Rational Drug Policy Statement

by

All India Drug Action Network

ALL INDIA DRUG ACTION NETWORK

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RATIONAL DRUG POLICY - STATEMENT

AIDAN

All India Drug Action Network (AIDAN), is a forum, and coordinating body of organizations, and individuals all over the country working towards the adoption and implementation of a people oriented Rational Drug Policy in India as a part of a Peoples Health Policy. It sets out the following outline for the Drug Policy :

Health Policy and drugs

Majority of the Indians suffer from the diseases of poverty and ignorance, i.e. communicable diseases, diseases due to undernutrition etc. Most of these illnesses are preventable and curable. In addition, distorted pattern of industrialisation and urbanisation has led to the development of so called diseases of industrialisation. What we need most is adequate nutrition, adequate and safe water, universal sanitation, development without damaging environmental balance and primary medical service, available to all.

Role of drugs

Although drugs constitute only a small part of the overall health care, they are most urgent, essential and hence a priority need in the country where incidence of death and disability from diseases is high. So long the basic elements of health care are not made available universally, medical care will continue to be the priority service to reduce death and disability and in this context, drugs understandably assume a vital and priority role.

Present situation

The fact that drugs can save life and relieve sufferings has been exploited by the drug industry, which is oriented mainly to profit making, to push all sorts of irrational drugs onto the consumers. The drug industry and the medical establishment has created a very drug-dependant health culture which eclipses the much-needed sustainable solutions to the real health problems. Doctors and non-doctors alike are made to believe that drugs are "cure all"

for all ills. Health is still regarded as basically an individual or personal responsibility and not a product of social factors.

It is also believed that freedom from diseases could be obtained by better an better and more and more drugs. Such a belief among educated and illiterate alike, has led to a universal craze for drugs and this DRUG CULTURE has come to dominate the society. In this situation it is not surprising that drugs provide an opportunity for unlimited profit-making by the drug industry, since hardly any consumer asks for the necessity, utility, rationality, price-justifiability and harmful effects of a drug. It is not even asked whether a substance sold as Drug is actually a Drug at all. As a result, about 60% of the drugs in the market are unscientific or harmful or substandard; a large number of these are not actually drugs; many drugs are consumed by those who do not need it; people die or are disabled from the effects of harmful drugs; drugs are sold at fantastically high prices; and most serious of all life saving and essential drugs are not available to the majority that need them most.

Even 38 years after independence, multinational corporations continue to dominate the drug industry in India. Further, the majority of their production consists of drug formulations and not bulk drugs. Though, according to UNIDO, India has the capacity to be self sufficient in bulk drugs, we still import 40% of our bulk-drug requirement.

Objectives of the Rational drug policy

We feel that the Rational Drug Policy objectives should include the following :-

A. ASSESSING THE DRUG-NEEDS

1) To identify the drug needs in consonance with the health needs of the people, particularly those required for primary health care; to prepare a graded essential and priority list of drugs for different levels of health expertise inkeeping with actual health needs of the people.

2) To eliminate irrational, useless and hazardous drugs.

B. PRODUCTION, PRICE AND QUALITY CONTROL

1) To make all drugs available at low prices to the people, particularly the essential & priority drugs.

2) To ensure quality control of all drugs.

C. DRUG DISTRIBUTION

To establish a national corporation for the distribution of drugs; retailing of drugs through fair price shops and government's health infrastructures.

D. DRUG INFORMATION AND ETHICAL MARKETING

1) To ensure a drug information system for health personnel and consumers.

2) To ensure ethical marketing.

3) To abolish brand names and introduce generic names for all drugs.

E. SELF - RELIANCE

1) To develop self reliance in drug technology.

2) To foster and encourage the growth of the Indian Sector and to provide a leadership role to the public sector.

3) To aim at quick self sufficiency in the output of drugs with a view to reducing the quantum of imports.

F. RESEARCH AND DEVELOPMENT

To promote research and development for self-reliance and in accordance with the needs of the Indian people.

G. LEGISLATION AND ADMINISTRATION

1) To provide comprehensive drug legislation and administrative support to deal effectively with and implement all the above aims and objectives.

2) To ensure smooth Centre-State relations anc inter-departmental coordination for effective and relevant drug production, drug control and drug supply.

H. HUMANPOWER DEVELOPMENT

To fulfill the needs of the above Rational Drug Policy, different type of technical personnel (e.g. druggists, paramedics, etc.) need to be adequately and appropriately trained in adequate numbers.

A. ASSESSING THE DRUG NEEDS

A 1. Identification of Drug needs and Prioritized Essential Drug List

i) The National Drug Formulary should be revised and compiled by an expert multi-disciplinary committee with suitable representation from all the sections of health professionals. This committee should draw up the essential priority drug list, keeping the following criteria in mind -

* Medico-social justification should act as a primary criterion keeping in mind - efficacy, safety, cost, ease of administration, potential for misuse, indigenous production.

* Priority for production has to be given to the drugs required for diseases causing greater mortality (death), greater morbidity (illness), severe sequelae (after effects).

* Drugs used in National Programmes e.g. TB, leprosy, malaria, blindness, goitre control, and immunisation programmes should get priority.

This list should be revised periodically.

ii) Selection of the essential and priority drugs would be followed by preparation of graded drug list for different categories of health personnel and health institutions. These lists should form the basic guidelines for bulk purchase procurement and requisition stocking and dispensing.

An appropriate authority (see section G2) should continuously assess drug needs and drug production and monitor capacity utilisation in the industry, drug utilisation patterns, health needs, changing pattern of diseases, drug requirements, new information on old drugs, introduction of new drugs, efficacy of the existing policy of production, distribution and use of drugs.

2. **Withdrawal of hazardous, irrational and therapeutically useless drugs.**

i) All the drugs in the market should be scrutinised to assess their rationality on the basis of standard text books of medicine and pharmacology. All drugs which are not recommended in these text books should be banned. Those drugs which have life-threatening or serious side-effects and for which equally effective alternatives are available should be banned immediately. The rest of these drugs should disappear from the market within one year.

ii) No fixed dose combination forms should be allowed to be manufactured if an alternative single ingredient drug is available for the purpose, which is therapeutically equivalent and more cost effective.

iii) Drug Legislation should be modified to ensure that no stay order is granted in cases pertaining to banning hazardous drugs in the interest of public health.

B. PRODUCTION, PRICE AND QUALITY CONTROL

1. **Production and Price Controls**

i) The priority drug list should be a part of much larger essential drug list based on WHO recommendations as well as those of our own National Drugs and Therapeutics Authority. In this essential drug list, life saving drugs and drugs for primary health care shall be put as category I termed as priority drug list and the rest of the list shall be put in category II.

ii) The production of essential drug formulations shall be a minimum 75% of total formulation turnover of each manufacturer now and shall be brought up to 90% in five years. The priority drugs shall constitute 60% of the above essential drugs and shall be raised to 80% of the essential drugs in the next 5 years. The above production quota should include all dosage forms of essential and priority drugs.

iii) All companies having equity above 26% shall be identified as foreign companies (as per RBI definition).

iv) All foreign companies shall produce bulk as to formulation ratio of 1:5. For other companies the ratio shall be 1:10.

v) A mechanism should be evolved to provide incentive to those companies which produce more than the required quota of essential/priority drugs and deterrent punishment to those companies which produce less than the required quota as given above.

vi) The priority drugs should be made available at low prices. If required, they may even be subsidized. Before any major revision in the pricing policy is done, as a policy there should be an independent study to assess the cost, profitability as well as availability and price from the point of view of consumers. Profit-making should not be the sole basis of the drug industry. All taxes from priority drugs should be abolished to reduce the prices of such drugs.

vii) The trade commission shall be fixed at 20%. However, this is the total commission which will be paid from the principal manufacturer to the distributors and the intermediaries. While the markup under the head of trade commission will be increased, the markup under the head of sales promotion will be decreased for essential and priority drugs.

viii) All drugs including nutritional supplements, except that produced by small scale sector, shall be under price control.

ix) The small scale sector can be free from price and production controls. However, the small scale sector will be defined as those companies whose turnover is less than 20 lakhs and not linked to large scale and organised sector units through ownership, financial participation or marketing arrangements.

B 2. **Proper Drug Registration and Monitoring**

Registration

1. All pharmaceutical products, both ethical drugs and over-the-counter (OTC) preparations offered for sale should be duly registered by a competent authority.

2. Commercially sold indigenous medicines should also be registered and pharmaceutical products which are not registered should not be allowed to be marketed.

3. Pharmaceutical manufacturers and traders must provide the registration authority with a list of all countries in which the specific product has not been accepted for registration.

4. Pharmaceutical manufacturers and traders should inform the registration authority if a pharmaceutical product already registered in the country has been removed from the register of any other country together with the reason for its removal.

5. Pharmaceutical manufacturers and traders, when applying for registration of a product, must be made to undertake that subsequent to the product's registration, they will provide the registration authority and consumers with all new informations they receive about its effects, adverse reactions and interactions.

6. Central Drug Control authorities should have an up-to-date information about the various drug formulations in the market, their combinations, their date of licensing, drug information being given with them by the producers and the latest international medical views on the products.

7. Drugs which have been banned from sale after being marketed for some time in one country must not be submitted for clinical trial or marketing in India. The onus of proving why such a non-essential drug should be introduced or allowed to continue in the market should be with the manufacturers.

8. Whenever a new drug is tested on healthy human subjects or on patients, the clinical trial must be authorised and monitored by a local "Ethical Committee" and must be carried out only with the full informed consent of the people and patients concerned.

Medical Audit System

It should be introduced to review the medical costs, the prescription practices, patient complaints of negligence or financial exploitation and drug misuse. At least minimal medical/clinical record keeping should be made mandatory. Medical audit systems should be introduced in a systematic manner.

Physicians and pharmacists should be answerable to Rational Therapeutics Committee of Experts. This could be appointed by Medical Council or any other academic neutral body. Medical experts involved in primary, secondary and tertiary medical care, chemists and consumer organisations should be represented.

C. DRUG DISTRIBUTION

i) A National Corporation for distribution of drugs and pharmaceuticals to retail drug outlets, hospitals and dispensaries should be established.

ii) National Drugs and Therapeutics Authority (see section G2) (or its sub-committee) should look into the drug needs of the peripheral health units to identify the bottle-necks and deal with them as a priority and ensure timely drug supply.

iii) This corporation should look into

- requirement estimation of various drugs and their dosage forms;
- purchasing effective, safe and quality drugs at most reasonable costs through bulk purchase and other purchase procedures;
- operating an efficient inventory and stock control system;
- developing an efficient workable system, where drug needs of the peripheral institutions can be a gauged and timely drug supplies ensured.

iv) Adequate drug distribution through the Government's health service infrastructure should be ensured. Essential drugs in adequate quantities and at subsidised rates should be available at PHCs, and their sub-centres.

v) Quality essential drugs should be made available from Government fair-price pharmacy shops. These could be handed over to PHCs and sub-centres.

vi) Education and relevant material on good pharmacy management as produced by WHO should be made available to pharmacy management system.

vii) Trained and qualified pharmacists should dispense drugs.

D. DRUG INFORMATION AND ETHICAL MARKETING

1. Drug Information

i) It should be the statutory duty of the drug control authorities to inform health personnel and consumers of the WHO's concept of essential drugs, India's graded essential drug lists, drug policies and their rationale regarding banning of drugs. Rational drug policy as a topic should be included in medical and para-medical education.

ii) Names of the brands banned for manufacture and sales should be widely publicized in medical journals, magazines, national newspapers, giving briefly the explanation and rationale of the ban.

2. Ethical Marketing

i) All sales promotion material including package inserts, medical data sheets by the drug units should be screened by a permanent National Drug Information body, which will be part of the National Drugs and Therapeutics Authority. This body should be responsible for screening as well as ensuring availability of unbiased drug information to the health personnel and consumers.

ii) Use of audio-visuals for sales promotion on drugs to doctors in absence of a printed copy (to be kept with the doctor), of the claims made, should not be allowed.

iii) All drug promotional literature should contain balanced and verified scientific information about indication, contra-indications side effects and drug interaction and antidotes.

iv) Inadequate and inaccurate information in medical promotional literature or package insert or worse still of the total commission of the package insert (as is the trend at present) should be considered a punishable offence.

v) Seminars, scientific sessions held by drug companies to present mainly industry sponsored research studies should be closely monitored and if need, be restricted as it is associated with presentation usually only of favourable results and tend to create a sense of obligation in the minds of certain medical personnel towards drug companies for sponsoring their research.

vi) Sponsoring of National Conventions of professional medical and academic societies by drug industry should be discouraged since consumers have to ultimately indirectly foot the bill and such sponsorship inevitably introduces bias in favour of the company and its products. The health ministry should take up the responsibility for making funds available for such seminars.

vii) Advertisement of tonics and food supplements should not be allowed in the lay-press. OTC sales advertisements making false or misleading or inaccurate claims should be banned. Authorities should ensure that adequate consumer caution is provided to the consumer in regional languages.

viii) Labelling should be clear. International non-proprietory names (generic names) should be used. Consumer caution should be in regional languages.

For food supplements, nutrients, tonics in the consumer caution in regional languages it should be added that "This is not a substitute for normal food" and message given pictorially wherever possible.

ix) "The International Code for Ethical Marketing" as drafted by the Health Action International should be adopted by India.

D 3. **Drug Nomenclature**

International non-proprietary names should be used for sales, labelling and prescription writing. This being so because of several advantages:

i) Generic drug names are used in under-graduate/postgraduate medical and pharmaceutical education.

ii) Generic names are used in medical text books, scientific medical journals and WHO publications.

iii) All purchases of medicines from international tenders and international markets are based on generic names.

iv) Use of generic names also ensure production, sale and dispensing of more rational single ingredient drugs.

v) Generic name assures clarity by giving information of the class of drug and thus avoiding confusion arising out of many dissimilar brand names of one drug.

vi) Drugs of equal quality are usually cheaper when purchased by their non-proprietary names than when bought using brand names.

vii) Use of non-proprietary names is a valuable aid to memory as health workers have to learn and remember each drug by one name only.

E. SELF - RELIANCE

1. Technological self-reliance

i) In view of the high importance of achieving the goal of self-reliance in the drug sector, it is imperative that all technology transfer agreements are made in accordance with the United Nations Council for Trade and Development draft code.

ii) Protective mechanisms should be evolved for process that are being developed in the national laboratories so that technology being developed indigenously does not get aborted as it has happened in the recent past in case of processes developed at NCL and Central Drug Research Institute.

iii) While encouraging in house R&D activity through fiscal incentives, mechanism should be evolved that the R&D effort undertaken by different firms is in accordance with the priority drug needs of the Indian people.

2. Encouragement to Indian Sector

i) Make priority drugs, already produced in the country from basic stage by the public sector and wholly Indian companies, a reserved category for which companies holding foreign equity more than 26% should not be allowed any fresh license.

ii) Stipulate a strict time limit of five years for all foreign companies to start production from basic stage for the existing already licensed production capacities.

iii) Ensure implementation of the time limit of two years stipulated for foreign companies to undertake production from the basic stage for fresh license.

iv) No Carry on Business license or production over the licensed capacity should be allowed for MRTP, FERA and ex-FERA companies.

v) Loan licenses being used by the small scale sector units linked through ownership, financial participation and/or marketing arrangements should be cancelled.

E 3. **Reduction of Imports**

i) The canalisation of all imports should be streamlined. Open general licence system should be abolished. There should be raw material pool in each State to ensure proper pricing and availability of raw materials.

ii) Import and excise duties should be fixed in such a way that the landed cost of imported raw materials and bulk drugs should not be lower than that of indigenous raw materials and bulk drug production.

F. RESEARCH AND DEVELOPMENT

i) Priorities in research should be guided by the health needs of the people in India. Drugs required in diseases causing greater mortality, morbidity, serious sequelae should get priority. Vaccines should get priority over other drugs.

ii) Even 38 years after the cessation of British Colonial Rule in India, research on non-allopathic drugs continues to get step-motherly treatment. Hence research on these drugs should be encouraged. None of these drugs, however, should be allowed to be produced on commercial scale unless their efficacy and safety has been proved through scientific research.

iii) Research policy on drugs should be reviewed every ten years to respond to changing pattern of diseases in India.

iv) All medical research on human beings must be statutorily required to conform to the 1975 Helsinki (Mark II) Declaration. All research proposal must be approved by a central authority before research is started. This should be strictly adhered to in case of contraceptive research also.

The present policy of giving priority to research on hormonal contraceptives rather than to barrier methods must be reversed.

G. DRUGS LEGISLATION AND ADMINISTRATION

1. Drug legislation should provide for the following:

   - a system of registration of all medical products (including traditional medicines)
   - enforcement of good manufacturing practice
   - full control of labelling and advertisement
   - control of prices of finished drugs and therapeutic raw materials
   - prescription control of toxic/poisonous and habit forming drugs
   - summary trial for violations against the drug policy by manufacturers and traders in special drug courts
   - heavy penalties including confiscation of equipments and properties for the manufacture and/or selling of spurious and sub-standard drugs.

   The legislation should be reviewed, regularly modified and updated in the interest of the public and they should not become bottlenecks for implementation of the national drug policy.

2. **National Drug and Therapeutics Authority**

i) The greatest need of the moment is greater public accountability and a greater social control over pharmaceutical industry. For this, setting up an independent machinery such as a National Drug and Therapeutics Authority is imperative, which can scrutinize all the drugs currently marketed in India on an ongoing basis and be held responsible for the nature of drugs in the market. This permanent body should have representatives with medical, pharmacy and management expertise. Representation being from :

   1) drug and health authorities from states
   2) Ministry of Chemicals and Fertilzers and Ministry of Finance
   3) medical professional and medical academic bodies
   4) consumer groups and NGOs involved in health work

5) Trade Unions related to drug industry

6) chemists and druggists.

The Government should establish National Drug Authorities (NDA) at the State level also. The Drug Controllers should be accountable to NDAs.

ii) The recommendations of the National Drugs and Therapeutics Authority should be binding on the drug industry.

iii) Appropriate powers be delegated to Central Drug Controller and State Drug Control Authorities for the proper implementation of the recommendations of the Drug and Therapeutics Authority.

iv) Relationship of NDA with centre and state drug and health authorities should be clearly defined. Its constitution, functioning and powers should be aimed at proper implementation of National Drug Policy. Suitable drug legislation support should be given to this authority so that its decisions are not unnecessarily challenged in the court.

v) Drugs should be dealt with by this NDA rather than by Ministry of Chemicals and Fertilizers, to give greater emphasis to the therapeutic relevance rather than industrial profits and Government's revenue.

H. HUMAN POWER DEVELOPMENT

Not merely medical and pharmacology related manpower development is required, but also development of drug managers, drug inspectors, quality control technicians, researchers and scientists willing to do R and D in areas of grater concern to the health of our people. The training and development should include training of legal personnel who will be dealing with Food and Drug Courts.

Exposure and training of policy makers to other dimension of drug issues as experienced by consumers and health personnel in the field is also relevant.

Drug control mechanism has to be developed in keeping with the growth of our drug industry and be proportionate to our drug production and sales.

THE ALL INDIA DRUG ACTION NETWORK (AIDAN) COORDINATION COMMITTEE CONSISTS OF

(1) Arogya Dakshata Mandal, Pune.
(2) Catholic Hospital Association of India, Delhi.
(3) Consumer Education & Research Centre, Ahmedabad.
(4) Consumer Guidance Society of India, Bombay.
(5) Drug Action Forum West Bengal, Calcutta.
(6) Delhi Science Forum, Delhi.
(7) Kerala Sashtra Sahitya Parishad, Kerala.
(8) Locost, Baroda.
(9) Lok Vigyan Sangathana, Bombay.
(10) Medico Friends Circle, Pune.
(11) Voluntary Health Association of India, Delhi.

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All India Drug Action Network -AIDAN

OUR DEMANDS

* **availability of essential and life saving drugs** (i.e. adequate production and streamlined distribution to peripheral areas).
* **withdrawal of hazardous and irrational drugs**
* **availability of unbiased drug information** to health personnel and consumers (including updating our National Drug Formulary), and provision of therapeutic guidelines as in British National Formulary; provision for consumer caution in regional languages for problem drugs
* **adequate quality control and drug control** so that every fifth drug in the market is not sub-standard as in at present according to Government's own figures
* **drug legislation reform** to prevent drug companies from misusing legalistic loopholes against the people.

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