUMAN RESOURCES DEVELOPMENT:

- 12.1 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.
- 12.2 Drug management system at all levels shall be managed by appropriately trained and skilled personnel. Facilities would be developed for training of adequate number of pharmacy professionals in the State so as to manage the hospital pharmacies and drug supply system.
- 12.3 Appropriate in-service training programmes shall be designed and implemented at different levels to enhance the skills and meet the emerging challenges.

13. PROMOTING OPERATIONAL & CLINICAL RESEARCH:

- 13.1 Operational research facilitates implementation, monitoring and evaluation of different aspects of drug policy. It is an essential tool in assessing the drug policy's impact on State Health service systems and delivery, in studying the economies of drug supply, in identifying problems related to prescribing and dispensing, and in understanding the socio-cultural aspects of the drug use.
- 13.2 The Government shall encourage development of multi-disciplinary research in areas such as medicine, pharmacy, pharmacology, medicinal chemistry and training of research personnel in the relevant areas.

13.3 The Government shall promote collaborative research with recognized research institutes within and outside the state for drug research.

13.4 Research on use of drugs shall be promoted to provide information on attitudes and beliefs that contribute to inappropriate drug use or non-use.

14. **POLICY IMPLEMENTATION:**

The Department of Health & Medical Education 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.

15. **MONITORING AND EVALUATION:**

Monitoring and evaluation is an essential component of the State Drug Policy. Monitoring and evaluation shall take place at regular intervals and complete external evaluation will be got 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.

16. **AMENDMENTS:**

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

DEFINITIONS:

1. **Appropriate storage conditions:** means suitable storage conditions that will keep the efficacy of the drug intact till its expiry.
2. **Brand name:** is a name given to a drug by the manufacturer. The use of the name is reserved exclusively for its owner.
3. **Counterfeit medicine:** is medicine that is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products. Counterfeit products may include products with the correct ingredients or the wrong ingredients, lacking active ingredients, with incorrect quantities of active ingredients, or fake packaging.

4. **Drug, Medicine, Medicinal product, Pharmaceuticals products:** are terms used inter-changeably in this document and include herbal medicines and any substance included in any publication, or any substance or mixture of substances prepared, sold or represented for use in the diagnosis, treatment, mitigation or prevention of disease, disorder or abnormal physical state or symptoms thereof, or restoring, correcting or modifying organic functions in humans.

5. **Efficacy:** refers to the ability of a drug, whether orthodox or herbal to treat or control a disease.

6. **Essential Drugs:** are those that satisfy the health needs of the majority of the population. They should therefore, be available at all times and in appropriate dosage forms. It also includes vaccines.

7. **Essential Drugs Concept:** is that use of limited number of carefully selected drugs based on agreed clinical guidelines leads to a better supply of drugs, to more rational prescribing and to lower costs.

8. **Generic drug:** is a pharmaceutical product, usually intended to be interchangeable with an innovator product, that is manufactured without a licence from the innovator company and marketed after the expiry date of the patent or other exclusive rights. Generic drugs are marketed under a non-proprietary or approved name rather than a proprietary or brand name. Generic drugs are frequently as effective as, but much cheaper than brand name drugs. For example, paracetamol is a generic name of the ingredient found in a number of brand-name painkillers, but is also sold as a generic drug (not under a brand name).

9. **Government:** means the Government of Jammu & Kashmir.

10. **Pharmaceuticals sector:** refers to the sector of health care concerned with the knowledge or art of pharmacy and its practice according to specific rules and formulas. It includes the public sector (pharmacies and dispensaries), the manufacturing sector and the private sector (pharmacies, chemical shops and dispensaries).