Government of Jammu and Kashmir
Health and Medical Education Department
Civil Secretariat- Jammu

Subject: **Drug Policy for the J&K State**

Reference: Cabinet Decision No: 10/02/2012 dated: 12-01-2012

Government Order No: 80-HME of 2012
Dated: 02- 02- 2012

Sanction is accorded to adoption of the Drug Policy for the J&K State as contained in Annexure-A alongwith the Essential Drugs List for allopathic discipline for Government health institutions in Health and Medical Education Sector of the State as per Annexure-B.

Sher-i-Kashmir Institute of Medical Sciences (SKIMS) Soura Srinagar, may separately consider adoption of the State Drug Policy and Essential Drugs List with the approval of its Governing Body.

By Order of the Government of Jammu & Kashmir

Sd/-
(G. A. Peer) IAS,
Commissioner/ Secretary to Government
Health & Medical Education Department

No: HD/Plan/Drug-Policy/78/09-II Dated: 02-02-2012

Copy to:

1. Principal Secretary to HCM
2. Principal Secretary to Govt. Planning & Development Department
3. Commissioner/Secretary to Govt. General Administration Department
4. Director SKIMS Soura Srinagar
5. Principal Govt. Medical College Jammu/ Srinagar
6. Principal Govt. Dental College Jammu/ Srinagar
7. Special Secretary to Govt. (H) H&ME Department
8. Director Health Services Kashmir/ Jammu
9. Director, ISM J&K Jammu
10. Director Family Welfare J&K Jammu
11. Mission Director NRHM J&K Jammu
12. Project Director JKSACS Jammu
13. Controller, Drug & FC Org. Jammu
14. Additional Secretary (ME) H&ME Department
15. Special Assistant to Hon'ble Minister for Medical Education
16. PS to the Hon'ble Minister for Health
17. PS to the Hon'ble MOS H&ME Department
18. Govt. Order File (w4scs)
19. Stock file.
20. Concerned file.

(S. Shabir Shafi)
Joint Director (P&S)
Health & Medical Education Department

KEY FEATURES OF DRUG POLICY

Selection of essential Drugs.

1) The core of the concept of selection of essential medicines is that use of a limited number of carefully selected medicines based on Standard Treatment Protocols which leads to a getter supply of drugs, rational prescribing, reduction in costs and finally to better health outcomes.

2) Selection of Essential Drugs List has been proposed to be entrusted to an Expert Committee known as State Drug Committee which will comprise Clinicians, Microbiologists, qualified Pharmacists and independent experts besides senior functionaries of the departments like HoDs. For Indian System Medicine separate Committee has been proposed.

3) The EDL(Essential Drug List) would be revised after every two years so as to reflect therapeutic advances and changes in cost, resistance pattern and public health relevance.

4) There are some drugs which though not listed in the EDL are required for specific diseases/exceptional cases. Keeping this in view, a Complementary Drug List (CDL) would be drawn up and a provision of grants not exceeding 10% of the allocated budget

for procurement of drugs shall be earmarked for purchase of drugs in the complementary drugs list.

5) The quantification of drugs would be done taking into consideration the parameters such as demand, lead time, transportation constraints and emergency needs as also the need to maintain buffer stock keeping in view the state specific constraints of accessibility to remote areas.

6) Only drugs listed in the EDL shall be procured centrally.

7) There shall be appropriate inventory control system to prevent excessive stocking of individual items and also prevent stock outs.

8) Proper re-call and disposal procedures shall be followed as per standard guidelines.

9) The Drug & Food Control Organization would be strengthened through a capacity building process by augmenting infrastructure, manpower and financial resources. The Drug Testing Laboratories would be strengthened by providing equipment, qualified analysts and other requirements as may be consistent with the work load. Approved private sector laboratories would also be involved in the process.

10) Efforts will be made to promote rational use of drugs in the State so that patients receive the medicines appropriate for their clinical needs in doses that meet the individual requirements for adequate period of time. In all the hospitals of the State, Drugs and Therapeutic Committees would be established.

11) The concept of essential drugs, rational drug use and generic prescribing shall be an integral part of basic and in-service training of health professionals. A Drug Information Centre would be established preferably in Government Medical Colleges to provide appropriate drug information.

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

13) Pharmacovigilance centres would be established to monitor and document adverse drug reactions and events.

14) Operational research would be used to facilitate implementation, monitoring and evaluation of different aspects of drug policy. Monitoring and evaluation would take place at regular intervals and a complete external evaluation would be got conducted after every five years. A mechanism for redressal

of public grievances would also be developed and made effective.

15) Approved private sector laboratories under overall supervision of the State Government shall also be involved to ensure the quality of drugs in the State. Annual testing load and average testing time of existing Drug Testing Laboratories shall be fixed for proper accountability.

16) **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 Drug and Food Control Organization, J&K. Special checking squads under the leadership of Deputy Controllers will be constituted to undertake periodic inspections in this regard.**

17) **Schedule-H drugs shall be strictly dispensed on the prescription of Registered Medical Practitioners.**

18) An Intelligence-cum-Legal Cell shall be established in the office Drug and Food Control Organization, J&K to facilitate busting of spurious drug rackets and their prompt prosecution. Efforts shall be made to provide incentives to informers giving information about spurious drugs. **Efforts shall be made to rationalize number of Drug licenses;**

19) In order to prevent risks of misuse and marketing of drugs by quacks, wherever required, laws would be made and strengthened.

Annexure "A"

Draft Drug Policy for the State

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. 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 patientsô money. 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.

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 cost effective, 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 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 out comes. 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 (348 list)** 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 **the essential drug list every two years** for the public sector. The Committee will comprise Clinicians, Pharmacologists, Microbiologists, **qualified** 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, **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 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. **(New list attached).**

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 existing procurement mechanisms of drugs & 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 developed.

3.4 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.

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 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.

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

4.6 **Proper re-call 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 ï 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 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. Efforts will be made for accrediting the Drug Testing Laboratories as per national standards.

6.3 **Approved** private sector laboratories **under overall supervision of the State Government shall** also be involved to ensure the quality of drugs in the State. **Annual testing load and average testing time of existing Drug Testing Laboratories shall be fixed for proper accountability.**

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

6.8 **Efforts shall be made to strictly enforce the provisions of the J&K Pharmacy Act, Samvat 2011 and the rules framed thereunder. Regulatory laws related to quality control of AYUSH drugs shall be examined. Suitable amendments in the said regulations shall be made, wherever necessary.**

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

6.10 **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 Drug and Food Control Organization, J&K. Special checking squads under the leadership of Deputy Controllers will be constituted to undertake periodic inspections in this regard;**

6.11 **Schedule-H drugs shall be strictly dispensed on the prescription of Registered Medical Practitioners;**

6.12 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.

6.13 **An Intelligence-cum-Legal Cell shall be established in the office Drug and Food Control Organization, J&K to facilitate busting of spurious drug rackets and their prompt prosecution;**

6.14 **Efforts shall be made to provide incentives to informers giving information about spurious drugs;**

6.15 **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. LOCAL MANUFACTURE OF PHARMACEUTICALS:

8.1 In order to promote self-sufficiency, the State Government will encourage local manufacturers of pharmaceuticals in line with the State Industrial Policy.

8.2 The regulatory agency shall enforce relevant guidelines on manufacture including 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 all 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 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.

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. 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.

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

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

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 policyôs 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.

13.5 Best practices will be followed in Blood Banking and Transfusion of Blood.

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:** 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).

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Government of Jammu and Kashmir
Health & Medical Education Department
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MEMORANDUM FOR SUBMISSION TO THE CABINET

Subject:- Approval of Drug Policy for the State.

1. Access to health care is well recognized as a basic right of the people. Even the Constitution of Jammu & Kashmir casts a duty upon the State to make every effort to safeguard and promote health of the people and ensure widespread and efficient medical services through out the State.

2. 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.

3. The single most vital component of health care is drugs as they account for substantial part of household expenditure on health. In the State of Jammu & Kashmir, the consumption of drugs and expenditure on drugs is quite high. 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 lot of money of patients. 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 standard of the drugs under the provisions of law.

4. Although the Government is committed to provide 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 health care services, a state specific drug policy for 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.

5. The Health & Medical Education Department initiated the exercise for formulation of a State specific Drug Policy in June, 2008. The experts from Delhi Society for Promotion of Rational Use of Drugs were invited by Health and Medical Education Department to give a presentation. On the basis of discussions held with the experts and departmental officers, a tentative draft was prepared and circulated to various Heads of the Department for their comments.

6. During the review meeting held under the chairmanship of Hon'ble Chief Minister on 22nd of January, 2009 the issue came up for discussion and it was desired that Health and Medical Education Department should take immediate steps to formulate a state specific Drug Policy. While replying to the motion of thanks on Governor's Address during the Session of Legislature in February/March, 2009, the Hon'ble Chief Minister stated that a state specific Drug Policy will be formulated soon.

7. A two day consultative workshop on "Formulation of State Drug Policy" was organized at Jammu from 25th-26th March, 2009. Eminent experts in the field from outside the State participated in the said Workshop. The workshop was also attended by the concerned Heads of the Department of Health and Medical Education Department. During the course of the workshop, the issues related to formulation of state specific Drug Policy were discussed threadbare and the experts from outside the State shared their experiences and the best practices outside the State with the participants.

8. Two Working Groups one each for Jammu and Kashmir Divisions were constituted under the chairmanship of the respective Principals of Government Medical Colleges to prepare a draft Drug Policy. Similarly, a State Level Committee was constituted under the chairmanship of then Commissioner/Secretary to Government, Health and Medical Education Department with members from each Division to finalize the draft Drug Policy for the State. The above said Working Groups also prepared a draft Essential Drugs List and Complementary Drugs List which is a key feature of the proposed Drug Policy. The said Essential Drugs List comprises 383 drugs.

9. On the basis of the recommendations of the Divisional Working Groups and the suggestions of the Civil Society Forum, the draft Drug Policy has been prepared by the State Level Committee. The main features of the policy are as follow: -

(A) Key Features of the Draft Drug Policy

Objectives of the draft Drug Policy has been specified as follows:-

(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.

In order to achieve the objectives of the draft Drug Policy various strategies and policy measures have been proposed which are briefly mentioned as follows:-

(B) Selection of essential medicines

(i) The core of the concept of selection of essential medicines is that use of a limited number of carefully selected medicines based on Standard Treatment Protocols which leads to a better supply of drugs, rational prescribing, reduction in costs and finally to better health outcomes. 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. 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 (348 list)** in Essential Drugs List of Government of India, it would be possible to tackle almost all disease conditions.

(ii) Selection of Essential Drugs List has been proposed to be entrusted to an Expert Committee known as State Drug Committee which will comprise Clinicians, Microbiologists, qualified Pharmacists and independent experts besides senior functionaries of the departments like Heads of the Department. A separate Drug Committee is proposed in respect of the drugs pertaining to the Indian Systems of Medicines.

(iii) Selection of essential drugs would be based on the Therapeutic need, relevance to the State morbidity pattern, safety, quality and efficacy, cost effectiveness etc.

(iv) Only medicines with sound and adequate evidence of efficacy and safety would be selected by the State Drug Committee. Relative cost effectiveness would be a major consideration for choosing medicines within the same therapeutic category. The drugs would be identified and listed by their generic name or International Non-proprietary Name (INN) only.

(v) The Essential Drugs List would be revised after every two years so as to reflect therapeutic advances and changes in cost, resistance pattern and public health relevance.

(vi) It is recognized that there are some drugs which though not listed in the Essential Drugs List are required for specific diseases/ exceptional cases. Keeping this in view, a Complementary Drug List would be drawn up and a provision of grants not exceeding 10% of the allocated budget for procurement of drugs shall be earmarked for purchase of drugs in the complementary drugs list.

(C) Procurement of Essential Drugs:

(i) The quantification of drugs would be done taking into consideration the parameters such as demand, lead time, transportation constraints and emergency needs as also the need to maintain buffer stock keeping in view the state specific constraints of accessibility to remote areas.

(ii) The procurement of essential drugs is to conform to the principles of transparency, accountability and efficiency. Only drugs listed in the Essential Drugs List shall be procured centrally. The drugs included in the complementary drugs 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.

(D) Inventory and Distribution

There shall be appropriate inventory control system to prevent excessive stocking of individual items and also prevent stock outs. Loses due to spoilage or time expiry would be minimized. There would be focus on appropriate system of accounting and physical verification of stock.

Furthermore, steps shall be taken to ensure that the drugs by generic name are available to the public. The practice of ñPrescription Auditò will be introduced to ensure that doctors working in Govt. institutions prescribe medicines by generic names only. **Proper re-call and disposal procedures shall be followed as per standard guidelines.**

(E) Quality assurance and regulation

(i) The 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 would be strengthened through a capacity building process by augmenting infrastructure, manpower and financial resources. The Drug Testing Laboratories would be strengthened by providing equipment, qualified analysts and other requirements as may be consistent with the workload. **Approved** Private sector laboratories would also be involved in the process.

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

(iii) Steps shall be taken to ensure proper implementation of drug regulations especially with regard to offences related to adulterated or spurious drugs. **Efforts shall be made to strengthen the provisions of J&K Pharmacy Act. Samvat 2011 and also enforce education regulations thereof** and also examine regulatory laws related to quality control of AYUSH drugs. Suitable amendments in the said regulations shall be made, wherever necessary

(F) Rational use of Drugs

(i) Efforts will be made to promote rational use of drugs in the State so that patients receive the medicines appropriate for their clinical needs in doses that meet the individual requirements for adequate period of time at the lowest cost. Evidence-based Standard Treatment Protocols would be developed as the basis for training, prescribing and drug supply. In all the hospitals of the State, Drugs and Therapeutic Committees would be established and made effectively functional. These will be responsible for reviewing drug utilization and promoting rational use of drugs.

(ii) The concept of essential drugs, rational drug use and generic prescribing shall be an integral part of basic and in-service training of health professionals. In the public sector drugs shall be prescribed and dispensed by their generic name or International Non-proprietary Name (INN) only. A Drug Information Centre would be established preferably in Government Medical Colleges to provide appropriate drug information. A State level Formulary

would be published annually which will be funded by the available budget for procurement of drugs.

(iii) Any advertisements and promotion of drugs will be required to provide complete drug information.

(G) Pharmacovigilance

Pharmacovigilance activities are proposed to be funded to safeguard the public from the possible adverse drug reactions and false public alarm and misinterpretation. Pharmacovigilance centres would be established to monitor and document adverse drug reactions and events.

(H) Human Resources Development

To support the successful implementation of the policy, it is necessary to develop expertise and human resources in the pharmaceutical field. Drug Management System at all levels shall be managed by appropriately trained and skilled personnel. Appropriate in-service training programmes shall also be designed and implemented to enhance the skills.

(I) Monitoring and Evaluation

(i) Operational research would be used to facilitate implementation, monitoring and evaluation of different aspects of drug policy. Mechanism for coordination and collaboration shall be developed to facilitate implementation of the policy.

(ii) Monitoring and evaluation would take place at regular intervals and a complete external evaluation would be got

conducted after every five years. A mechanism for redressal of public grievances would also be developed and made effective.

(iii) The policy is proposed to be reviewed at appropriate intervals but at-least once every five years.

10. The draft state Drug Policy is enclosed as **Annexure-A** and the list of drugs included in the Essential Drugs list and the Complementary List is enclosed as **Annexure-B** to this memorandum.

11. With the approval of Hon'ble Minister for Health and Hon'ble Minister for Medical Education the draft Drug Policy was published in local newspapers and also made available on website to invite suggestions from the people.

12. Several suggestions have been received in response. Broadly speaking following issues have been raised:-

(i) That purchase preference for local small scale industrial units needs to be mentioned in the drug policy.

(ii) That equal opportunities should be allowed to the Homeopathic system of medicine and Homeopathic drugs should also be provided in the Institutions where Homeopathic Practitioners are available.

(iii) That all medicines may be exempted from taxes in the State.

(iv) That doctors trained in any particular system of medicine should prescribe medicines from the same discipline only.

(v) That other factors that are responsible for non-utilization of medicines like absence of staff, excessive, unwanted and un-demanded supplies need to be covered.

(vi) That use of local medicinal plants in Hospitals should be encouraged.

(vii) There should be a mechanism for distribution of low cost drugs through Govt. /Co-operative drug stores.

(viii) The regulatory laws especially with regard to offences related to adulterated drugs or spurious drugs should be implemented strictly and that Govt should enforce education regulations under J&K Pharmacy Act, Samvat 2011.

13. Regarding the above comments, the following submissions are made:-

(i) As far as purchase preference for Small Scale Industrial units is concerned this is already contained in the State Industrial policy. Thus it is not required to be mentioned in the State Drug Policy. As and when there are changes in the State Industrial Policy, the same would be applied to the Small Scale Industrial Units of the Pharmaceutical sector also.

(ii) The State is already considering ISM Sector at par with Allopathic sector. The Drug Policy provides for a separate State Drug Committee for the drugs of ISM sector. The said Committee would be asked to prepare Essential Drugs List for each discipline viz., Ayurveda, Unani, Homeopathy etc. which are popular in the State.

(iii) Exemption of medicines from taxes needs to be carefully examined separately in consultation with the Finance Department. This need not be a part of State Drug Policy as it can be dealt with separately and the position can be reviewed from time to time.

(iv) It is already the policy of the Government that doctors trained in a particular discipline (MBBS or ISM) must practice their concerned specialty only. This is also contained in the relevant laws governing medical practitioners, Ayurvedic/Unani practitioners and Homeopathic practitioners.

(v) The draft Drug Policy also deals with efficient procurement system and other mechanism of checks and balances to prevent excessive stock of medicines and stock-outs.

(vi) Regarding use of local medicinal plants, it is mentioned that a practitioner can prescribe medicines that have sound and adequate evidence of efficacy and safety. There is also a provision in the draft drug policy for development of Standard Treatment Protocols as the basis for training, prescribing and drug supply. Those formulations (including the ones from medicinal plants) which are approved in the Standard Treatment Protocols can be used by the clinicians/practitioners while prescribing.

(vii) The suggestions put-forth at (vii) & (viii) have been suitability incorporated in the draft drug policy.

14. During the Task Force meeting held under the Chairmanship of the Hon'ble Chief Minister on 11-12-2009, it was decided as under:

> ñ*While the H&ME Department would finalize the Drug Policy for the State, it would also be essential to ensure a mechanism for checking the menace of spurious drugs*ò

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

16. The draft drug policy was submitted to the General Administration Department on 14-06-2010. The General Administration Department vide No: GDC-120/2010 dated: 15-07-2010 intimated that the Hon'ble Chief Minister has desired to have a presentation on the policy. Accordingly, a presentation on draft drug policy of the State was made before the Hon'ble Chief Minster on 29-11-2010, in which among others, the Hon'ble Minister of Health, Hon'ble Minister for Medical Education and Hon'ble Minister of State for Health & Medical Education were also present. The suggestions made during the course of the presentation have been incorporated in the draft drug policy.

17. In light of the above submissions, it would be appropriate to approve the **Drug Policy** as also **Essential Drugs List** and **Complementary Drugs List** for Allopathic sector which has been prepared by the Working Groups. Subsequently, review of the Essential Drugs List/complementary drugs list would be carried out in terms of the State Drug Policy.

18. As far as SKIMS is concerned, it is proposed that the Institute may separately consider the State Drug Policy and the Essential Drugs List/complementary drugs list for adoption by their Governing Body.

19. Accordingly, the Commissioner/Secretary to Government, Health & Medical Education Department, with the approval of Hon'ble Minister for Health and Hon'ble Minister for Medical Education, submits the following resolution for approval of the Cabinet:-

"Sanction is accorded to adoption of the Drug Policy for the State as contained in Annexure-A alongwith the Essential Drugs List and Complementary Drugs List for allopathic discipline for Government health institutions in Health and Medical Education Sector of the State as per Annexure-B. Sher-i-Kashmir Institute of Medical Sciences (SKIMS) may separately consider adoption of the State Drug Policy and Essential Drugs List/Complementary Drugs List by their Governing Body".

Commissioner/Secretary to Government,
Health & Medical Education Department