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Consumer Drug Information in India: A Situational Analysis

In collaboration with CDSCO, MOHFW, GOI and WHO Country Office for India

Centad
Centre for Trade & Development

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Preface

It is a settled principle of law that all manufacturers have a duty of care towards the consumers of their products. To ensure that they honour this duty of care, it is necessary to educate consumers about their rights by creating mechanisms in place to inform them about the various aspects of the products they consume. It is particularly important to have a well-developed informative system in the sphere of pharmaceutical products since they form essential commodity which must be affordable and accessible to all. The duty of care towards consumers, therefore, is greater for all manufacturers, suppliers, and dispensaries of drugs. Moreover, consumers have limited scope for choosing a drug of their liking since the range of different brands of a pharmaceutical substance is limited. Hence, it is important for consumers to have adequate information on drugs to enable them to effectively exercise their choice.

Awareness of and knowledge about medicines has expanded over the last two decades. Even though the health movement often despairs at the lack of knowledge about health matters among the lay public, it has to be admitted that there is much more information available in the public domain now than ever before. This information has been generated in various ways by various stakeholders, viz. the drug consumer movement, the health activists, regulatory authorities, as well as the drug industry and the medical associations. However, the information produced by the drug industry has been directed largely at promoting particular pharma products rather than at increasing public knowledge about drugs and pharmaceuticals. Although over the years various drug information mechanisms have come up, there is lack of information in regard to the kind of consumers they cater to? This is because consumers of drugs occur at different levels. For instance, to a drug manufacturer the doctor is the consumer and not the patient who ultimately buys the drug.

In the context of the existing drug information mechanisms, this study attempts to address issues such as the nature of information produced by stakeholders especially the government and the consumer movement / civil society, the quality and usefulness of the information material used, the efficiency of the regulatory and monitoring authorities in discharging their responsibility to disseminate information about pharmaceutical products to consumers, and the level of information produced by medical associations to aid prescription practices or consumers.

It is hoped that the analysis in this paper will be useful for policy-makers, researchers and civil society. It is also hoped that it will help take forward India's law and policy on the subject in accordance with international best practices. Suggestions and feedback would be welcome.

Dr Samar Verma
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Executive Summary

Consumer drug information includes all information directed to patients and consumers regarding drugs and treatments used by them with a view to enabling them to take informed decisions. The need for such information emanates from the basic right to the health of individuals. People must have knowledge about what medications they are being advised to consume in the interest of their own health. It is a basic right to know what one is consuming. The Alma Ata Declaration states: "People have the right and duty to participate individually and collectively in the planning and implementation of their health care". Moreover, the issue of right to essential medicines, right to safe medicines is closely tied with the right to health, right to livelihood with dignity and right to life.

Generally speaking, the information about drugs should be accurate, reliable, understandable, relevant to people in different contexts, accessible, and comparative (where possible). Drug information is also the basis for the development of tools essential for rational prescribing and use such as formularies and standard treatment guidelines. There is a range of actors involved in the dissemination of different types of information to consumers relating to drugs. Organisations that are considered as the actors providing consumer drug information are considered as such because of their mandates, which are relevant, even indirectly, to issues of consumer drug information. These include governmental and quasi-governmental authorities, civil society and non-governmental organisations, patients' associations, pharmaceutical associations, drug manufacturers' associations, and societies involved in promoting rational drug use.

The objective of the project involves the following:

- To determine the type of information referred to when discussing 'consumer drug information'.
- To determine the nature of information currently being disseminated to consumers.
- To identify which actors are involved in dispensing such information and the type of information that each provides.
- To identify models and guidelines for what kind of information should ideally be provided, how this should be done, and how this can further the cause of helping consumers make informed choices.
- To examine the law and policy regimes applicable to drug information disseminated to consumers.

This paper seeks to address the above objectives through a study of a sample of materials and information obtained relevant to drug information for consumers. The first step of the project involved the identification of contacts to approach for information. This was done through searching for organisations and individuals on websites, posting requests on online mailing groups dealing with issues on drugs, as well as approaching individuals for providing relevant contacts.

The main conclusions that can be drawn from a situational analysis of the provision of consumer drug information in India are:

- The availability of consumer drug information in India is very low in terms of quantity.

- Information is not provided in a user-friendly manner in most cases. It is provided mostly on allopathic drugs, and there is only limited information on traditional medicines, medical technologies and equipment, and on diagnostics.
- There is a particular lack of information relating to drug prices, and there is no single, dedicated actor concentrating only on consumer drug information.
- There is no coordination among different actors providing consumer drug information, and there is no level of consistency with respect to the information supplied. Information directed at consumers is largely aimed at awareness creation on preventive strategies and is not very technical in terms of providing medical details pertaining to the drugs or in terms of providing practical information regarding the usage and consumption of the drug. Most technical information with respect to drugs is directed to medical professionals and not consumers.
- Information to consumers in not made available in a simple manner, since this is usually done through the publication of books, booklets or CDs or other formats that would not normally be accessed by common consumers. Information is sometimes being provided in both English and local languages though for some sources of information such as labels on medicines or those in the internet, information is primarily in English.
- The current law and policy regime does not deal comprehensively with issues of consumer drug information.

There is no comprehensive, single database of information, which contains technical information on drugs that has been approved by government. The Ministry of Consumer Affairs does not provide exclusive information on drugs. Government websites, such as that of the Ministry of Chemicals and Fertilizers, do provide information on prices in the form of relevant government orders, notifications and news dealing with the drugs under price control, lists of essential drugs, and so on. As against this, the US FDA site provides comprehensive and authentic information to consumers. This can be considered as a possible standard for the development of a similar database in India.

The paper makes the following recommendations that need to be immediately implemented to address the pressing issues of consumer drug information:

- For bigger packs of medicines, leaflets and printed materials should be given. This should be made compulsory for drug companies, and a team of pharmacologists, clinical professionals, and consumers should review all drug-related information. Disseminating detailed information on drugs to consumers in a simple, easy to understand manner, and not only English but also in local languages.
- Making information on prices of drugs and comparisons between the prices of various branded and generic versions of the drug, more readily available for consumers.
- Developing a forum wherein the actors involved in disseminating information can meet and deliberate as to the common steps to be taken to take forward the movement for advocating rational drug use, particularly regarding consumer drug information.
- Encouraging consumers to be more proactive in seeking information.

Other recommendations that need to be implemented include developing a single, comprehensive, verified, and authentic source of information, which can be readily accessed by consumers; developing comprehensive regulations and guidelines and ensuring their implementation for all possible sources of consumer information and the actors providing this information; a format according to which information may be provided should be developed in the lines of the British National Formulary (BNF); considering the use of the Physician Drug Review (PDR) in the US as a

standard for the comprehensive information to be provided; coordination among different actors to develop a common approach with respect to the standards and guidelines to be evolved, etc. Apart from the above, the paper also makes certain recommendations that can be specifically directed to each set of actors like governmental and quasi-governmental authorities, civil society and non-governmental organisations, healthcare professionals, pharmaceutical companies, etc.

In conclusion for the purpose of this paper, certain issues arise for consideration as future research questions and areas for examination. These include the necessity for understanding consumer drug information from the demand side as well. The provision of consumer drug information can be effective only if it meets consumer needs. There is a need for linking research done on the marketing and drug promotion strategies pursued by the pharmaceutical industry, with the mechanisms for the provision of consumer drug information and the quality of such information. The report also draws attention towards the need for a detailed study of advertisements, as they are a direct and predominant source of information for consumers.

Abbreviations

ASCI	Advertising Standards Council of India
BNF	British National Formulary
CDSCO	Central Drugs Standard Control Organization
CDL	Central Drugs Laboratory
CORE	Consumer Online Resource Empowerment
DATA	Drugs and Therapeutics (Regulation) Act
DIC	Drug Information Centres
DTAB	Drugs Technical Advisory Board
IDMA	Indian Drug Manufacturers Association
KSPC	Karnataka State Pharmacy Council
LOCOST	Low Cost Standard Therapeutics
MRTP	Monopolies and Restrictive Trade Practices
MRTPC	Monopolies and Restrictive Trade Practices Commission
NACO	National AIDS Control Organization
NIPER	National Institute of Pharmaceutical Education and Research
NPPA	National Pharmaceutical Pricing Authority
NVBDCP	National Vector Borne Disease Control Programme
OPPI	Organisation of Pharmaceutical Producers of India
PDR	Physician Drug Review
US FDA	United States Federal Drug Authority
WHO	World health Organization

CONTENTS

I. Introduction

Consumers generally have many channels of information on a variety of products; however, the information specific to drugs is more limited. They depend on doctors for what drugs to purchase and consume, particularly for prescription drugs. Thus the consumer does not exercise the power of choice over what he/she is purchasing, as the doctor prescribing the drug makes this choice. Considering this unique position with respect to drugs, it is essential that consumers are well informed for them to be involved in the decision-making processes concerning their own health and make informed choices.

a) The Need for Consumer Drug Information

The need for consumer drug information emanates from the basic right to health of individuals. People must have knowledge about what medications they are being advised to consume in the interest of their own health. It is a basic right to know what one is consuming. The Alma Ata Declaration[1] states: "People have the right and duty to participate individually and collectively in the planning and implementation of their health care". Moreover, the issue of right to essential medicines, right to safe medicines is closely tied with the right to health, right to livelihood with dignity and right to life.[2]

Further, consumers have a right to be informed about the quality, quantity, potency, purity, standard and price of goods so as to protect them against unfair trade practices. There is also a right to consumer education. This means the right to acquire the knowledge and skill to be an informed consumer throughout life.[3]

According to the World Health Organization (WHO) consumers need information and education on medicines and appropriate treatment-seeking strategies for public health[4] so that:

- Individuals and communities can take responsibility for their health
- As patients they can be informed partners in therapeutic decision making and subsequent drug use
- As consumers they have the basic tools for rational and safe direct purchase of medicines, and can put in context the claims of commercial drug promotion.

Considering that the patient or consumer is the ultimate user of the drug, and usually also ultimately controls his/her own usage of the drug, a consumer needs information about the medications being taken by him/her. It is also important that the information provided to consumers must address what the consumer expects to know about the drug.

To summarise, consumers need information for the following reasons:

- ***Right to Health – Patients have a right to know what they are consuming. A knowledge of medication and treatment helps achieve the basic right to health.***
- ***Right to information – the right to be an informed consumer, right to consumer education.***

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1 Declaration of Alma Ata in: *Primary Healthcare*, Geneva, World Health Organization. 1978.

2 Dr. Mira Shiva and Dr. Wishvas Rane, "Banned & Bannable Drugs *Unbiased Drug Information Essential Drugs and Rational Drug Policy* (Voluntary Health Association of India, New Delhi, 2004).

3 Para 61 of the United Nations Guidelines for Consumer Protection (as expanded in 1999). The right to consumer education has also been recognised in the Consumer Protection Act, 1986. See for instance, Sec. 6(f) of the Act. See also: http://www.corecentre.org/rights_faqs.

4 "Public Education in Rational Drug Use – A Global Survey" (Daphne A. Fresle and Cathy Wolfheim; World Health Organization, Geneva, 1997).

- ***For patients to make informed decisions and protect their health.***
- ***Rational and safe drug use.***
- ***To prevent misinformation.***

b) Objectives

The objectives of this project include:

- To determine the type of information referred to when discussing 'consumer drug information'.
- To determine the nature of information currently being disseminated to consumers.
- To identify which actors are involved in dispensing such information and the type of information that each provides.
- To identify models and guidelines for what kind of information should ideally be provided, how this should be done, and how this can further the cause of helping consumers make informed choices.
- To examine the law and policy regimes applicable to drug information disseminated to consumers.

This paper seeks to address the above objectives through a study of a sample of materials and information obtained relevant to drug information for consumers. The paper has been divided into 8 parts. Part I ***Introduction*** discusses the issue of what 'consumer drug information' is and why it should be provided. The objectives of this study are also specified in this section. Part II ***Methodology,*** discusses the research methodology used for this paper including how materials were obtained and surveyed and the limitations to the project. Part III ***Models and Parameters*** examine the models that can be used to evaluate and provide information, as well as the parameters by which such information is examined. Part IV ***A Background to the Relevant Law and Policy Regime in India*** examines the relevant Indian law and policy applicable to the regulation of consumer drug information. In Part V ***A Survey of Information*** briefs descriptions of the main types of organisations involved in providing consumer drug information and of the information surveyed in the course of this project are given. Part VI ***Conclusion and Recommendations*** states the conclusions arrived at after surveying the information and the consequent recommendations.

II. Methodology

The first step of the project involved the identification of contacts to approach for information. This was done through searching for organisations and individuals on websites, posting requests on online mailing groups dealing with issues on drugs, as well as approaching individuals for providing relevant contacts. A precise list of the individuals and organisations involved in providing consumer drug information for this project is given in **Annexure I**. A broad spectrum of actors was also contacted through the general postings made online to groups such as India-Drug and AIDS India. A brief outline of the categories of actors surveyed is described below. As and when contact information was obtained, these organisations and individuals were approached with requests for information. This was done through emails and telephone requests, and the context and aim of the project was explained and discussed with them. The time period over which materials were examined was taken as the last 5—6 years. Most of the materials thus received were contemporary.

The survey of materials collected was done according to the type and content of materials, the medium of communication, and target groups. In this paper, information has been classified and described primarily in terms of the actors providing the information. The materials were also specified in terms of the parameters that each source of information satisfied, as well as the forms in which the materials were available, as seen in the tables provided in Annexures II and VII of this paper. A consultation was held involving different stakeholders such as representatives from the government, pharmaceutical industry associations, non-governmental organisations working on health issues or on consumer issues, healthcare professionals, etc. The feedback and suggestions thus obtained have also been incorporated in this paper.

a) Limitations

At the outset, the scope of 'consumer information' taken for the purpose of this paper was the information being provided to the ultimate consumers of drugs. Although from the perspective of actors such as drug companies, consumer information would mean information being provided to doctors and medical professionals, this is beyond the scope of the project. Thus categories of consumers such as doctors, pharmacists and other healthcare professionals as well as institutions, which buy drugs for health programmes such the malaria control programme, or the UNICEF, were not considered in the scope of this paper.

In the context of branded drugs, information is available in the patents' files. However, such information has not been examined in this project. An important limitation in this project was that the actual reach of the materials surveyed could not be judged, as the scope of the project did not include the determination of how much of the material disseminated actually reaches consumers. There was also no questionnaire directed to consumers to determine consumer response to the materials and hence evaluate the effectiveness of the materials and the channels through which information is being provided. However, a limited number of interviews of medical professionals were conducted. Responses were not obtained from all the actors contacted and the survey of information has been limited to only material that was actually received. Further, most of the information requested for and received was over a limited time frame, usually the last five years. Although attempts were made to study information dated before this period and to incorporate them as well, there was not an exhaustive analysis of the same.

It is recognised that accuracy, correctness and reliability of information are crucial prerequisites in the provision of information. However, the verification of whether the information studied was accurate and correct was beyond the scope of this project. An examination of quality of information, in terms of applying subjective standards to determine how 'good' or 'bad' the information was, was also not done. However, an objective evaluation of information was done by examining the content of each source of information according to the parameters used in this paper for what types of information need to be provided to consumers. This has been provided through the tables shown in **Annexure II**.

b) The Nature of 'Consumer Drug Information'

Consumer drug information can be considered to include all information directed to patients and consumers regarding drugs and treatments used by them with a view to enabling them to take informed decisions. Generally speaking, the information should be accurate, reliable, understandable, relevant to people in different contexts, accessible and comparative (where possible).[5] Drug information is

[5] Model Letter to European Health Ministers, 18B655D3-BDB2-4D70-8C82-B6C2FD9A8307_Model Letter DTCA and "Transparency and Accountability in Drug Information for Consumers", Consumers International , 7674DA3F-4C41-4499-BFCC-927A9BC6115B_ HealthConsumerIntergroup.

also the basis for the development of tools essential for rational prescribing and use such as formularies and standard treatment guidelines. A comprehensive list of the types of information that are needed by the consumer is discussed later as part of the models used in this paper for the analysis of materials.

For most persons, doctors and other medical professionals are the most reliable and direct source of information on drugs considering that they are depended on for prescribing medication and providing guidance to consumers. However, drug information provided to consumers from other sources is equally important for them to make informed decisions pertaining to their health. Other sources and channels of information for consumers include pharmacists, nurses, drug regulatory agencies, drug information centres, print and electronic media, health groups, patient groups, consumer groups, educational institutions including medical and pharmacy colleges, and the pharmaceutical industry.

With awareness and information, consumers would also be in a better position to interact with doctors and ensure that they get relevant and reliable information and guidance. The WHO manual on consumer drug use has identified some popular consumer beliefs about medicines, which could act as guidance for developing channels of information targeting consumers to correct these misbeliefs. Some of the important factors in individual beliefs about medicines are: the perceived need for medicines, ideas about efficacy and safety, and uncertainty resulting in poly-therapy.[6]

Other factors influencing the way consumers behave with respect to drug use are:[7]

1. Drug consumption roles
2. Cost of medicines
3. Literacy levels of consumers
4. Medicine supply systems
5. Information channels
6. Drug promotion
7. Consumer advocacy
8. Media
9. Public education on medicines for consumers

According to the WHO, this shows that consumer drug information is a factor that influences the choice of medication that consumers use. Thus consumer drug information has a powerful potential to change consumer behaviour for the better.

Although consumer drug information can be very comprehensive and detailed, the information that consumers require may not necessarily involve the provision of all of such information. Some consumers would prefer basic information while others prefer access to detailed and technical information in the sense of information provided in academic journals. However to some extent there is a percolation of information from these academic sources to laypersons through the media. Such information is also passed on indirectly through doctors and other medical professionals who rely on such information and also through interaction with patients. As stated by Dr. Anant Phadke, consumer drug information is of two types; minimum information (which would include information such as side effects) and comprehensive information (which would include information such as *rarer* side effects).[8] Some of the information that should be provided is because of legal requirements, such as the label requirements, while other sorts of information should be provided even though not legally mandated, so that the consumer has a better understanding of the medication. For instance, the provision of information on price comparisons for different brands of the same drug is not mandated by law, however the same is important information

[6] Anita Hardon *et al.*, "How to Investigate the Use of Medicines by Consumers". (World Health Organization and University of Amsterdam, 2004).
[7] Id.

of relevance to the consumer. The components of what should be provided as drug information also depend on the type of consumer interested in the information. This in turn often depends on the class and educational background of the consumer. Consumers who are less educated may be more interested in very basic information, such as knowing only what drug to take. More educated consumers may be interested in knowing not only about what medication is required but may also be interested in finding out details about drug action, costs and so on through sources other than doctors. In such a case, they would be more interested in knowing about the authentic and reliable sources of information that exist and would refer to these. The level and detail of information being provided to consumers thus depends on what they are looking for. A precise list of the elements of comprehensive consumer drug information is provided later in this paper.

To summarise:

- **Information changes consumer behaviour.**
- **Apart from doctors there are other important sources of information.**
- **There are different channels through which these sources impart information.**
- **The type of drug information provided may be basic or comprehensive depending on the needs of consumers.**

III. Models and Parameters

a) Models for Analysis

Different models have been developed by a number of international organisations, the government and NGOs for setting the standards by which consumer information should be analysed. These standards are usually set with the aim of ensuring the effective dissemination of information to consumers. The basic information that consumers need to know are on aspects such as brand and generic names, composition, price, dosage, precautions, side effects, special consideration to be kept in mind for certain patients and so on. A comprehensive list of informational issues that consumers need to be aware of is given below. The same is based on the different models and materials available on consumer drug information and has been used in this project to evaluate the consumer drug information scene. Thus consumer information about a drug should include:

- Whether a drug is a prescription drug or not.
- Details of its composition: patients should be educated about what a drug contains, including being told whether it is a combination or not. A component of rational drug use involves

[8] According to Mr. Srinivasan, the minimum information that should be provided to consumers includes when to take the medicines, for how many days, whether before or after meals, why the drug course should not be stopped (particularly in the case of chronic diseases), and when the patient should report to the doctor.

knowledge of what the drug contains and awareness about rational/irrational combinations.

- Brand and generic names: this helps the consumer know about the number and varieties in the market to choose from.
- Price: consumers should be made aware of the prices of the various alternatives of both generic and branded drugs available to them, as they ultimately pay for the drug even though they usually do not make the decision of taking that drug.
- Dosage: patients must be aware that adherence to the recommended dosage is a must as otherwise the drug could be ineffective or could have adverse effects.
- Side effects: awareness of this is necessary, so that consumers know what to expect from the consumption of particular drugs, and also to make them aware that the conditions that may occur are only side effects and are not additional medical problems.
- Precautions and risks: this involves making the consumer aware about situations in which the drug intake may be risky because of certain existing medical conditions of the patient.
- Storage conditions: it is important that storage conditions are adhered to so as to ensure that the value of the drug is maintained.
- Approved indications and contraindications: this refers to the medical conditions when the drug should or should not be taken. The indication refers to the ailments for which the drug has been approved for use.
- Expiry date: it is important to mention until when the drug can be consumed.
- Use of the drug in case of special situations: consumers must be made aware of the correct dosage and method of taking the drug in special situations such as pregnancy, lactation, in the case of children or the elderly and so on. This is because the effects of the drug in the body are different in these different situations.
- Alternatives to the drug: this information is important as the consumption of drugs may be avoided when there are other, equally effective treatments available.
- Diet behaviour: Consumers should be made aware of the type of diet to be followed and what all should be avoided while consuming the drug so as to ensure that the drug is effective. Also the effect of consumption of substances such as alcohol should be pointed out as this may inhibit the correct functioning of the drug.

Apart from the above, the following information is also of relevance to consumers[9]:

- Whether the drug is a banned or hazardous drug
- Whether the particular drug or its combination is useless and irrational. Encouraging consumers to avoid combination drugs and buy single ingredient drugs as far as possible.
- Guidance on buying generic equivalents of drugs and the reliable companies manufacturing the same. This should be done so that consumers can avoid purchasing unnecessary and expensive branded drugs.
- Advise regarding traditional home remedies that can be used for simple, common problems and can act as an effective substitute to expensive and unnecessary drugs.
- Consumers should be given guidance on what they should ask and clarify with their doctors when being prescribed or counselled about taking drugs, such as: how the drug should be taken, how often, what side effects may occur, how long the drug should be continued, what the expected benefits would be, whether there would be any other problem with any other drugs being taken, whether certain food and drink should be avoided while taking the drug,

[9] This includes elements from the model prescribed by the Voluntary Health Association of India.

and the availability of cheaper, equally effective alternatives. Further the consumer should be made aware that if he/she is given a long prescription, they should find out which medicines are the most essential and which can be avoided (such as costly tonics that can be substituted by food).

- Monitoring needs to be done regarding the inclusion or absence of package inserts (printed information with drug packs). These are important especially for newer drugs.
- Consumers must be educated about the importance of adhering to the schedule and dosage regimen for the drug being taken. For instance, if the consumer is prescribed antibiotics or put on long-term treatment, such as for TB or leprosy, he/she should ensure that medicines are taken regularly and for the prescribed duration to avoid the emergence of drug resistance.

Apart from the substantive aspects of information, the nature in which the information is provided to consumers is of equal importance. For instance, to disseminate the substantive aspects of information relating to diseases, medical conditions, prevention and treatment, the Ministry of Health has a dedicated information, education and communication (IEC) resource centre to complement its National Health Programmes. The main characteristics of how information should be communicated to consumers would include:

- Accurate and reliable information
- Provision of technical information in a simple, easy to understand manner, i.e. presenting information directed to medial professionals in a manner that can be understood by laymen
- Information should be *basic* or *comprehensive* depending on the type of consumer aimed at.
- Basic information would refer to the minimum necessary information: drug name, indications, price, dosage, storage requirements, and side effects.
- Comprehensive information includes all possible information related to the consumption of the drug. This means information on *how* the drug works; *when* the drug is to be consumed, i.e. the approved indications for the drug; *conditions* to be observed in drug use (dosage, duration, diet, storage, precautions, etc.); *side effects* of the drug; *price comparisons* for different brands of the drug in the market; *risks* and *precautions*; *alternate treatment* options; *clarifications* about drug promotions by companies and in the media. Also, each aspect of information would be explained in a detailed manner.
- Information must be provided in an accessible manner. For instance, information should be disseminated in local languages, should be made available to the visually challenged, and in a manner respecting privacy of consumers.

b) Parameters for Evaluating Information

The broad parameters taken for analysing the materials has been in terms of the horizontal reach of materials and the content of information.

In terms of *reach*, the factors influencing how effectively the information provided actually reaches consumers have been sought to be examined. These factors include:

- Form of the material: This refers to the manner in which the material has been provided such as through electronic or printed material. Printed material includes books, brochures, pamphlets, flyers, and posters. Electronic material includes information provided over the internet, CDs, videos, and so on.
- Type of information: This includes what the information is about, e.g. on drugs, devices, medical technologies, therapies, and so on.
- Language: This involves seeing whether the material is predominantly in English or in local languages as well.
- Style: This includes examining the manner in which the material is presented such as the

language style, pictures and diagrams, and so on.

Content of information refers to what sort of information is being provided to consumers. This is evaluated by first developing certain parameters of what type of information should be provided to consumers and then evaluating whether the information being provided by a given source is actually of the type identified in such parameters. However, this does not refer to an analysis of quality of the information supplied, but merely assesses whether information in accordance with the parameters is present per se.

IV. Background to the Relevant Law and Policy Regime in India

In India the law addressing issues of consumer drug information is not comprehensive enough. However there are different statutes, policies and guidelines, which are directly or indirectly applicable to different aspects of the provision of drug information to consumers. For instance these laws, policies and guidelines may govern the dissemination of health information to the public, regulate advertisements or prescribe codes of practice for healthcare professionals to follow while interacting with patients. In this section, the applicable statutes are first analysed. Following this is an analysis of the applicable policy regime. At the end, certain guidelines and codes prescribed for healthcare professionals are examined.

The relevant statutes, which are analysed in detail below, are:

- **Drugs and Cosmetics Act, 1940 – *regulates the manufacture, sale and distribution of drugs.***
- **Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 - *regulates the advertisement of drugs in certain cases, and prohibits the advertisement of allegedly 'magic' remedies***
- **Consumer Protection Act, 1986**
- **Monopolies and Restrictive Trade Practices Act and the Competition Act, 2002**
- **Code of Conduct issued by the Advertising Standards Council of India (ASCI)**
- **Statutes regulating healthcare professionals**

a) Drugs and Cosmetics Act, 1940

The Act regulates the import, manufacture, sale and distribution of drugs and cosmetics in India. It is to be noted that 'drugs' are deemed to include devices used for the diagnosis, treatment, mitigation or prevention of diseases or disorders and which are notified by the Central Government.[10] The Act prescribes certain quality standards applicable to drugs. These include references to standards maintained by international laboratories, standards relating to what must be prescribed on drug labels, specifications by the Indian Pharmacopoeia editions, and so on.[11] The Act also deals with misbranded drugs, adulterated drugs, spurious drugs and their import, manufacture, sale and distribution. The Central Government has the

[10] Section 3(b)(iv) of the Drugs and Cosmetics Act.
[11] Section 8 read with the Second Schedule of the Drugs and Cosmetics Act.

power to prohibit the manufacture of drugs in public interest such as when it feels that the use of the drug is likely to involve any risk to humans or animals or if the drug does not have the therapeutic value as claimed or if it contains ingredients for which there is no therapeutic justification.[12] Penalties under the Act for contravention of its provisions are imposed on the manufacturers, sellers, distributors, etc. of the drug as the case may be, even when the transaction is done by other persons on behalf of the manufacturer, etc.[13] However this does not exclude the prosecution of persons who are not manufacturers or distribution agents, etc., and in fact in such prosecutions too, the manufacturer, etc. may be impleaded.[14]

In its procedural aspects, the Act provides for the constitution of a Drugs Technical Advisory Board (DTAB) with a mandate of advising the Central Government and State Governments on technical matters relating to the administration of this Act.[15] However ayurvedic, siddha or unani drugs are outside the mandate of the DTAB.[16] The Act also provides for the setting up of the Central Drugs Laboratory (CDL) with functions prescribed by the Act or rules under the Act; which include conducting inspections on drug samples submitted to it.[17]

Provisions in the Act, which may be particularly relevant to consumers in the context of drug information being provided to them include the following:

- As mentioned above, the quality standards prescribed under the Act include specifications of what must be mentioned on the label or container of the drug such as the formula and list of ingredients.[18]
- The Act prohibits the misbranding of drugs. 'Misbranding' includes: where the drug is not labelled in the prescribed manner; or where the label or container, etc. makes any false or misleading claim. This applies to ayurvedic, siddha and unani drugs as well, although vaidyas and hakims manufacturing these drugs for their own patients are excluded from the application of this provision.[19]
- The Act prohibits the manufacture or sale of any patented or proprietary medicine, unless its label or container displays the true formula or list of active ingredients contained and the quantities thereof. However, it is to be noted that with respect to ayurvedic, siddha and unani drugs, vaidyas and hakims manufacturing these drugs for their own patients, are excluded.[20]
- Similar regulations are made to apply to ayurvedic, siddha or unani drugs. Here the government can make rules to prescribe the conditions for packing these drugs, the mode of labelling and what shall or shall not be included in these labels.
- Under the Drugs and Cosmetics Act and the DPCO, 1995, the following information is required to be printed on the label of a medicine: name of the formulation, composition of the formulation, pack size, address of manufacturer, manufacturing license number, date of manufacture, expiry date, maximum retail price, etc.[21] Section 33(h) of the Act gives the Central Government the power to make rules requiring the drug label or container to clearly state the date of manufacture and the date of expiry of potency of any specified drug or classes of drugs. Section 33(j) enables the Central Government to regulate the mode of labelling packed drugs and to prescribe the matters, which

[12] Section 26A of the Drugs and Cosmetics Act.
[13] Section 27 of the Drugs and Cosmetics Act.
[14] Section 32A of the Drugs and Cosmetics Act.
[15] Section 5 of the Drugs and Cosmetics Act.
[16] Section 7A of the Drugs and Cosmetics Act.
[17] Section 6 of the Drugs and Cosmetics Act.
[18] Section 8 read with the Second Schedule of the Drugs and Cosmetics Act.
[19] Section 33E and Section 33EEC of the Drugs and Cosmetics Act.
[20] Section 18(a)(iii) and Section 33EEC(a)(ii) of the Drugs and Cosmetics Act.
[21] http://nppaindia.nic.in/frequent.html

shall or shall not be included on the labels. Under Section 33(l) the government can require that the accepted scientific name of the drug should be displayed in the prescribed manner on the label or wrapper of the patent or proprietary medicine containing the drug. It is to be noted that Section 33 does not apply to ayurvedic, siddha or unani drugs.[22]

For ayurvedic, siddha and unani drugs, the Central Government has been given the power to regulate the mode of labelling for packed drugs and to prescribe which matters shall or shall not be included in such labels.[23]

- Quality specifications are also given for some drugs. Manufacture, sale or import of such drugs is not permitted without compliance with these standards. It is to be noted that only some of the standards and requirements referred to are to be provided to consumers on drug labels. Examples of these specifications are:
    - For patent or proprietary medicines (other than homeopathic medicines): *The formula or list of ingredients displayed in the prescribed manner on the label or container and such other standards as may be prescribed.*
    - For drugs included in the Homeopathic Pharmacopoeia of India: *Standards of identity, purity and strength specified in the edition of the Homeopathic Pharmacopoeia of India for the time being and such other standards as may be prescribed.*
    - For drugs included in the India Pharmacopoeia: *"Standards of identity, purity and strength specified in the edition of the Indian Pharmacopoeia for the time being and such other standards as may be prescribed…"*
    - The Act does not prescribe standards specifically for the category of traditional medicines; however among the classes of drugs given, the following classes may be applicable:

      'Substances commonly known as vaccines, sera, toxin, toxoids, antitoxins, and antigens and biological products of such nature', *'Vitamins, hormones and analogous products,'*

      Homeopathic drugs which are *'not included in the Homeopathic Pharmacopoeia of India or the United States of America, or the United Kingdom or the German Homeopathic Pharmacopoeia'*, *'Drugs not included in the India Pharmacopoeia but which are included in the official Pharmacopoeia of any other country'.*

The major lacuna of this Act from the point of view of consumer interest is that it does not provide for the provision of information to consumers, concerning the standards and quality of drugs, even though the Act concerns the regulation of drug quality. In a sense, the Act could be regarded as covering a narrow scope with respect to its regulation of consumer drug information as brands and labels are only one source of information for consumers. The Act could have been more comprehensive and specific, even with respect to technical aspects when standards are prescribed. For instance, the standards prescribed are often not substantive standards themselves but are references to standards maintained by international laboratories and thus the standard itself is not specified but reference is made only to the source of the standards such as the 'International Laboratory for Biological Standards'. With respect to specifications on quality, though the schedule provides for quality standards for different categories of drugs, it is not clear whether compliance with these standards is to be indicated on the drug label in all cases. The ordinary consumer would not be able to follow, for instance whether the composition indicated on the label conforms to these standards prescribed by law; but the consumer would be able to understand a symbol certifying that the drug product has been approved. However under this Act, it is not clear whether the requirement is for certain drug specifications to be indicated on the label or whether the certification of approval

[22] Section 33A of the Drugs and Cosmetics Act.
[23] Section 33N(f) of the Drugs and Cosmetics Act.

and quality if the drug is also to be indicated, or both.

In addition to the substantive provisions of the Act, there is also a question of the implementation and enforcement of these provisions. For instance, though the Act prescribes certain requirements for drug labels, it does not deal with how the label should be shown. Thus, the content of the label may be too technical for consumers to understand, or the way in which it is depicted may be such that it cannot be read properly because of the text side. These are practical considerations related to implementation and need to be addressed by the Act.

In the context of labelling, it must be remembered that labelling requirements are sometimes not specified for certain modes of drug sales, such as institutional sales. For instance, TB drugs sold under DOTS have different packaging for the five antibiotics, and many of these do not mention individual and combined information. Because of inadequate labelling, these drugs may surreptitiously enter the open market.[24] Further, though the Act prohibits the manufacture or sale of any patented or proprietary medicine, unless its label or container displays the true formula or list of active ingredients contained and their quantities; this requirement does not apply to ayurvedic, siddha and unani drugs. Although such exclusion may arise from practical considerations of monitoring such a small scale of operation, it creates the possibility of potential misuse of the exclusion.

b) Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954

Advertising is the most widespread and direct approach for providing consumers with information on products. From the consumer's perspective as well, advertisements are significant sources of information. However with respect to drugs, due to the health implications and problems and difficulties faced by laypersons to make choices regarding the medicines they can consume, advertisements issued for drugs must be regulated. With respect to advertisements by pharmaceutical companies, in India the *Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954* (the 'Drugs and Magic Remedies Act') regulates the advertisement of drugs in certain cases, and prohibits the advertisement for certain purposes of remedies alleged to possess magic qualities.[25] The Act defines 'drug' to include not only medicines but also substances used in the diagnosis, treatment and prevention of disease, and articles affecting the structure or any organic function of the body.[26] Under the Act the Central Government has the power to make rules, the scope of which include specifying the diseases or conditions to which the prohibitions in the Act apply, and rules for prescribing the manner in which advertisements can be send confidentially to registered medical practitioners. Some features of the Act, which are relevant to the provision of information through advertisements, in terms of both form and content are:

- With respect to the form in which information is provided through advertisements, it may be noted that under the Act 'advertisement' is defined to include notices, circulars, wrappers, announcements and so on.[27]
- The Act prohibits the publication of advertisements for drugs to be used for: causing miscarriage or preventing conception, relating to sexual pleasure, correcting menstrual disorders, certain diseases and conditions which are specified in the Schedule to the Act (*See Annexure III for the Schedule to this Act*), and so on.

[24] As told to us by Mr. Pranay Lal (Researcher).
[25] A "magic remedy" has been defined to include any charm, which allegedly possesses miraculous powers for the diagnosis, cure, mitigation treatment or prevention of any disease or which influences the structure or any organic function of the body. See Section 2(c) of the Drugs and Magic Remedies Act.
[26] Section 2(b) of the Drugs and Magic Remedies Act.
[27] Section 2(a) of the Drugs and Magic Remedies Act.

- The Act prohibits the advertisement of magic remedies for the treatment of certain diseases and disorders.
- The Act also prohibits the publication of *misleading* advertisements in relation to any drug. This includes advertisements, which give a false impression regarding the true character of the drug, which make a false claim for the drug, or which are false or misleading in any material particular.[28]
- The Act prohibits the import into and the export from India, any documents containing advertisements, which are prohibited under this Act.[29]
- With respect to ayurvedic and unani systems of medicine, the Act provides that rules on advertising related to these systems of medicine shall be made only after consultation with the Drugs Technical Advisory Board (DTAB) under the Drugs and Cosmetics Act, and also with persons having special knowledge or practical experience if the Central Government considers it necessary.[30]
- The prohibitions in the Act do not apply to advertisements sent confidentially to only registered medical practitioners.[31]
- The Act also does not apply to any drug advertisement published by the government.[32]
- The Act does not apply to any signboard or notice displayed by a registered medical practitioner on his premises, which indicates that treatment for any disease, disorder or condition (for which advertisements may be otherwise prohibited under the Act), is undertaken in those premises.[33]

One of the problems with the Act is the scope of exemptions from the application of the Act. For instance, the prohibitions in the Act do not apply to advertisements sent confidentially to medical practitioners. This leaves scope for misuse, particularly in light of the nexus between drug companies and doctors, with the former pursuing aggressive marketing for their products. Within the scope of this exemption, incorrect information may be supplied to doctors. Even the exemption given to drug advertisements published by the government may leave room for misuse. Another exemption from the application of the Act is the display of boards and notices by medical practitioners on their premises. The Act grants an absolute exemption without even specifying basic requirements of what must and what cannot be displayed on such boards and notices. Instead of absolute or total exemptions, some amount of regulation may be advisable. Another lacuna in the Act is that it is not up-to-date with technological changes regarding the media through which advertisements may be issued such as through the internet. The Act conceptualises advertisements as being issued in a print form or through announcements. The prohibition on the import and export of documents with prohibited advertisements ignores the fact that over the internet, advertisements may be issued from any part of the world to consumers all over the world. The failure to recognise this fact and the failure to issue appropriate regulations goes to show that the Act needs to be updated.

The actual implementation and effectiveness of the Act is another problem. For instance in its Schedule, the Act lists certain medical conditions and diseases with respect to which advertising is prohibited, including conditions such as obesity, diabetes, sexual impotence and venereal diseases. However in reality, advertisements with respect to drugs and treatments for these conditions are often seen on a daily basis in ads in the press, television, internet and other

[28] Section 4 of the Drugs and Magic Remedies Act.
[29] Section 6 of the Drugs and Magic Remedies Act.
[30] Section 3(d)(ii) of the Drugs and Magic Remedies Act.
[31] Section 14(c) of the Drugs and Magic Remedies Act.
[32] Section 14(d) of the Drugs and Magic Remedies Act.
[33] Section 14(a) of the Drugs and Magic Remedies Act.

media. The fact that advertisements which are prohibited in law are prevalent in reality, points to a lack of proper implementation of the Act.

Other regulations applicable to advertising, including drug and health-related advertisements, are prescribed by the Advertising Standards Council of India (ASCI) in its Code of Conduct (An analysis of the Code of Conduct is given under *Advertising Standards Council of India*).

c) Consumer Protection Act, 1986

The Consumer Protection Act, 1986 is aimed at providing protection to consumers in relation to all goods and services. For this purpose, the Act provides for the establishment of consumer councils and other authorities for the settlement of consumers' disputes and other related matters. This would include drug products as well, though there is no specific provision in the Act dealing only with drugs. Also the Act does not provide specific standards or examples of the minimum information, which should be provided to educate consumers. The types of complaints envisaged under the Act include complaints regarding defective goods, prices being charged in excess to what is stipulated by law, unfair or restrictive trade practices, or about goods which are hazardous to life and safety, being offered for sale in contravention to laws requiring traders to display information in regard to their contents, manner and effect of use of such goods.[34] Information in relation to drugs is regulated to the extent that representations amounting to 'unfair trade practices' are prohibited. The Act refers to unfair or deceptive practices as including false representations that the goods in question are of a particular standard, quality, quantity, grade or composition.[35] This also refers to representations that the goods have approval, performance or characteristics which they do not actually have.[36] Even false representations concerning approvals or affiliations of the seller or supplier, would amount to an unfair trade practice.[37] Warranties and guarantees about the performance, efficacy or life of the product, without the same being based on a proper test, as well as other misleading warranties also constitute unfair trade practices.[38] The Consumer Protection Act also deals with procedural issues such as the functioning of the Central and State Consumer Protection Councils, which include within their mandate the task of promoting and protecting the rights of consumers including 'the right to be informed about the quality, quantity, potency, purity, standard and price of goods…so as to protect the consumer against unfair trade practices'[39], 'the right to consumer education'[40]. The Act, however, does not further define or elaborate the ambit of this right. Thus issues of how this right would be implemented are not addressed. Although the implementing mechanisms would be the Central and State Consumer Protection Councils, there are no further details prescribed as to how these institutions would go about creating awareness among consumers about their rights; whether these bodies would actually act as a source of detailed information for consumers and what measures these institutions would take with respect to the manufacturers and suppliers of goods and services to consumers. Thus the absence detailed provisions regarding actual implementation so as to ensure the protection of rights is a lacuna in the Act .

An issue that arises under the Act is regarding the liability of manufacturers and traders.

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[34] S.2(c) of the Consumer Protection Act, 1986.
[35] S.2(r)(1)(i) of the Consumer Protection Act, 1986.
[36] S.2(r)(1)(iv) of the Consumer Protection Act, 1986.
[37] S.2(r)(1)(v) of the Consumer Protection Act, 1986.
[38] S.2(r)(1)(vii) and S.2(r)(1)(viii) of the Consumer Protection Act, 1986.
[39] S. 6(b) of the Consumer Protection Act, 1986.
[40] S. 6(f) and S. 8 of the Consumer Protection Act, 1986. (i) Makes or manufactures any goods or parts thereof; or (ii) Does not make or manufacture any goods but assembles parts thereof made or manufactured by others and claims the end-product to be goods manufactured by himself; or (iii) Puts or causes to be put his own mark on any goods made or manufactured by any other manufacturer and claims such goods to be goods made or manufactured by himself.

Pharmaceutical companies do not always manufacture the drug by themselves but may license the manufacturing activities to other companies. Later, marketing of the drug could be done by separate entities. In such a case, the issue arises of who would be responsible or liable in case of a failure to comply with the provisions of the Act, whether this is with regard to product quality defects, unfair trade practices or misinformation. Though this must be seen on a case-by-case basis after examination of the agreements existing between manufacturers, marketers and the companies owning intellectual property over that drug, it would also be useful to see the parties on whom liability is placed under the Consumer Protection Act. The Act has provided separate definitions for 'trader' and 'manufacturer' but the term 'trader' has been defined to include a manufacturer.[41] As per Section 2 (q), "trader" in relation to any goods means a person who sells or distributes any goods for sale and includes the manufacturer thereof, and where such goods are sold or distributed in package form, includes the packer thereof.

As per Section 2(j) "manufacturer" means a person who— Also, with respect to the complaints being made against traders and manufacturers, the Act does not differentiate between these categories, as complaints are made by consumers only against 'opposite parties'. When the Act defines what a 'complaint' is, it makes a specific reference to the practices of 'traders' for complaints regarding unfair or restrictive trade practices, charging of excess price or when information which is required to be provided for goods that are hazardous to life and safety, is not provided. However, considering that the definition of 'trader' includes 'manufacturers', such complaints can be made against manufacturers as well. Thus it would seem that in the situation where a complaint is brought against a drug manufactured by a pharmaceutical company but sold or distributed by another entity, then complaints can be made against both the manufacturer and trader. In the situation where a company whose product is being marketed, outsources the manufacture of the product to another entity, it would seem that both parties are liable if any complaint is brought against the product. This is because complaints can be brought against 'traders' which include 'manufacturers' and because the Act defines 'manufacturer' to include both the person who makes/manufactures the goods and the person who claims the goods made or manufactured by any other manufacturer to be goods made by himself and who's mark is put on the goods. In addition, as per the Drugs and Cosmetics Act, which regulates the import, manufacture, sale and distribution of drugs; penalties for the contravention of its provisions are imposed on the manufacturer of the drug even when the manufacture is done by other persons on behalf of the manufacturer.

The remedies available under the Act include actions to be taken by the supplier of the goods for removal of the defect, replacing the goods, compensating for the price paid by the consumer or paying compensation for any loss or injury suffered by the consumer. Where the person against whom the complaint is made does not comply with the orders of the relevant forum, the punishment could be imprisonment or a fine.[42]

This Act has the potential to be a powerful regulatory tool to protect and educate consumers. Though the scheme of the Act does not envisage provisions vis-à-vis particular goods and services for consumers, it should further define and stress upon the right to consumer education. This would provide an essential

[41] As per Section 2 (q), "trader" in relation to any goods means a person who sells or distributes any goods for sale and includes the manufacturer thereof, and where such goods are sold or distributed in package form, includes the packer thereof.
As per Section 2(j) "manufacturer" means a person who—
(i) Makes or manufactures any goods or parts thereof; or
(ii) Does not make or manufacture any goods but assembles parts thereof made or manufactured by others and claims the end-product to be goods manufactured by himself; or
(iii) Puts or causes to be put his own mark on any goods made or manufactured by any other manufacturer and claims such goods to be goods made or manufactured by himself.

base to ensure that adequate information on drugs is available to consumers. Central and State Consumer Protection Councils should be required to take specific steps in terms of monitoring the type of information that is being provided to consumers. A specific governmental cell dedicated to monitoring of drug information could be set up, where monitoring could be done by medical experts as well. Further it may also be recommended that at the time of drug testing, authorities should not only test the drug but should also check the information that is proposed to be provided by the drug company. This could be done by the same authority that monitors and verifies the drug testing.

d) The Monopolies and Restrictive Trade Practices Act and the Competition Act, 2002

The Monopolies and Restrictive Trade Practices (MRTP) Act prohibits the prevention or lowering of competition in the production or supply of goods or services 'by the adoption of unfair methods or unfair or deceptive practices'.[43] An unfair trade practice refers to a trade practice which adopts any unfair method or unfair or deceptive practice. This would include: false representations that the goods are of a particular standard, quality, quantity, grade or composition[44]; false representations about the performance, characteristics, uses or benefits about the goods[45]; false representations about the approvals and affiliations of the seller or supplier[46]; false or misleading representations concerning the need for or usefulness of the good[47]; warranties or guarantees given about the performance, efficacy or life of the product, that is not based on any proper test[48]; false or misleading facts disparaging the goods, services or trade of another person[49]. The forms in which such statements with representations are made include statements expressed on the article, its container, anything accompanying the product, and so on.[50] Penalties under this Act are in terms of imprisonment and fines.[51] Thus under both the Consumer Protection Act and the MRTP Act, unfair trade practices are envisaged in similar ways. The instances given of what practices would constitute unfair trade practices show that drug companies can be challenged on grounds of the claims and representations made by them in the course of providing information to consumers and doctors. On the other hand, a criticism against the MRTP Act with respect to its relevance to the regulation of consumer drug information is that the Act does not elaborate any standards, or even minimum standards which are to be complied with, including with respect to informational requirements in relation to goods.

The MRTP Act is being replaced by the Competition Act 2002, which has the objective of including not only the promotion of competition in markets but also the protection of interests of consumers. With the repeal of the MRTP Act, cases relating to unfair trade practices and which are pending before the Monopolies and Restrictive Trade Practices Commission (MRTPC) are proposed to be transferred to either the National Commission (constituted under the Consumer Protection Act) or the Competition Commission of India.[52] However considering that the MRTP Act is being replaced with the Competition Act, it must be noted that the detailed provisions discussed above relating to unfair trade practices are not reflected in the Competition Act. This would leave a gap in regulation, which has to be completed.

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42 Section 27 of the Consumer Protection Act.
43 Section 2(i)(vi)
44 S. 36A(1)(i) of the Monopolies and Restrictive Trade Practices Act.
45 S. 36A(1)(iv) of the MRTP Act.
46 S. 36A(1)(v) of the MRTP Act.
47 S. 36A(1)(vi) of the MRTP Act.
48 S. 36A(1)(vii) of the MRTP Act.
49 S. 36A(1)(x) of the MRTP Act.
50 Explanation to S. 37 of the MRTP Act.
51 Chapter VIII of the MRTP Act.
52 Section 66 (4) and (5) of the Competition Act, 2002.

e) Advertising Standards Council of India

In relation to advertisements issued with respect to drugs and medical treatments, in addition to the Drugs and Magic Remedies (Objectionable Advertisements) Act, the Code of Conduct issued by ASCI (Advertising Standards Council of India) must be considered. The Code, which applies to advertisers, advertising agencies and the media, states that advertisements cannot be framed as to abuse the trust of consumers or exploit their lack of experience or knowledge. A basic requirement under the Code is that advertisements must be truthful and all factual descriptions and claims should be capable of being substantiated; advertisements must not distort facts or mislead consumers through implications or omissions; claims must not be exaggerated, etc.[53] Some features of the Code particularly relevant to consumer drug information are:

- Special care has to be exercised in advertisements addressed to those suffering from: weakness, any real or perceived inadequacy of any physical attributes, obesity, illness, impotence, infertility, baldness, and so on.
- It is to be ensured that claims or representations do not exceed what is considered prudent by generally accepted standards of medical practice and the actual efficacy of the product.
- Any written or graphic matter on packaging, or contained in it, is subject to this Code.[54]

Lacuna of the Code lies in its implementation. It is to be noted that advertisements on the subjects that are regulated under the Code of Conduct are often seen in the newspapers, television and other media on a daily basis, such as in relation to weight loss, baldness, infertility, and so on. The legality of these advertisements should be examined on a case by case basis, as some of them may fall under categories prohibited under the *Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954* while others though not prohibited, are still regulated under the Code of Conduct. Several advertisements for products claiming to have medicinal properties or capable of producing effects on the body (such as height increase, etc.) have been questioned and even consequently withdrawn.[55] However, this shows that the procedure under the Code of Conduct is not pre-emptive and reflects the fact that strict checking of advertisements is not done before the ad is aired/published. Often by the time the ad is questioned and withdrawn, it has already been shown to consumers. Consumers would also not be aware of the reasons why the particular ad was withdrawn. Where the Code applies, it must be remembered that these are guidelines and not enforceable rules; though the ASCI Code has been made compulsory for TV ads.[56] Also as seen above, the Code refers to the maintenance of certain standards and not outright prohibition. Thus the advertisements should be evaluated in terms of their compliance with such standards. In order to ensure stricter monitoring of advertisements in relation to drugs and treatments, the principles and provisions of the Code should be strictly legally enforceable and binding by incorporating them into legislation such as the *Drugs and Magic Remedies (Objectionable Advertisements) Act*.

f) Statutes Regulating Healthcare Professionals

Apart from the above regulations applicable to the health and pharmaceutical sectors in India, there are a variety of statutes prescribed for the establishment of councils governing medical professionals such as doctors, nurses and pharmacists and codes of conduct prescribed for these professionals. The statutes establishing regulatory bodies governing

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[53] Chapter I of the Code of Conduct. http://www.ascionline.org/two/code1.htm.

[54] http://www.ascionline.org/two/code1.htm

[55] See: 'Complaints that were upheld by the Consumer Complaints Council (CCC) from October 2006 to December 2006', http://www.ascionline.org/five/cccdecisions.htm.

[56] The Government of India issued a notification to this effect in the Gazette of India: Extraordinary [Part II – sec. 3(i)] on 2 August 2006. http://www.ascionline.org/five/recentdvpt.htm.

different categories of medical professionals are usually of an administrative nature as they are about the constitution and functioning of such governing bodies. These statutes and codes include the Indian Medical Council Act, 1956, Pharmacy Act, 1948, Indian Nursing Council Act and the Code of Medical Ethics. Eventhough the statutory regulation is often procedural, the codes of ethics for these medical professionals prescribe certain duties to be observed towards patients and the standard of care and responsibility to patients. The provision of reliable and relevant information to patients could be considered as a part of the duty of care to be exercised. The Code of Ethics Regulations, 2002[57], notified by the Medical Council of India, prescribe some general and specific obligations and duties for physicians, which include:

- Physicians are required to, as far as possible, prescribe drugs with generic names and to ensure that there is a rational prescription and use of drugs.[58]
- Drugs prescribed by a physician or brought from the market for a patient should explicitly state the proprietary formulae as well as generic name of the drug.[59]
- The drugs prescribed by a physician should always carry a proprietary formula and clear name. The prescribing or dispensing of secret remedial agents of which the physician does not know the composition, or the manufacture or promotion of their use is unethical and is prohibited.[60]
- Physicians should merit the confidence of patients entrusted to their care, rendering to each a full measure of service and devotion.[61]
- Physicians should try continuously to improve medical knowledge and skills and should make available to their patients and colleagues the benefits of their professional attainments.[62]

The issue of how and what type of information is to be provided by the physician to the patient is not directly discussed in the Code of Ethics Regulations, 2002. However as seen above, there are some general duties and principles which physicians are required to adhere to. This reflects a basic duty of care that medical professionals must exercise with respect to their patients. The provision of basic and comprehensive information to patients and their families in relation to medications and treatments, in a manner that can be easily understood, is essential for the proper exercise of this duty of care. The fact that the same is not expressly reflected in the Code shows that there is a lacuna which must be addressed. It is suggested that a provision recognising this duty of medical practitioners must be reflected in the Code.

To summarise:

- **There is a lack of clarity regarding the legal requirement to provide comprehensive information according to the characteristics of consumer drug information which we have mentioned earlier.**
- **This lack of clarity applies to the duties of the government, pharmaceutical companies and medical professionals including doctors, pharmacists, and nurses.**
- **There is no guideline dealing exclusively with the subject of consumer drug information.**
- **Often the requirements are expressed through ethical guidelines and are not mandatory under law.**
- **The enforcement of law, including labelling and advertisement guidelines is poor.**

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[57] Code of Ethics Regulations, 2002, Medical Council of India Notification (New Delhi, 11 March 2002). See: http://www.mciindia.org/know/rules/ethics.htm.
[58] Regulation 1.5 of Regulations.
[59] Regulation 6.3 of the Code of Ethics Regulations, 2002.
[60] Regulation 6.5 of the Code of Ethics Regulations, 2002.
[61] Regulation 1.2.1 of the Code of Ethics Regulations, 2002.
[62] Regulation 1.2.1 of the Code of Ethics Regulations, 2002.

g) Approaches Under Government Policies

In addition to statutes, the health sector is regulated by a number of policies brought out by the government. Here again there is no comprehensive policy focusing on the issue of the provision of drug information to consumers. However, a number of policies deal with aspects that would be relevant to this issue. The issues dealt with range from the recommendations to the pharmaceutical industry, issues of drug price control, spreading awareness on health issues and so on. This section deals with some policies that address issues of relevance to consumer drug information.

The policies discussed in this section are:

- Pharmaceutical Policy, 2002
- National Health Policy, 2002
- Task Force to Explore Options other than Price Control for Achieving the Objective of Making Available Life-saving Drugs at Reasonable Prices" of September 20, 2005 (under Mr. Pronab Sen)
- Draft National Pharmaceutical Policy, 2006
- Recommendations of the Working Group on Drugs, Pharmaceuticals and Medical Equipment/Devices

The Draft National Pharmaceutical Policy, 2006 is in the process of being finalised, and until this is done, the Pharmaceutical Policy, 2002 will apply. The Pharmaceutical Policy, 2002 does not directly discuss the issue of drug information. The main objectives of the Policy are to ensure reasonable drug prices, to strengthen production and exports of pharmaceuticals, to strengthen quality control over pharmaceutical production and distribution, to encourage R&D on diseases endemic to India, and to promote investment into the pharmaceutical industry. However, the policy discusses the issue of identification of drugs for price regulation, noting that there is no ready data available for determining the mass consumption nature and absence of sufficient competition for a particular bulk drug. In this context, it recognises that there is a need for information to be collected from different sources on the composition of each brand, dosage form-wise and pack-wise. The sources for this information recognised in the policy include the Indian Pharmaceutical Guide, Current Index of Medical Specialities, Monthly Index of Medical Specialities, information provided by some manufacturers and label compositions indicated on market samples. It is recognised in the 2002 Policy that though these sources are not exhaustive and comprehensive in regard to market information, they may be the best available in the given circumstances. With respect to pharma education and training, the policy recognises the National Institute of Pharmaceutical Education and Research (NIPER), set up by the Government of India as an institute of "national importance" to achieve excellence in pharmaceutical sciences and technologies, education and training. A basic critique of the Pharmaceutical Policy, 2002 is that the issue of information on pharmaceuticals and medical devices and technologies is hardly addressed. This is a reflection of the fact that consumer drug information is not an issue that is being considered very seriously. However for an effective law and policy framework to be developed, a recognition and understanding of the issue is what is required at the outset. Drug information to be directed to consumers is an issue, which would come within the scope and mandate of the Pharmaceutical Policy. It is suggested that the new pharmaceutical policy which is being finalised, must recognise the issue and suggest a policy framework to address concerns. For instance, at a policy level, recommendations should be made for developing guidelines for ensuring that consumers are educated about drugs, the nature of such information, the actors involved in providing such information and how the information is to be checked and monitored. The Draft National Pharmaceutical Policy, 2006 is discussed later.

Under the National Health Policy, 2002, the status of dissemination of public health related

information is discussed. The Policy states that the present strategies for information, education and communication (IEC) are too fragmented, and rely heavily on the mass media.[63] The suggestions and proposals in the Policy are:

- An IEC policy should be pursued which maximises the dissemination of information to those population groups, which cannot be effectively approached by using only the mass media. The focus would be on the inter-personal communication of information and on folk and other traditional media to bring about behavioural change.
- The IEC programme would set targets for the association of NGOs, Trusts and so on in these activities. The success of the initiatives would be dependent on dispelling misconceptions pertaining to religious and ethical issues and the role of community leaders in achieving this is recognised.
- It is envisaged that the Central/State Government initiative will also focus on the development of modules for information dissemination in such population groups, who do not normally benefit from the more common media forms.
- With respect to the role of the private sector, the Policy envisages the establishment of a comprehensive information system, and based on that the establishment of a regulatory mechanism to ensure the maintaining of adequate standards by diagnostic centres, medical institutions, as well as the proper conduct of clinical practice and delivery of medical services.[64]

The approach under the NHP 2002 seems to be one of spreading general messages on public health that are more focused on awareness creation and preventive strategies. This does not seem to include detailed information on drugs. As the importance of dissemination of information has been recognised in the policy, this should be further built upon. Information on drugs and medical technologies must be considered as a fundamental part of the information being disseminated through the IEC programme. It is suggested that issues of what sort of information needs to be provided to consumers, who should provide it, how it should be monitored, and how it should be disseminated should be addressed. The media for dissemination of information should be extended beyond select bodies (whether governmental or not) and the mass media should be recognised as a powerful tool. In this respect, it would be useful if issues relating to monitoring of information provided through advertisements were addressed in this policy. The target audience of IEC programmes must also be examined. Different classes of consumers have different informational requirements, depending on factors such as literacy and education, income, type of medical condition, etc. Doctors and healthcare professionals must also be considered as targets for relevant and up-to-date technical drug information.

The report of the "Task Force to Explore Options other than Price Control for Achieving the Objective of Making Available Life-saving Drugs at Reasonable Prices" under the chairmanship of Mr. Pronab Sen (Pronab Sen Report) makes certain direct and indirect observations relating to consumer drug information. Some of these are:

- The pharmaceutical sector is the only sector where the consumer has no meaningful choice regarding the class of products. The decision on what medicine must be taken is made by the doctor or the pharmacist. Thus the normal dimensions of consumer choice, i.e. product, price and quality, do not exist. Also the choice-maker, i.e. the doctor or pharmacist, has no incentive to be price-sensitive.
- This situation of limited information leads to prescriptions being driven by the promotional

[63] National Health Policy, 2002. Seen from: http://mohfw.nic.in/np2002.htm
[64] National Health Policy, 2002. Seen from: http://mohfw.nic.in/np2002.htm

efforts of drug companies. Since the intensity of such promotions is resource-driven, they are likely to be positively correlated to the price of the drug or to the resource base of the company.

- Considering that in India there is distinct market segmentation between different brands of the same API (Active Pharmaceutical Ingredients); it is necessary that doctors are provided with information support systems, which will enable them to prescribe in the most case-sensitive manner possible.[65] The absence of adequate information may result in 'adverse selection' behaviour where different formulations of the same API are perceived to have different levels of effectiveness, and a higher price might be associated with better quality.[66]
- Certain information is needed for price regulation. This includes mandatory price reporting, establishing a prescription monitoring system (whereby trends in specific brands or formulations being disproportionately prescribed, either nationally or even regionally, could be tracked) and establishing a system to measure the availability of drugs on an on-going basis to assess whether artificial scarcities are being created.[67]
- A website is recommended to be set up with data on prices of all formulations by APIs, which could be accessed by doctors, retailers and consumers for price comparison purposes. It is envisaged that the price monitoring system suggested by the Task Force would provide the data for developing such a website. It is also recommended that the system be query-based and API specific, but not therapeutic class-based or disease condition-based in order to avoid the danger of self-medication by patients.[68]
- There is also a recommendation for creating a website for enhancing public awareness and education.
- It is recommended that a database on brands and their compositions be maintained by the drug regulator, and all brand registrations must be approved by the drug regulator.
- For creating public awareness about the alternative available drug formulations and their prices, the publication of booklets, newsletters, magazines, etc. in both English and other languages is also encouraged. For this, state governments should be involved. To focus on this task, it has been recommended that an agency be set up under the Department of Chemicals and Petrochemicals to undertake this work with an annual budget.

The Pronab Sen Report has thus not only recognised the need for consumer drug information, but also makes concrete suggestions how the issue should be addressed. For instance, the need for a comprehensive database of certain types of information, such as prices, has been recognised. This recommendation should be further extended to include all aspects of drug information (as discussed earlier in this paper) and not only on prices, brands and varieties, so that a comprehensive database of accurate and verified information is available for consumers.

The Draft National Pharmaceutical Policy, 2006 makes certain proposals, which may be relevant to the provision of consumer drug information. Certain recommendations are addressed directly to consumer awareness while some have an indirect application. These are:

- The policy advocates consumer awareness campaigns through print and electronic media on price fixation, revision, use of generics and consumer education and empowerment. It is proposed that a website would be created for providing information on drug prices and related matters. It is specifically mentioned that

[65] Report of the "Task Force to Explore Options other than Price Control for Achieving the Objective of Making Available Life-saving Drugs at Reasonable Prices" (September 20, 2005) at 22.
[66] Pronab Sen Report at 22.
[67] Pronab Sen Report at 36.
[68] Pronab Sen Report at 41.

publicity would be done not only in English but other Indian languages as well. State governments should also be involved. A helpline would be set up under the Department of Consumer Affairs for addressing grievances about overcharging, quality, availability and so on.

- A Drug Price Monitoring and Awareness Fund (DPMA Fund) is envisaged, the utilisation of which includes expenditure on public awareness including publicity campaigns, prices of generics, comparative drug prices, banned drugs, misbranding, facilities given by the government for different categories of patients or any other aspect of public interest through the use of print and electronic media.
- The DPMA Fund would also be used to create an electronic data filing system with the NPPA by the State Drug Controllers and industry. The proposed Fund represents an indirect effort in the direction of providing a comprehensive and authentic database of consumer drug information. It would thus be used for dissemination of drug information through a variety of channels. Although this would involve a stepping up of efforts for increasing awareness and disseminating consumer drug information, the Fund does not envisage the creation of a single point of contact for all possible information.
- A new law, the Drugs and Therapeutics (Regulation) Act (DATA) is proposed to be enacted which would replace the existing system of Drug Price (Control) Orders under the Essential Commodities Act.
- DATA would authorise the government or its designated authority to compel disclosure of information from manufacturers, marketers, distributors or retailers of drugs.
- Under DATA, the government would also be granted the power to approve a brand name for a specific product, to prevent changes in the composition of a product marketed under an approved brand name and to determine the nomenclature under which a product can be marketed, if necessary, for all drugs and therapeutic products.
- To prevent misbranding, the Draft NPP, 2006 recommends that branding of drugs and other therapeutics should be brought under the Central drug regulatory system, with the drug regulator being required to maintain a database on brands and their compositions, and all brand registration of drugs should compulsorily be approved by the drug regulator. Particularly, no change should be permitted in the composition of a given brand.
- As a measure of quality certification of drugs, the government would institute a method of publicising GMP certification as a guarantor of quality of the certified drug. Also a quality mark like the ISI or Agmark approvals would be evolved through industry involvement.

Although the policy recognises certain informational needs of consumers, it does not discuss in detail the specifics of the information to be provided. For instance, the website envisaged should provide information on all aspects of information that have been discussed earlier in the paper as parameters for consumer drug information. It is also recommended that guidance for the design and substance of the website could be taken from the US FDA website which has comprehensive and accurate information presented in a reader-friendly manner. Further, in addition to proposals on funding, the policy should envisage specific timelines for the implementation of its recommendations and responsibility for the implementation of these recommendations should be fixed on specific actors.

At a broader level, a criticism has been raised that there is discordance between the approaches taken in the health and pharmaceutical policies.[69] Under

[69] Dr. Anurag Bhargava, "Pharmaceutical Policy and National Health Policy: Discordance in Perspectives and Content" http://www.cpiml.in/060322.htm.

the National Health Policy, the focus is public health and on ensuring the basic right to health. Under the National Pharmaceutical Policy, the focus is on the competitiveness of the Indian pharmaceutical industry, eventhough the objectives of this policy also envisage facilitation of implementation of the country's health policy and recognise the goal of ensuring access to medicines by all patients. The health sector must be understood from the perspectives of both patients/ consumers and the pharmaceutical industry and thus it is important that the laws and policies dealing with these aspects should function under a common outlook or approach.

In addition to the above policies, recommendations on issues related to information on drugs and medical equipment and devices have been made by the Working Group on Drugs, Pharmaceuticals and Medical Equipment/Devices, convened by Mr. Rajan Gandhi, a consumer activist. The Working Group was constituted by the Department of Consumer Affairs. In the light of the consumers' right to be informed, the recommendations of the Working Group include the following[70]:

- Existing Package Leaflet to be augmented or supplanted by a Patient Package Insert (PPI) written in simple, non-technical language in a legible font size, intended for the patient.
- Establish a website providing comparative information on drug prices.
- Make the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, more stringently applicable to extend to homeopathic, ayurvedic, unani, herbal and alternative medicine therapy, including devices.

To summarise, it is seen that in India's policy framework, there is no comprehensive policy dealing exclusively with the issue of consumer drug information. Even within important policies such as the health policies or pharmaceutical policies, the issue of the provision of drug information to consumers is not discussed as one of the main focus areas. However issues related to consumer drug information are discussed, such as the need for greater availability of drug information in the context of drug price regulation or the need to supply information to the public on general health issues. The health policies and pharmaceutical policies of the government thus do not give much attention to this issue. However, there are still some recommendations made by various groups and committees constituted by the government, which have made specific and precise recommendations on this particular issue, such as the recommendations of the Pronab Sen Committee and the Working Group on Drugs, Pharmaceuticals and Medical Equipment/Devices. The need of the hour, however, is the actual implementation of these recommendations.

h) Codes Prescribed by the Pharmaceutical Industry

Often in addition to the legal and policy regime prescribed by the government, industry associations evolve voluntary codes of practice and policies. For instance, the Organisation of Pharmaceutical Producers of India (OPPI) has evolved the OPPI Code of Pharmaceutical Marketing Practices 2007 (OPPI Code). The OPPI Code emphasises the responsibility of the pharmaceutical industry to provide accurate information and education about its products to healthcare professionals. Important exclusions under the OPPI Code which this Code does not seek to regulate include: the promotion of prescription-only pharmaceutical products directly to the general public (i.e. direct to consumer advertising); the promotion of self-medication products that are provided over-the-counter; pricing or trade terms for the supply of pharmaceutical products; the provision of non-promotional information by member companies.[71] This shows that the provision of drug information to consumers

[70] Executive Summary of Recommendations of the Working Group on Drugs, Pharmaceuticals and Medical Equipment/Devices (29 April 2005).
[71] OPPI Code of Pharmaceutical Marketing Practices 2007, http://www.indiaoppi.com/OPPI%20Code%20of%20Marketing%202007.pdf

is not within the purview of this Code. This implies that drug companies, which are members of the OPPI, do *not* have a voluntary mechanism regulating and guiding them in the provision of drug information to consumers. They would only be regulated by the legal and policy regimes prevailing in the country, as there is no industry guidance for the same.

However, the OPPI Code recognises that national laws and regulations usually regulate the format and content of product information, and product promotion should not be inconsistent with such regulation. The Code prescribes certain parameters to be observed for the provision of information, such as that promotional information should be clear, legible, accurate, balanced, fair, objective and sufficiently complete to enable the recipient to form his/her own opinion of the therapeutic value of the pharmaceutical product concerned. Ambiguity should be avoided and absolute claims should be made only with adequate qualification and substantiation. Descriptions such as 'safe' and 'no side effects' should generally be avoided and should be adequately qualified. Promotion should be capable of substantiation either by reference to approved labelling or scientific evidence.[72] The OPPI Code requires that all printed promotional material including advertisements should include[73]: name of the product (normally the brand name); active ingredients; name and address of the pharmaceutical company or its agent responsible for marketing the product; date of production of the advertisement and abbreviated prescribing information which should include an approved indication or indications for use together with the dosage and method of use; contraindications; precautions and side- effects. The OPPI Code has the same requirements for electronic materials and also specifies that for pharmaceutical product-related websites, the following considerations should be kept in mind[74]: the identity of the pharmaceutical company and of the intended audience should be readily apparent; the content should be appropriate for the intended audience; the presentation (content, links, etc.) should be appropriate and apparent to the intended audience; India-specific information should comply with the Drugs and Magic Remedies Act.

The Indian Drug Manufacturers Association (IDMA) is an association of manufacturers producing pharmaceuticals. However as seen from its website, the IDMA has not framed a code such as that framed by the OPPI. Considering the gaps in law and policy framed by the government, it is suggested that the framing of codes of conduct by the industry would be useful in providing guidance to companies on issues such as the provision of drug information by them to consumers. In addition, such uniformly applicable guidelines would help in ensuring that the same standards regarding content and format of information is maintained by all.

To summarise:

- **Current policies do not deal comprehensively with the issue of consumer drug information. Different policies deal directly and indirectly with different aspects of the issue.**
- **Enough focus and importance is not being given to issues of consumer drug information in current policies.**
- **Of late, there is a policy shift which recognises the importance of consumer drug information.**
- **Industry should be more active in developing codes of conduct for pharmaceutical companies, particularly regarding promotional activities and provision of information to both consumers and healthcare professionals.**

[72] Article 4.3 of the OPPI Code of Pharmaceutical Marketing Practices 2007, http://www.indiaoppi.com/OPPI%20Code%20of%20Marketing%202007.pdf.
[73] Article 5 of the OPPI Code of Pharmaceutical Marketing Practices 2007, http://www.indiaoppi.com/OPPI%20Code%20of%20Marketing%202007.pdf.
[74] Article 6 of the OPPI Code of Pharmaceutical Marketing Practices 2007, http://www.indiaoppi.com/OPPI%20Code%20of%20Marketing%202007.pdf.

V. Survey of Information According to the Parameters Discussed

An overview of materials shows that information was usually scattered as different types of information were given by different sources. At the outset it must be remembered that for consumers, doctors are a primary source of contact and an important source of information. Patients depend on and trust their doctors for medical advice. There is thus an obligation on doctors to provide comprehensive and understandable information to patients. Doctors are not only an important source of information in themselves, but also in turn depend on other sources of information. In the opinion of some medical professionals interviewed in the course of this project, the primary source of information for doctors in India is drug companies. Apart from pharmaceutical companies, doctors rely on medical journals and publications such as the Current Index of Monthly Specialities. What is important from the consumer's perspective is that such information should be passed on to them in a non-technical and simplified manner, i.e. in a manner where medical jargon understood by professionals is not used. In this respect sometimes information provided to doctors is biased, and consequently information going to consumers is also biased.[75] A number of actors are involved in disseminating consumer drug information and there was no single organisation, including under the government, which exists as a single point of contact for comprehensive consumer drug information. Thus there was also not a consolidated, single comprehensive source or database of information for the Indian consumer, which was developed according to the parameters of reach and quality, and which provided the basic information needed by consumers for at least all essential drugs. It was observed that there were multiple sources and forms of information. The quality of consumer drug information usually varied according to the source of the information. From the information seen, it was observed that the information disseminated was usually in English. Information given in local languages was limited, even with respect to information about the drug on its label or packaging. Written material in local languages was usually in the nature of general information for awareness creation, such as through flyers and posters with pictures, creating public awareness on different health subjects. Government advertisements relating to national health programmes were in English as well as local languages.

Although information was usually general, in one instance it was seen that specific information was given in local languages through posters. These posters, designed by an individual doctor, were meant to provide educative information on subjects such as: what drugs are, the methods by which drugs are manufactured, when they are used, the different ways in which they can be consumed, questions patients should ask their doctor, key information that the doctor should know about the patient before prescribing drugs, how medicines should be applied or taken in specific situations (eg. eye drops), precautions, cautions regarding other food and drinks that can or cannot be consumed while taking medicines, and so on.

With respect to the contents of the materials, it

[75] Interview with Dr. Gopal Dabade.

was seen that some aspects of consumer drug information were usually not described even when the information was being targeted to consumers, such as drug prices. Further, although details were more likely to be given for medicinal products, there is less information given on devices and techniques/ therapies which are directed to the consumer. There were instances of greater concentration of materials in relation to specific diseases, particularly AIDS. The information specific to AIDS drugs, however, was usually quite technical (i.e. using medical jargon), being directed to medical professionals (such as drug information provided by NACO).

A similar observation can be made with respect to advertisements issued by the government, where detailed technical drug information is missing. The focus here is largely on awareness creation and preventive strategies. Another area of medicine, which was largely neglected was that of traditional medicines. The focus was usually on allopathic medicines. Even where traditional systems of medicine were discussed the information provided was not very technical or detailed.

Another observation is that overall the information regarding drugs, which was very technical and comprehensive, was usually directed to medical professionals and not consumers. Regarding the reach of information, it was found that information was usually available in written formats on the internet or published through books and booklets. In a few cases, CDs were also available though these were directed to professionals and not consumers, such as CDs for training medical practitioners. Considering that most of the material was available in written formats, this would not be useful to illiterate patients/consumers. Posters were not used very often and if so, they usually dealt with awareness creation on general health issues and were not designed from the perspective of educating consumers about specific aspects of rational drug use. At the same time, in some organisations dissemination of information was done orally. For instance in some NGOs working on AIDS, patients are counselled about the importance of strictly adhering to the schedule of medication given.

Before moving on to the discussion of the specific information provided by different sources, a brief outline of the main actors involved in providing information is discussed below.

a) Actors Providing Consumer Drug Information

There is a range of actors involved in the dissemination of different types of information to consumers relating to drugs. Organisations that are considered as the actors providing consumer drug information are considered as such because of their mandates, which are relevant, even indirectly, to issues of consumer drug information. For instance, the government has a duty to ensure the regulation of information on medicines and treatments to safeguard public health. Among the NGOs seen in the course of this project, none had an exclusive mandate for providing only consumer drug information. However, a number of NGOs work on health issues and some on consumer issues, and both such categories are sources as well as users of consumer drug information. Actors such as LOCOST (Low Cost Standard Therapeutics) also have a mandate relevant to consumer drug information as they are engaged in ensuring access to medicines. The survey of information provided to consumers has been done according to the sources of information in terms of the actors providing the information.

i) Governmental and quasi-governmental authorities

The Ministry of Health and Family Welfare, the Ministry of Consumer Affairs, Food and Public Distribution, and the Ministry of Chemicals and Fertilizers are the nodal ministries concerned with issues of public health, consumer affairs and drugs and pharmaceutical issues in India. The Ministry of Health is responsible for a number of National Health Programmes and specifically targets certain diseases.

Apart from central government ministries, the Central Drugs Standard Control Organization (CDSCO) also has a relevant mandate as it provides technical information (i.e. information specific to particular characteristics of drugs and not information on general health issues) on drugs and also specific information directed to consumers. There are also quasi-governmental organisations, which are concerned with different aspects of public health and medicines. These organisations include the Pharmaceutical Council, the National AIDS Control Organization (NACO) and various State Pharmacy Councils.

ii) Civil Society and non-governmental organisations

The organisations whose mandate would include issues of consumer drug information are basically of two types: health organisations and consumer organisations. The range of NGOs working on health issues that were surveyed in the course of this project included those working on women's issues, AIDS, reproductive health, and so on.

iii) Private actors

Pharmaceutical companies are also involved in disseminating information on the drug products manufactured by them to consumers. This is done directly through the drug information leaflets and labels attached with the drug product. Information is also disseminated through the websites of different companies, as well as through advertisements issued by them. It is important to note that pharmaceutical companies often do not target information to consumers directly, but rather to doctors and medical professionals who are involved in making medication-related choices for the consumer. They also bring out publications on medical treatment and conditions. These are usually directed to doctors and other healthcare professionals, and not for consumers. Medical articles have technical and scientific information on new drugs and developments in medicine, analysis of tests and on the working of chemical compounds, discussions on medical conditions and diseases, medical devices and technology, and so on. It was observed that in some publications, even policy issues relating to the pharmaceutical sector were discussed.[76]

iv) Other associations and individuals

Other organisations that are involved in disseminating consumer drug information include patients' associations, pharmaceutical associations, drug manufacturer associations and societies involved in promoting rational drug use. There are also a number of individuals making efforts to disseminate information on rational drug use, such as doctors, pharmacists and other medical practitioners. In the course of this study, we met a doctor who made an individual effort in creating consumer awareness through posters designed by him. Certain other doctors were involved in publishing information through newspaper articles. Doctors are the primary, the most direct and the most trusted sources of information for patients. A discussion on their role and the type of information they provide, based on interviews with certain medical professionals has been done later in the section '*Information Provided by Medical Professionals*' in this paper.

v) Information from mass media

Mass media account for the most direct and prevalent source of information targeted directly to consumers. In the press, sections and columns are often devoted to health issues and news. The nature of information is about creating awareness about medical conditions, prevention strategies, dietary habits, symptoms of the condition, precautions and general information regarding the treatment of the disease. Specific information such as the names of

[76] For instance, an article was brought out in a publication by Cipla on the benefits of the Patents Act 1970. See: Dr. R. D. Lele, "The Prescription that Changed Practice – Unique Benefits of the Patents Act 1970", Current Medical Scene http://www.cipladoc.com/publications/cms/vol20no2/cms1.htm.

drugs required for treatment, their prices and other detailed information regarding the use of such drugs is usually not supplied. Health information supplied through articles in newspapers, magazines and so on is usually not detailed medical information advising consumers on the options available for medication and other forms of treatment and how to use particular drugs. Even where specific medical conditions and diseases are discussed, these are usually the more prominent conditions that are commonly encountered, such as diabetes, obesity, migraine, cholesterol, heart conditions, AIDS, and so on. Complex medical conditions are not usually discussed. In the present scenario, articles in the print media are available online as well. As an example, a series of articles written in the 'Health and Science' section of the site *http://www.newindpress.com* can be taken. For instance, in an article on the effects of alcohol intake while a patient is under medication, instances of possible adverse reactions were highlighted. However this was very basic, and it may have been more comprehensive if a detailed list was provided. Examples were also given of medicines that are affected by alcohol ingestion, such as sleeping medications and anti-depressants. As precautions and remedial measures, it was suggested in the article that doctors and pharmacists must keep in mind the ethanol-drug interaction. The article cautions doctors, pharmacists and patients, helping to bring about awareness that patients and doctors must consult with each other and keep in mind certain precautions. A useful aspect of this article is that it is in a simple easy-to-understand language with simple explanations of what happens when alcohol is taken while the medication process is on. A separate analysis of more online materials in the media has been separately in **Annexure IV** of this paper.

The advertisements seen were both in the nature of awareness creation through health campaigns of the government, and advertisements for treatments and products by private companies. For instance, advertisements were both about creating awareness about AIDS (ads issued by NACO), polio vaccination, dengue prevention and also advertisements for medical condition such as obesity, hair loss and also for contraceptives. Advertisements issued by the National AIDS Control Organization (NACO) gave general information about ART treatment, the importance of adherence and its availability at select government hospitals.

vi) Information provided by the central government and state pharmacy councils

a)Ministry of Health and Family Welfare

The Ministry of Health and Family Welfare is responsible for a number of National Health Programmes:

- National Vector Borne Disease Control Programme (NVBDCP)
- National Filaria Control Programme
- National Leprosy Eradication Programme
- Revised National TB Control Programme
- National Programme for control of Blindness
- National Iodine Deficiency Disorders Control Programme
- National Mental Health Programme
- National Aids Control Programme
- National Cancer Control Programme

These programmes include the provision of information on these diseases and medical conditions, which is available online. The information covers the nature of the disease, symptoms, risks in special situations such as pregnancy, control strategies, and so on. With respect to drugs, details are sometimes given on which drugs can be used for treatment and about their dosage. Some of this may be technical information that can be better comprehended by medical professionals rather than patients/consumers. Advertisements brought out by the government were seen to be directed at spreading awareness about diseases and other health topics. The strategy usually reflected a preventive approach. The information and advertisements issued generally addressed issues of reproductive health and also topics such as dengue,

polio, iodine deficiency, oral dehydration solution and ARV treatment for AIDS offered at government health centres. The approach was largely directed at educating consumers about preventive strategies. However, some of the advertisements with messages on awareness and prevention of diseases also gave drug information such as that aspirin should not be taken in case of dengue or that iodised salt must be taken to prevent iodine deficiency. There were also advertisements emphasising the importance of adhering to the course of medication prescribed. For instance, some ads issued on AIDS treatment, highlighted the importance of adhering to ARV treatment for the medication to succeed.

It was seen that information provided with respect to National Health Programmes provided online by the Ministry of Health was very technical when dealing with drugs and medications; in the sense that the nature of information was more academic and would be understood more by medical professionals rather than by consumers. In addition to specific information on the details of drug products, often the material provided also dealt with subjects such as rational drug use and the importance for consumers to be educated about the same. This could point towards a growing realisation that the provision of consumer drug information is a necessary component of rational drug use. The Ministry of Health also provides a link to the IEC (Information, Education, Communication) Resource Centre, which provides information on different diseases in print, audio and video formats. Taking the tuberculosis programme as a sample it was seen that the materials were aimed primarily at the health service providers and not to patients directly. However, the nature of information was more in the form of awareness creation. In specific, the objectives of the brochures were *"To educate health service providers on TB, types of TB, diagnosis, treatment process under DOTS, drug administration and side effects; and to guide health service providers on messages to be conveyed to the patients.*[77] The key message that is sought to be conveyed is that *"TB is a dangerous and infectious disease, TB spreads through air through small droplets of sputum coughed out by TB patients, Symptoms of TB, Treatment for TB, Consequences of non-compliance, Safe sputum disposal (do not spit here and there) and prevention for TB, Responsibilities of Panchayat Members, Responsibilities of Primary Health Centres."* The brochures provided are in local languages as well. There were also online versions of outdoor materials such as banners and also PPM (Public Private Mix) kits providing materials such as posters, treatment charts, CDs and so on for district TB staff. Other print materials included flip books/ charts, booklets, posters, stickers, and so on conveying messages for awareness creation about TB and treatment such as the DOTS (Directly Observed Treatment for Tuberculosis with Short Course Therapy) system of treatment. Here the target audience included not only service providers but also patients and the general public. For instance, the importance of completing treatment was emphasised. The booklets provide information on what TB is, how it is caused, symptoms, how diagnosis is done, treatment, side effects, prevention measures, and so on. The information on treatment includes the number of drugs required to be taken, duration of treatment, and frequency of medicine intake. DOTS treatment is encouraged where it is proposed that medication has to be taken in front of the doctor.

Another National Health Programme is the National Vector Borne Disease Control Programme (NVBDCP). The mandate of the NVBDCP is the prevention and control of vector-borne diseases such malaria, dengue, kala-azar, and so on. The NVBDCP Directorate is responsible for framing technical guidelines and policies as to guide the states for implementation of programme strategies.[78] The guidelines include recommendations for diagnostic

[78] http://mohfw.nic.in/NVBDCP%20WEBSITE/aboutus.html.
[79] Training Module for Community Volunteers on Control of Vector Borne Diseases (National Vector Borne Disease Control Programme, 2006).

testing, treatment, framing of drug policies, NGOs, etc. The materials, whether online or in print form, are usually targeted to healthcare professionals working in the field such as through training manuals. The material includes information on the nature of the disease, causes, how it spreads, the health effects of the disease, symptoms, how it is diagnosed, treatment (including details of treatment in special situations such as pregnancy), strategies for control and prevention, and so on. For instance, in the training module for community volunteers on control of vector-borne diseases, the information provide relates to the following characteristics of different vector-borne diseases: what the disease is, how it is transmitted, symptoms, the type and dosage of the drug to be consumed, how and when medication must be consumed, prevention strategies, detection techniques, what age groups and sex are most affected by the particular disease, whether there exists any vaccine, etc.[79] The information is provided in a concise, simple and easily understandable manner, with diagrammatic representations and pictures as well. The training manual is aimed at training volunteers who work at the village levels about testing, dispensing drugs, dissemination of messages on prevention and control of disease, and so on. As per our interview with the NVBDCP office, the information and materials prepared for this programme are targeted primarily to healthcare service providers and trainers who train community volunteers. The information being provided to the healthcare professionals and workers is technical. Information to consumers is provided indirectly through them. Information to consumers is provided usually through direct interpersonal communication with the patient by the healthcare professional. We were also informed that reporting and feedback on adverse drug reactions is made immediately. We were also told that though there are no legal or other hurdles to providing information directly to consumers, this is usually not done for practical considerations. Usually healthcare professionals provide the information to consumers through direct communication.

There is also a separate link to IEC materials on the Ministry of Health website. Here, materials are provided for a list of certain diseases and conditions such as diabetes, high blood pressure, heart diseases, cancer, osteoporosis, asthma, stress management, hygiene, smoking, and so on. The nature of information provided is aimed at awareness creation and is explained in a simple manner. Pictures are given alongside brief messages, in a style representing a poster-format. For instance, on diabetes, the messages are on prevention, food that should and should not be taken and exercise. Tips are also given on yoga and ayurvedic treatment such as various preparations that can be made and consumed.[80]

The Ministry of Health and Family Welfare also provides information on traditional systems of medicine through its Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy (AYUSH). As per the department's website, http://www.indianmedicine.nic.in, in the FAQ section, there are even remedies provided for some medical conditions. Common sources of information for consumers on traditional medicines are the advertisements issued for a variety of products (eg. Dabur's Chyawanprash). This is a predominant source of information as messages are disseminated through the mass media and are thus seen by consumers on a daily basis. It is to be noted, however, that the medical information and even educational materials about these schools of medicine is largely missing in the current scenario. Usually the emphasis is on allopathic medicines. However, guidelines have been evolved by WHO for developing and disseminating information to consumers on traditional medicines. These have been discussed in **Annexure V.** In relation to the National Rural Health Mission under the Ministry of Health, the online information provided was more in the nature of the

[80] http://www.mohfw.nic.in/health_awareness.html

list of activities conducted under the programme and there was no direct information for to consumers.

b)National AIDS Control Organization

The National AIDS Control Organization (NACO) is a quasi-governmental organisation providing information on HIV/AIDS including treatment and medicines. However as per the NACO website, the more informative and educational materials on drugs are meant for medical professionals. NACO also provides information through its advertisements on ARV treatments. These ads do not have technical information, but create awareness regarding the availability of treatment with government centres and the importance of strict adherence to the dosage regimen prescribed. Details of advertisements recently issued by NACO in newspapers can be seen in **Annexure VI.**

c) Central Drugs Standard Control Organization

Other organisations such as the Central Drugs Standard Control Organization (CDSCO) provides information through its website[81] on topics such as the national list of essential medicines, drugs approved for marketing in India, bulk drugs registered, vaccines registered, drugs banned in India, and so on. In this project only the online information was examined. For essential drugs, the site provides the National List of Essential Medicines 2003 where medicines are listed under different therapeutic categories. This technical information would be more useful for and better understood by pharmacists than consumers. However, informed consumers would benefit from such information as it consolidates detailed information on drugs under the above heads. A form is also made available for reporting adverse drug reactions by healthcare professionals. The CDSCO website also has a separate section for consumers in which contact information of CDSCO, general precautions that patients should follow, applicable legislation to be followed for submitting drug samples to government analysts, and for importing drugs for personal use. However, the information does not include which drugs are prescription drugs and which are not. This information targeted to consumers is limited as it does not provide detailed practical information on consumption and use of drugs. General guidelines regarding the consumption of medicines has been given, such as that cautions about expiry dates, storage, the necessity of adherence, procurement of medicines only from licensed retail pharmacies, and so on. An adverse drug event reporting form has also been provided on the site. With respect to medical devices, a list of such devices registered in India, their manufacturing site and the authorised agents for import have been given on the site.[82] With respect to the conduction of clinical trials, the site displays information on the requirements for filling applications for conducting clinical trials.

d)State Pharmacy Councils

Quasi-governmental organisations such as the Pharmaceutical Council and various State Pharmacy Councils provide drug information. They do not provide drug information directly to consumers. The State Pharmacy Councils are designed to serve the needs of pharmacists. It was seen that the educative materials on drugs provided by the Pharmacy Councils such as that of Maharashtra and Karnataka, were directed primarily to pharmacists and medical professionals. The Pharmacy Councils also provide information through Drug Information Centres (DIC), although these too are directed to pharmacists. With respect to online information, taking the sample of the Karnataka State Pharmacy Council (KSPC), the topics covered through the material on the website included rational drug use, pharmacy education, online editions of the DIC newsletters, patient counselling, lists of banned drugs and investigational drugs. Guidelines are given for counselling patients on the proper use of

[81] http://cdsco.nic.in/
[82] See: http://cdsco.nic.in/html/medicaldemain.html

medications and it is pointed out that there is a difference between the provision of information to patients and counselling them, with the latter being described as 'integrating drug information, patient information, communication, and patient assessment'.[83] There are also links to other websites on drug news, drugs approved by the DCGI, and USFDA new drug approvals. The site also has a system for the online reporting of adverse drug reactions. Further, online drug enquiries can also be submitted to the KSPC. The published materials seen which had been produced by these councils, including newsletters and handbooks, as well as online materials and facilities such as reporting of adverse drug reactions, were meant for pharmacists. The specific drug information is also meant for the use of pharmacists. For a detailed analysis of materials brought out by state pharmacy councils, please see **Annexure VI**.

e) Ministry of Consumer Affairs

The Ministry of Consumer Affairs does not itself provide information online to consumers on the subject of drugs. The ministry supports consumer organisations such as Consumer Online Resource Empowerment (CORE). Advertisements aimed at creating consumer awareness about their rights and consumer empowerment have also been issued by the government, and are commonly seen in the mass media such as television and print media.

f) Ministry of Chemicals and Fertilizers

The Ministry of Chemicals and Fertilizers regulates issues relating to the pharmaceutical sector through its Department of Chemicals and Petrochemicals and the National Pharmaceutical Pricing Authority (NPPA). The NPPA is an independent body of the government responsible for fixing, revising and monitoring the prices of controlled bulk drugs and formulations.[84] It also monitors the prices of decontrolled drugs.[85] Consumers can lodge complaints about quality of medicines and prices with the Drugs Inspector of the District or the State Drug Controller. Complaints regarding violation of prices can be lodged with NPPA directly also.[86] The Department of Chemicals and Petrochemicals provides an online facility to consumers for mailing their grievances about availability, quality, pricing, policy matters, and so on related to pharmaceuticals directly to the Department through chemgriev@nic.in.

To summarise, the following observations and suggestions can be made with respect to government actors providing information:

- **The government and quasi-governmental agencies are providing information through various media.**
- **The information is scattered and not comprehensive.**
- **Information on National Health Programmes provides holistic information, covering the disease and preventive strategies. The aim is to create awareness. Information specific to drugs is sometimes directed to medical professionals rather than laypersons.**
- **Advertisements issued by the government do not contain detailed information on drugs. The aim is awareness creation and preventive strategies.**
- **Though there is a dedicated IEC Resource Centre under the Ministry of Health providing materials in different formats, the aim here is to create awareness and not to providing detailed technical information on drugs.**
- **Technical information, i.e. scientific and practical medical information, and educational material on alternative and traditional systems of medicines are**

[83] http://www.kspcdic.com/counseling_patient.php
[84] http://nppaindia.nic.in/index1.html
[85] http://nppaindia.nic.in/index1.html
[86] http://nppaindia.nic.in/frequent.html

usually not available. The focus is on allopathic medicines.

- **There are language barriers as only some information is provided in local languages.**
- **Guidance for developing a comprehensive database of information may be taken from sources such as the US FDA website for developing a comprehensive database of technical information directed to consumers.**

vii) Information provided by civil society organisations working on health

Usually the mandates of both health and consumer organisations are of a broader scope and issues of consumer drug information are considered as part of these larger mandates. For most health organisations, for instance, issues of awareness creation on health issues are usually the focus and technical and specific information on drugs is not provided. Similarly consumer organisations usually focus on educating consumers about their rights, mechanisms for redressal of grievances, and provide information on the quality standards of various products.

At the same time, many non-governmental health organisations have provided information which is useful not only for educating consumers but also information that can be used to develop parameters and standards by which such information can be evaluated, such as through guidelines advising consumers on what they should consider when being prescribed or when purchasing drugs. These guidelines have already been considered in the section on 'Parameters for Evaluating Information'. In this section, the actual information that is being provided directly to consumers is evaluated. The analysis of information has been classified according to the source of information, i.e. the types of organisations which are providing such information. The information provided by different organisations has been either basic or comprehensive and detailed information.

At the outset it must be noted that in the course of this project, we did not come across any NGO dealing exclusively with the issue of consumer drug information. Instead a number of NGOs dealt with consumer drug information issues indirectly or because their mandate of working on health issues or consumer issues for laypersons meant that they too would have to address issues of information being provided to consumers on medicines and treatments. The NGOs working with the relevant mandates were seen to be both users and providers of such information. But the concern over consumer drug information was most often part of their mandate and not an exclusive mandate. For instance, many NGOs worked on issues of rational drug use, such as the Karnataka Drug Action Forum, and in this capacity they provided information and guidance to consumers. The information being provided by NGOs working on health issues was in the form of counselling patients orally through trained medical practitioners and publications in different local languages creating awareness on different subjects of health. The printed material sometimes included information on drugs and treatment techniques in a simple language, often illustrated with diagrams, such as was seen for information dealing with reproductive health and contraceptives. Some organisations brought out detailed and technical drug information, such as on irrational combinations, comparative prices, dosage, side effects, brand and generic names, and so on, in the context of advocating rational drug use. Some others also bring out recommendations for formulating policy for rational drug use, which include guidelines to be followed by consumers while being prescribed or purchasing drugs.

A number of publications have also been brought out by these NGOs for awareness creation on a number of health issues ranging from specific diseases such as malaria and AIDS to reproductive health, general awareness on disease prevention, and so on. Publications have also been brought out for raising public awareness on aspects of a rational drug policy, with specific information on medicines also being provided. Regarding awareness creation

on issues of rational drugs, the information given often includes topics relating to banned drugs such as instances when a banned drug would not be banned. The instances include: when the government decides to lift the ban, when the ban is diluted so as to leave out some drugs, when the ban in ambiguously worded and so on. This would have practical value for consumers as it highlights important considerations for consumer safety while using drugs.

In certain instances, case studies are done on particular drugs or classes of drugs, for creating awareness about the same and discussing details such as when the drug is contraindicated. The information is usually brief and explained in a simple language. Other information that was found to be covered included topics such as drugs usage in special situations such as during pregnancy and breast feeding, price comparisons between different brands and companies, comparisons of generic medicines prices and other retail prices, and so on. Sometimes the publications also provide contact details for different drug control organisations, and publications on relevant topics relating to drugs, brought out by different groups. This has the effect of furthering the cause of creating consumer awareness.

a)World Health Organization

At the international level, the World Health Organization (WHO) is the prominent inter-governmental organisation working on health. Its work includes research on health issues, setting standards, offering technical assistance to countries and coming out with policy recommendations.[87] The WHO has brought out comprehensive publications providing drug information which have detailed writings on developments and updates on topics such as rational use of medicines, safety and efficacy issues, quality assurance, international pharmacopoeia, lists of international non-proprietary names, etc.[88] It also brings out a 'WHO Pharmaceuticals Newsletter' which gives information on the safety and efficacy of pharmaceutical products.[89] The WHO's medicines policy includes providing guidance to countries on how to develop and implement national drug policies; effective medicines regulation; ensuring the safe use of medicines; traditional medicines; rational use of medicines, etc.[90] With respect to rational use of medicines, the interventions advocated by WHO include use of independent information on medicines; continuing in-service medical education, and so on.[91] The WHO also has a network of information officers for a direct relationship between the organisation and all national drug regulatory authorities in Member States. Each national information officer provides information to the WHO on the safety and efficacy of pharmaceutical preparations and information on serious adverse effects.[92] An example of the guidelines evolved by WHO have been discussed in **Annexure V** relating to Guidelines for Information on Traditional Medicines.

b)Publications by LOCOST

Low Cost Standard Therapeutics (LOCOST), is a public, non-profit charitable trust which makes essential medicines for those working with urban and rural poor in India at prices which are often one-fourth or one-tenth the price of drugs being sold in the retail market. It has recently published a book *A Lay Person's Guide to Medicines*, which provides information for guiding consumers on the use of pharmaceutical drugs. The drug details given include drug classification, forms of drugs and administration, drug action and effects, drug dependence, drug storage and poisoning, drug interactions with food, alcohol, and dangerous drug

87 http://www.who.int/about/en/
88 http://www.who.int/druginformation/
89 See for instance: http://www.who.int/medicines/publications/newsletter/2007pharmnews2.pdf.
90 http://www.who.int/medicines/publications/policyperspectives/en/index.html
91 http://www.who.int/medicines/areas/rational_use/en/index.html
92 http://www.who.int/medicines/areas/quality_safety/safety_efficacy/druginfo_officers/en/index.html

interactions as well as special considerations in drug usage in special circumstances (pregnancy), and categories like children and the elderly. Information is given on combinations of drugs, as well as pointing out which combinations are irrational, with a list of combination drugs that are hazardous. It guides patients regarding discussing the management of drug treatment with their doctors and suggests precautions to be taken while on drug therapy. There is also discussion on the action that needs to be taken by consumers themselves, such as points which patients must discuss with their doctors when drugs are being prescribed to them. There are also specific points which women patients are advised to discuss with doctors, as it is emphasised that drugs affect women differently from men. As the scope of the book covers awareness creation on rational drug use, practical guidelines for consumers to follow, and technical specifications for drugs and combinations which can be understood by patients, it is suggested that this can be used as a model for development of consumer drug information. An analysis of information provided through the LOCOST publication, *A Lay Person's Guide to Medicines*, is provided in **Annexure VI.**

LOCOST has brought out other useful publications as well such as its book, *Impoverishing the Poor: Pharmaceuticals and Drug Pricing in India* which deals with the policy and ground-level scenario on drug pricing in India and its impact. The book provides considerable data on drug prices for a number of medicines available in the market for treatment of a variety of medical conditions. For instance, the information provided covers prices for the most expensive brand, least expensive brand, percentage comparisons of price differences, and the total costs of treatment based on these prices. The book has comprehensive information on governmental policies regarding drug prices, their approach and prices, mechanisms used by the industry in formulating prices, thus giving a detailed picture of how prices are arrived at, how they are justified, arguments against these mechanisms, impact of policy and prices, and so on.[93]

c)Organisations promoting rational use of drugs

One organisation has brought out a booklet emphasising that knowledge of patients of drugs is a key component of any rational use of drugs programme. The information provided in the booklet includes the purpose of the medication, the dose, the frequency of drug administration, duration of treatment, precautions, guidelines to deal with side effects, how to withdraw, cautions regarding storage, and so on. Advice on drug devices and techniques has also been given, such as guidelines for using inhalers, along with diagrams for the same. Some commonly occurring problems encountered during the treatment have been incorporated. The booklet describes around 52 medicines/drugs, each being described in about a page in each language, Hindi and English. The All India Drug Action Network is a network of NGOs campaigning for a rational drug policy.

d) Organisations working on women's health and rights

NGOs working on women's issues often provide information about issues of women's health. This information is created largely from the perspective of awareness creation and educating people about women's health issues, particularly reproductive issues. In some cases the information directed to women consumers is technical as well, in the sense that practical information on medication was given. This information included publications in both Hindi and English educating women about contraceptives and birth control. Details were given with diagrams and the information though technical can be easily understood. Some organisations focusing on reproductive health conduct research and develop drugs and devices such as contraceptive devices.

[93] LOCSOT and Jan Swasthya Sahyog (JSS), Impoverishing the Poor: Pharmaceuticals and Drug Pricing in India (2nd edn., Vadodara/Bilaspur, 2004).

e)Patient groups

Patient associations have also taken up the task of raising awareness about the disease/medical condition they suffer from, providing information on how the disease is caused, symptoms, what it does to the body, precautions, treatments, and so on. For instance, the Cancer Patients Aid Association provides a wealth of information online on its site http://www.cpaaindia.org. The site discusses different forms of cancer and explains treatment types in a simple, easy to understand manner. The details of the treatment in detailed medical terms are not done, as the information seems to be directed to laypersons rather than medical professionals. Under the FAQs section also treatment types are discussed. The extent of discussion on drugs relates to whether the drugs are given in combination or not, the form of the drug (tablet, capsule, etc), side effects, and so on.

f) AIDS organisations

Various organisations provide counselling to AIDS patients. However in most cases, information and advise is provided orally by doctors working with these organisations while counselling patients. As the patient groups they interact with are often illiterate, the interactions with patients are through oral counselling and not through distribution of printed materials. The counselling itself is not technical, i.e. about medical/scientific facts pertaining to the drug and its use, but is in the form of general advise such as stressing the importance of adhering to the dosage regime and abiding by the instructions of the doctors who recommended the medicines to them.

However in some cases, printed materials are also brought out by these organisations. For instance, the Delhi Network of Positive People (DNP+) has brought out an *Antiretroviral ARV Information Booklet*.[94] The booklet is aimed at patients and this is done because it is believed that for patients to remain healthy and make informed choices for their health, they must have accurate and updated information. The manner in which information is provided is in an easy to understand language, brief and non-technical. The booklet takes the reader through explanations of HIV, AIDS, CD4, viral load, combination therapy, antiretroviral, and so on. It explains how ARV works in the body, for how long the drugs work, what the side effects are, and how these may be managed. The importance of adherence is emphasised and it is explained why adherence is important, the consequence of missing doses, the level of adherence needed and tips for adherence. Special cases such as ART and pregnancy are discussed. ARV drug resistance is also explained, as well as how it may be avoided. HIV prevention is another topic covered. Practical information is also given for patients in Delhi by listing out where free ARV clinics, CD4 count tests and HIV/AIDS care homes are available in Delhi. Guidance is also provided as to the type and sources of information that patients should look for, and the importance of asking for information such as from doctors. For the discussion on each of the topics covered, practical information is provided for patients keeping in mind the daily routines and behaviours that patients would follow.

g)Consumer groups

There are a number of consumer organisations operating in India. The Consumer Guidance Society of India (CGSI), Mumbai Grahak Panchayat, and Consumer Voice are some of the prominent organisations. However it was found that it was only in some instances that consumer groups provided *drug* information to consumers. This was done with the perspective of awareness creation. In some cases the consumer organisation also conducted its own tests and studies with respect to medicinal products. For instance, surveys have been done on whether information pertaining to dosage, storage and labelling was provided in relation to the sample of

[94] "Antiretroviral ARV Information Booklet for People Living with HIV and AIDS", (Tides Foundation and DNP+).

medicinal products taken. Some consumer organisations bring out magazines for creating consumer awareness on specific issues and about specific products. Some of these include information on drugs, under topics such as what the drug is used for treating, information that the doctor must know about the patient before prescribing it, cautions in using the drugs, guidelines for safe usage of the drug, reported interactions with other drugs, adverse effects, and so on. Some consumer organisations also provide for consumers to air their grievances. For instance, VOICE provides a helpline for complaints about MRP. This measure is more of a consumer grievance redressal mechanism. The VOICE website also hosts a blog for young consumers to express their opinions about consumer-related issues. For details on the type of information provided by consumer organisations, please refer to **Annexure VI.**

In summary, some observations that can be made about the information being provided by civil society organisations are:

- **Most civil society organisations working on health or consumer issues deal with consumer drug information issues indirectly and as part of a larger mandate. No organisation deals exclusively with the subject of consumer drug information.**
- **There are no uniform standards for the nature and formats for providing information. There is no shared understanding on what information should be provided and how this should be done.**
- **Different organisations are bringing out different levels of information and in varying detail. While some focus on awareness creation, others prescribe guidelines to be followed by both those who provide information and consumers who look for information.**
- **Pricing information is usually not focused on.**
- **The formats in which information is being provided also differs online, whether in online or print forms and within that whether in the form of books, booklets, brochures, posters, and so on.**
- **However the level to which such information is actually reaching consumers and catering to consumer demand must be examined.**
- **There are some efforts to provide information in local languages.**

viii) Information provided by healthcare professionals

Doctors and other professionals in the field of medicine are also making individual efforts to promote consumer awareness on drug use.[95] They make these efforts by contributing to the press and other media, where specific topics, such as the effect of consumption of alcohol on drugs, are explained in simple terms that can be understood by laypersons. The awareness creation on topics of drug use is useful for both doctors and patients and can also be used as guidance by both. Doctors have also collaborated to bring out studies on specific topics on drugs and drug use. In some cases, prices of various drugs were also included in these publications. An example of the work done by individual doctors is a *Study On Drugs For Treating Anaemia*, which was brought out by four doctors.[96] The study is described as an attempt to bring to the notice of consumer action and women's groups, the types of anti-anaemia drugs available for the treatment of anaemia in India. It was also meant to provide evidence and influence policy makers on the need for and promotion of rational drug policies. Among the details given were also the prices of

[95] In the course of this project, the inputs provided by Dr. Guru Prasad Mohanta, Dr. Saravadekar (of J.J. Hospital, Mumbai) and Dr. Gopal Dabade were particularly useful.
[96] Dr Gopal Dabade, Dr. R. R. Kongovi, Dr. S. L. Pawar and Dr. A. N. Kabbur.
[97] See Dr. Gopal Dabade, Dr. R. R. Kongovi, Dr. S. L. Pawar and Dr. A. N. Kabbur, "Study on Drugs for Treating Anaemia".

various drugs used to treat anaemia. The finding of the study was that there are no rational and scientific drugs to treat anaemia, with explanations and discussions on the reasons for this situation.[97]

Although significant efforts have been made on an individual basis by a number of medical professionals, very often however, enough drug information is not being provided by doctors to their patients in terms of quality and quantity. In the course of conversations with medical professionals, it was learnt that often, doctors and pharmacists hardly provide comprehensive consumer drug information. In fact most doctors do not give such information and may be quite uncommunicative. Even where doctors tell patients about side effects, precautions and so on, most do not give details such as how the drug works. Another situation that was pointed out was that in many cases, when doctors realise that patients do not take full dosages, they will prescribe medicines that are more expensive but have a shorter duration to be consumed. This is the shortcut taken by doctors instead of providing cautionary information to patients and advising them on the importance of adhering with the full dosage regime.[98] It was also pointed out that in many cases unnecessary drugs are prescribed by doctors. For instance in case of diabetes, patients are often put on unnecessary B-complexes. To avoid situations where unnecessary and irrational drugs are prescribed, there is a need for information to be provided. Also in many cases drugs act as placebos and there is a need to give information to patients about what placebos are.[99]

Also in terms of practical considerations, it has been suggested that it would be better for doctors to advise patients to get back to them in specific situations, rather than providing detailed information on all aspects of the working of the drug. For instance, a doctor could recommend the patient to contact the doctor again in case of any side effects, instead of telling patients about the whole list of side effects, especially if many drugs have to be given to the patient. Doctors should give precautionary information.[100]

- **In summary it can be suggested that doctors and other medical professionals make individual efforts to ensure that the information they provide to consumers is comprehensive, technical and explained in manner that is understood by the consumer. The doctor should be responsible in ensuring that consumers have understood the information provided to them.**
- **There could be a re-look at the ethical codes and concerned statutes governing healthcare professionals.**

ix) Information provided by educational institutions

It was noticed that apart from technical information, information that is useful to consumers was also sometimes provided by some of the educational institutions either on their websites or through published materials. The type of information included the mechanism of action of the drug, clinical pharmacology, adverse effects, and so on.

Taking the example of JIPMER, it was seen that apart from technical information, information that is useful to consumers was also provided. An important feature noticed was the facility for reporting of adverse drug reactions facilitated by JIPMER. This can be done through a form provided online on its site.[101] JIPMER also publishes materials with technical medical information on drugs, such as 'Drug Alert' under which for a particular drug, information is provided about its mechanism of action, clinical pharmacology, adverse effects, JIPMER experience, and so on.

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98 Interviews with Dr. Anant Phadke and Dr. Gopal Dabade.
99 Interview with Dr. Gopal Dabade.
100 Interview with Dr. Anant Phadke.
101 http://www.jipmer.edu/

- **In summary, medical institutions must continue with their efforts but must also ensure that the information they provide reaches the consumer and not only healthcare professionals.**

x) Information on the internet

Many websites provide information to patients and also medical professionals with the aim of educating them about medical conditions. These websites can also provide technical information to consumers, such as providing lists of irrational combinations and discarded drugs. Education information covers not only drug details but also informs consumers on other factors that go into choosing medication, such as which are the reputed pharmaceutical companies, hospitals, links to support groups, and so on.[102] However, there are risks involved in diagnosing medical conditions or purchasing medicines online as the authenticity of information is usually questionable. Also in all cases, the patients must consult with their doctor and cannot solely depend on online information.

Some sites are directed specifically to professionals and may even include access to journals, whether subscription-based or not.[103][103] For instance, sites such as:

Some websites do not directly provide information but provide only links to other websites, whether the URLs are Indian or not, which may have useful information for doctors and patients. For instance the Indian Medlars Centre (http://www.indmed.nic.in) provides links categorised in terms of utility to professionals or consumers.

The pages of organisations connected with organisations whose mandate concerns the provision of drug information, have been examined and discussed in other parts of this paper, along with the discussion on the relevant organisation. For instance, the website of the Central Drugs Standard Control Organization (CDSCO) provides technical information, and also has a separate section for consumers. As seen earlier, the information in the consumer section was limited and not technical or detailed.

Considering that online information cannot usually act as a substitute for the patient's consultation with a doctor, in some cases it was seen that websites had disclaimers to this effect and specified that the information was provided merely from an educational perspective. Common features of many Indian sites were: educational material in the form of articles and discussions related to different categories of health concerns, FAQs on diseases, and general information on different medical conditions and treatments. In some sites the description of treatment covered listing out which medicines have to be taken, and timing related to the taking of medicines, at what stage the patient must see the doctor, adverse reactions, cautions about where the safety of particular forms of treatment has not been fully established, medicines that can and cannot be taken in certain special situations such as pregnancy, side effects, dietary instructions, storage instructions, guidelines on what the patient must discuss with the doctor, and so on.[104]

A more detailed survey of websites has been provided in **Annexure IV.**

To summarise:

- **Reliability and authenticity of information are the major issues of concern.**
- **There are no common standards and**

[102] For instance NDTV has made available online information on such topics through websites such as http://www.doctorndtv.com/drugs/, http://www.doctorndtv.com/drugs/discarded.asp?flag=I and http://www.doctorndtv.com/drugs/discarded.asp?flag=D.

- BIOME
- BioMedNet
- CenterWatch Clinical Trials Listing Service
- Doctor 's guide to the Internet
- eMedguides

[103] For instance, sites such as:

Note: These and other sites include non-Indian sites as well.

formats for the provision of information.

xi) Information provided by pharmaceutical companies

Pharmaceutical companies often give product details on their websites. The drug information on their websites was usually technical details, which were not directed to consumers but to medical professionals. The information that is directed to consumers is usually in the form of labels and package inserts for the particular drug product being marketed. In the course of this project, the websites of some of the leading pharmaceutical companies in India were examined.[105] It was found that the information on drugs was directed to medical professionals. Brief but technical details on drugs were provided, which would sometimes be better understood by professionals rather than consumers. For instance, the nature of information provided on drugs covered details of active ingredients, product type (eg. capsules), pack type, pack size, and product brand. In one site, information given was not only about drugs but also on diagnostics and devices. In another instance in the consumer division section of a company's site, it is stated that the consumer business of the company spans over food and skincare products. Brief descriptions are given of these products in layman terms. No technical information is provided. Pictures of the products are also displayed. This information seems to be directed to consumers directly from a marketing perspective. For details on the nature of information provided by pharmaceutical companies on their websites, please refer to **Annexure VI.**

Apart from websites, information on company products is also available through press releases and news reports. Press releases would also cover the launch of diagnostic products, devices, test kits, and so on. The kind of information provided through press releases is essentially about how the new launch is better than what is provided in the existing market, the brand names under which the product is marketed, prices, and details of the companies developing the products.

To summarise:

- **Clear distinctions between advertisements and other sources of information provided by companies are required.**
- **There is a need for clear guidelines governing the provision of information by companies.**
- **Stricter enforcement of norms and guidelines is required.**

VI. Conclusions and Recommendations

Although efforts exist for educating consumers about the elements of rational drug use, the level of these efforts and the quality and reach of information usually differs according to who is providing the information. The fact that there are a variety of actors involved in providing information and that multiple efforts are being made by them could be considered as both furthering as well as hampering the cause of providing a single source of basic and comprehensive drug information to consumers. In terms of both quantity and quality, more efforts need to be made to comprehensive

[104] For instance, such information was provided on sites such as www.diagnosishealth.com, www.apollolife.com.

[105] These were: Ranbaxy Laboratories, Dr. Reddy's Laboratories, Cipla, Sun Pharmaceutical Industries, Aurobindo Pharma, Wockhardt, Cadila Healthcare, Lupin, Nicholas Piramal India Ltd., Orchid Chemicals & Pharmaceuticals, Pfizer, GlaxoSmithKline and Novartis.

information. The reasons for the current lacunae in the provision of information need to be identified.

a) Conclusions

The main conclusions that can be drawn from a situational analysis of the provision of consumer drug information in India are:

- The availability of consumer drug information in India is very low in terms of quantity. This can be observed from the information and actors seen in the course of this project, and this is also the opinion of medical professionals.[106]
- In most cases, information is not provided in a user-friendly manner. Information is usually not both comprehensive and brief. It is usually not presented in a manner that can be understood by laypersons and yet also provides all details of treatment and the drug.
- Information is provided mostly on allopathic drugs. There is limited information on traditional medicines, medical technologies and equipment and on diagnostics.
- There is a particular lack of information relating to drug prices. There is no comprehensive database for the same and only some actors engaged in providing consumer drug information provide price information. In the course of this project no information was observed to be provided on clinical trials; another neglected area.
- There is no single, dedicated actor concentrating only on consumer drug information.
- The multiplicity of actors makes it possible for the range and reach of information to be as broad as possible, thus reaching out to a large number of consumers. At the same time the multiple efforts made might differ in their standards and content. The consumer may in some cases be at a loss as to which source of information is the best.
- There is no coordination among different actors. Some people have the impression that if information were directed to consumers or laypersons, they would not understand. Although organisations such as NGOs tend to be more sympathetic, a systematic setting up of a centre has not yet happened.
- There is no level of consistency with respect to the information supplied. For instance, there are differences over even the dosage requirements prescribed for drugs as per the different sources of information.[107]
- Another flaw in the current Indian system that must be kept in mind while formulating information is that western formats are copied. For instance this is often done with respect to dosages. Dosage depends on body weight and thus to use western standards may be incorrect as average Indian body weights are different.
- Information directed at consumers is largely aimed at awareness creation on preventive strategies and is not very technical in terms of providing medical details pertaining to the drugs or in terms of providing practical information regarding the usage and consumption of the drug.
- Most technical information with respect to drugs is directed to medical professionals and not consumers.
- Though efforts have been made by different organisations to provide comprehensive information to consumers in a simple manner, this is usually done through the publication of books, booklets or CDs or other formats that would not normally be accessed by common consumers.
- Though considerable information is available in journals and academic papers, particularly on

[106] For instance in an interview with Dr. Anant Phadke, he pointed out that in his opinion the availability of consumer drug information in India is very low in terms of quantity and quality.
[107] Interview with Mr. Srinivasan.

issues of rational drug use; such sources of information are not accessed by laypersons. Although there are chances that such information percolates to laypersons from the technical persons accessing the information; there is no way of assessing this directly. However these are secondary and indirect sources of information.

- Information is sometimes being provided in both English and local languages though for some sources of information such as labels on medicines or those in the internet, information is primarily in English. In the opinion of some medical professionals, consumer information is primarily in English.[108] Another limitation is that information provided in local languages is usually basic information and not comprehensive and technical information.
- The current law and policy regime does not deal comprehensively with issues of consumer drug information. Though some aspects are dealt with, there is no holistic examination of this issue and there are gaps in the current framework. To comprehensively address issues of consumer drug information, there is a need for amendments to be made to laws and policies.

b) Conclusions Drawn with Respect to Each Set of Actors Providing Information

i) Governmental and quasi-governmental authorities

It can be concluded that the information provided by governmental bodies was not consistent across different bodies. Even within different programmes under the same ministry, such as the Ministry of Health, the amount and quality of information varied. Also technical aspects of drug information such as composition and dosage of drugs was usually addressed to medical professionals and comprehensive information was usually provided in the format of training manuals. Information directed to patients/consumers was more general as it was usually aimed at awareness creation on diseases and prevention strategies. Thus the information provided to consumers was more holistic with respect to the disease being dealt with, but on the specific aspect of drugs, the information was not as comprehensive as all parameters of information that should be supplied to consumers was not covered.

At the same time, the importance of consumer drug information has been recognised and the Ministry of Health has a dedicated IEC Resource Centre. Information is given in user-friendly formats (whether in print, audio or video). However, here too, the information is given from the perspective of creating awareness about medical conditions and preventive strategies. Advertisements brought out by the government also focus on the preventive aspects and general awareness creation.

The Ministry of Consumer Affairs does not provide exclusive information on drugs to consumers. Government sites, such as that of the Ministry of Chemicals and Fertilizers, do provide information on prices in the forms of relevant government orders, notifications and news dealing with the drugs under price control, lists of essential drugs, and so on.

However there is no comprehensive, single database of information from the government which contains technical information on drugs that has been approved by governmental authorities. As against this, the US FDA site provides comprehensive and authentic information to consumers and the manner in which information is provided can be considered as a possible standard for the development of a similar database in India.

As a limitation to this paper, it should be noted that at the time of writing this paper, most of the information seen from government sources was what was available online only.

[108] Interview with Dr. Anant Phadke.

ii)Civil society and non-governmental organisations

Considering the number of actors operating within this category and the variety of information provided by them, it is difficult to draw conclusions encompassing all these actors. It may be noted that in the course of this study, it was observed that there was no organisation concerned exclusively with the provision of consumer drug information. The main difficulty from a consumer's perspective is that there would be confusion as to which source of information is an authentic source. Further, the question of whether information targeted to consumers is reaching them at all is to be considered. Consumers may search for information that is relevant to only a particular medical condition that is affecting them. They may not usually look for and purchase books, CDs, etc. providing detailed information on all drugs and all medical conditions. Thus the question of reach and the importance of matching the supply of information with the demand for it is an important one.

iii)Private actors

Comprehensive and technical medical information such as on drug compositions, given by pharmaceutical companies is usually directed to medical professionals. Information directed to consumers is usually in the forms of labels and package inserts. This provides basic information to consumers for that particular drug. Issues of concern are instances when label requirements may not be observed or misleading advertisements are made by pharmaceutical companies. Larger issues are the marketing methods pursued by these companies and the nexus with medical professionals, with the aim of promoting the sales of drugs manufactured by them. However, this particular issue is presently beyond the scope of this project.

iv)Healthcare professionals

Healthcare professionals are often unable to provide comprehensive drug information to consumers for various reasons. There is a need to address this problem.

v)Other associations and individuals

Commendable efforts are being made by individual doctors and medical professionals in educating consumers about medications and rational drug use. While these should definitely continue, the entire medical community must make such efforts. Doctors are usually the only and the most reliable source of information for patients and are in the best position to provide guidance and education to patients regarding treatment, medications and rational drug use.

c)Recommendations

The recommendations that need to be immediately implemented to address pressing issues of consumer drug information are:

- For bigger packs of medicines, leaflets and printed materials should be given. This should be made compulsory for drug companies, and should be reviewed. Also the print on medicine labels should be of a large size.[109]
- For the review of all information and materials provided by pharmaceutical companies, there should be a team of pharmacologists, clinical professionals, and consumers.[110] It has also been suggested that drug companies be compulsorily made to use a part of their profits for the development of consumer drug information.[111]
- Making information on *prices* of drugs and comparisons between the prices of various branded and generic versions of the drug, more readily available for consumers.

[109] Interview with Dr. Anant Phadke.
[110] Interview with Dr. Anant Phadke.
[111] Interview with Dr. Gopal Dabade.

- Disseminating detailed information on drugs to consumers in a simple, easy to understand manner.
- Disseminating information in local languages, and not only English.
- Developing a forum wherein the actors involved in disseminating information can meet and deliberate as to the common steps to be taken to take forward the movement for advocating rational drug use, particularly regarding consumer drug information.
- Encouraging consumers to be more proactive in seeking information. Patients are usually more proactive about obtaining information on how to treat medical conditions that require continuous or lifelong monitoring, such as diabetes. In such situations patients are more demanding about information on the drugs and treatment required, including details such as drug prices.[112]

Some other recommendations that need to be implemented are:

- Developing a single, comprehensive source of information which can be readily accessed by consumers. This could be a source provided by the government, as a source of verified and authentic information.
- Developing comprehensive regulations and guidelines and ensuring their implementation for all possible sources of consumer information and the actors providing this information. This involves developing guidelines for providing consumer drug information that acts as a common standard for all those who are involved in dispensing such information. In addition, a format according to which information may be provided can be developed. This would be a basis for uniformity of standards for the provision of at least basic information. This also involves the examination of current law and policy in greater detail.

One suggestion has been that the government can set up Standard Treatment Guidelines. Many hospitals and other governments have their own standard treatment guidelines and also have their own formularies, which are reviewed every year. The British National Formulary (BNF) has been suggested as a good standard.[113] It was also suggested that every doctor should receive a copy of standards and guidelines similar to the BNF.[114]

- Developing guidelines, which are specific to the different types of media through which information is disseminated. For instance, guidelines could be developed with respect to online information, advertisements, labels, etc. This would be in addition to the guidelines developed with regard to the content of information.
- As a standard for the comprehensive information to be provided, the Physician Drug Review (PDR) in the USA may be considered. The information provided in PDR is reviewed by the FDA. There is also separate information for consumers.[115]
- Coordination among different actors is necessary so that a common approach can be developed with respect to the standards and guidelines to be evolved. One suggestion has been that the responsibility of initiating coordination lies with the government, which should be responsible for bringing all stakeholders together.[116]

[112] Interview wit3h Dr. Gopal Dabade.
[113] Interview with Dr. Gopal Dabade. However Dr. Dabade also pointed out that doctors may adversely react to such standards as they may feel that this would interfere with their right to prescribe treatment for patients; and that in the case of treatment and drug prescription, the doctor would know best about the patient's condition, and pre-determined guidelines for treatment may not be relied upon.
[114] Interview with Mr. Srinivasan.
[115] Interview with Dr. Anant Phadke.
[116] Interview with Dr. Gopal Dabade.
[117] Interview with Dr. Anant Phadke.
[118] Interview with Dr. Anant Phadke.

- There should be an authority to assess the information being provided. The assessment should be done in a manner, which involves the inputs and efforts of different actors including NGOs and not only the government.[117]
- In our discussions with medical practitioners and professionals, it was suggested that websites and books are the best way that information can be provided effectively; considering that information from doctors, pharmacists, and drug labels is often inadequate. It was also suggested that a range of journals and websites be available, so as to reach out to different levels of understanding among different sections of the public.[118]
- Continuing with current efforts for providing consumer drug information.
- Continuing with efforts of providing information to medical practitioners, as they are both the direct and indirect sources of drug information to consumers.
- Focusing on subjects where there is a greater lack of information such as in traditional medicines.
- Further analysis is required for determining what the current obstacles are for the development of comprehensive consumer drug information. This includes determining what prevents the government from organising a centralised database of information and what can be done to address this.
- It is important to keep in mind similar recommendations regarding sources of information for doctors.
- As patients consider doctors as their primary and the most trusted source of information, it is recommended that doctors provide at least basic and comprehensible information to patients, according to the standards prescribed for the provision of drug information to consumers.

Apart from the above, certain recommendations can be specifically directed to each set of actors. This has been attempted below:

i)Governmental and quasi-governmental authorities

- The primary recommendation that should be acted upon by the government is the setting up of a comprehensive and single database of disease and drug information for laypersons. This should be accessible online as well as through the print media. As a model for comparison, the database of the US FDA can be referred to. Information should be provided in a simple manner. At the same time it must cover all aspects of information, as highlighted in the parameters and models discussed earlier in this paper.
- Comprehensive guidelines are to be developed for the guidance of other actors providing drug information to consumers, with specific guidelines targeting particular actors such as pharmaceutical companies. Compliance with guidelines should be followed by review and monitoring of information by a team of experts before information is made available to the public; and could be done with inputs from NGOs and other actors as well. Guidelines should also be framed depending on the format in which information is provided, such as online information. Here in particular, it is advised that there should be a system of accreditation that verifies the online sources of information.
- It is also necessary that such information is available in local languages and disseminated even at the grassroots level.
- A database of information with prices and price comparisons for different brands of the same drug should be made available both online as well as in the print medium.
- Information disseminated to consumers should be provided in a simple and easy to understand manner.

- The government could initiate coordination among different actors involved in providing and demanding consumer drug information.
- A more proactive approach is required to be taken by the Ministry of Consumer Affairs for providing information specific to drugs to consumers and for monitoring the information currently being provided, such as through advertisements.
- The Ministry of Chemicals and Fertilizers provides price information for only some drugs. Information should be provided on all drugs in a format that can be easily referred to by consumers.
- The Health, Consumer Affairs and Chemicals ministries should coordinate efforts in developing a comprehensive database of information for consumers.
- The government should develop holistic and comprehensive legislation and policy for dealing with issues of consumer drug information. As an initial step current gaps in law and policy should be addressed and clarifications should be provided in the light of the need to provide a framework for the governance of drug information being disseminated to consumers.

ii)Civil society and non-governmental organisations

- In order to ensure the effective reach of information provided by civil society organisations, it is necessary that the information is provided in a manner that caters to the demand being raised by consumers. As consumers would usually be expected to ask for information specific to particular medical conditions, these organisations should provide information to cater to such a demand.
- Information directed to consumers should be presented in a simple and comprehensible manner.
- Information should be disseminated in local languages and not only in English.
- Civil society organisations should encourage consumers to be more proactive in seeking information.
- Organisations should continue with their efforts to raise awareness on issues related to rational drug use for consumers and empower them by educating them on the need for the same. It is necessary that they develop linkages with each other and with other actors such as the government, pharmaceutical companies, individual medical professionals and consumers themselves.
- They should also focus on providing information and monitoring the information that is provided by pharmaceutical companies directly to medical professionals.

iii)Healthcare professionals

- Efforts should be made by doctors and other medical professionals interacting with patients to make sure that basic information is provided by them to patients and is understood by them.
- Sensitisation is required, including as part of the educational requirements for healthcare professionals.
- Better implementation of the code of ethics and statutes regulating professional bodies is required.
- A re-look at the code of ethics and relevant statutes is also needed.

iv)Pharmaceutical companies

- There must be strict monitoring of information being provided by pharmaceutical companies. This refers to approving information before it can be made publicly available; mandating that certain basic information must necessarily be provided along with the medicine or medical device; and continuous monitoring of the type of information that is released.
- Information should be provided in local languages as well as English.

- At a broader level, the marketing strategies pursued by pharmaceutical companies and their networking with medical professionals should be monitored and controlled.

In conclusion for the purpose of this paper, upon an initial survey of consumer drug information and the actors providing and receiving it, certain issues arise for consideration as future research questions and areas for examination:

- Issues of consumer drug information must be understood from the demand side as well. This means that the information expected and demanded by consumers and organisations representing and protecting consumer interests must be understood. The provision of consumer drug information can be effective only if it meets consumer needs.
- Considering the level and type of information available to consumers presently, the major legal, ethical and other reasons behind the current state of play need to be identified.
- There is a need for linking research done on the marketing and drug promotion strategies pursued by the pharmaceutical industry, with the mechanisms for the provision of consumer drug information and the quality of such information.
- Doctors and other medical professionals are required to be surveyed for their views on the promotional activities being pursued by pharmaceutical companies; and how this impacts them.
- Advertisements are to be studied in greater detail, as they are a direct and predominant source of information directed to consumers. The issue of monitoring of drug advertisements also needs to be examined, as for certain diseases and medical conditions advertisements are prohibited. However, the level of actual compliance with the law is to be determined. Instances of false and misleading ads are also to be determined. The issue of how such ads can be prevented and monitored is also to be considered.

Annexure I

List of Contacts

The following is a list of contacts whose materials were referred to and examined for the project. It also includes contacts whose materials were not ultimately used, contacts which did not give printed material but with whom correspondence was maintained through email or telephonic conversations, or whose help was used in the course of this project.

The materials examined in the course of this project, sourced from the below contacts included approximately 25 printed publications (books, booklets, newsletters), and several posters. Online information included a range of websites and e-magazines. In some cases oral information was obtained such as from counselling centres which did not have any published materials.

a) State Pharmacy Councils and other Pharmacies

Maharashtra State Pharmacy Council

E.S.I.S. Hospital Compound, L.B.S. Marg
Mulund (W), Mumbai – 400 080
Tel: 2568 4291
E-mail: dicmspc@yahoo.co.in,
dicmspc@hathway.com, info@mspcindia.org,
mspcl@vsnl.net

Karnataka State Pharmacy Council

514/E, 1st Main, Vijayanagar Club Road
R.P.C. Layout, Vijayanagar 2nd Stage
Bangalore – 560 040
Tel: 3383142, 3404000
Fax: 3202345
E-mail: kspcdic@blr.vsnl.net.in;
Kspcdic@hotmail.com

Hindu Pharmacy (Dr. Raj Vaidya)

Cunha Rivara Road,
Panaji – Goa – INDIA
403 001
Tel: (O) 91-832-2223176, 2432903
E-mail: pharmhin@sancharnet.in,
hindupharmacy@gmail.com

Pharmacy Council of India

Combined Councils' Building
Kotla Road, Aiwan-E-Ghalib Marg
New Delhi-110 002.
Tel: 011 - 23239184, 23231348
Fax: 011 – 23239184
E-mail: pci@ndb.vsnl.net.in

b)Non-Governmental Organisations (NGOs)

Naz Foundation (India) Trust

A-86, East of Kailash,
New Delhi 110014
Tel: 2691 0499, 41325042
E-mail: nazindia@airtelbroadband.in,
nazindia@bol.net.in

AIDS Awareness Group

119 – D, Humayunpur
Safdarjung Enclave
New Delhi 110 029
Tel: 2618 7953/54
E-mail: aagindiya@yahoo.co.in

Jagori

B-114, Shivalik, Malviya Nagar
New Delhi 110017
Tel: +91 11 2669 1219, +91 11 2669 1220
Fax: +91 11 2669 1221
E-mail: jagori@jagori.org

iv)Population Council
53, IIIrd Floor, Lodhi Estate
New Delhi.
Tel: 2464 9047, 2464 2901
E-mail: vmahendra@popcouncil.org

v)Chelsea
B-17/4, West Jyoti Nagar
Shahdra, Delhi 95.
Tel: 2213 0451/52
E-mail: wagchelsea@vsnl.net,
wagchlesea@yahoo.com

vi)Family Health International
Opp. Convention Hall, Ashoka Hotel,
Chanakyapuri, ND 110021
Tel: 26873950 / 53
Fax: 26873954
E-mail: bgeorge@fhiindia.org

vii)Positive Lives Foundation
H.No. 133/A, Behind Omer E-Maszid
Near Gurudwara Road, Mangoor Hill
Vasco Da Gama, Goa – 403802.
E-mail: plf@rediffmail.com,
poslivesfoundation@yahoo.com

viii)HIV and Human Development Resource Network
New Delhi
E-mail: hdrn@youandaids.org

ix)Jan Swasthya Abhiyan / People's Health Movement
E-mail: jsad@bol.net.in, navjyoti@bol.net.in

xi)Medico Friend Circle
C/o Manisha Gupte
11, Archana, Kanchanjunga Arcade
163, Solapur Road, Hadapsar
Pune 411028.
Tel: 020 6875058
E-mail: masum@vsnl.com

xii)Voluntary Health Association of India (VHAI)
B-40, Qutab Institutional Area, South of IIT
New Delhi – 110016
Tel: 41688152/53, 26518071/72, 26515018
Fax: 011-26853708
E-mail: vhai@vsnl.com

xiii)Medicins Sans Frontiers (MSF)
C 106, Defence Colony
New Delhi 110 014
Tel: +91 9811365412, +91 1124332419

xiv)Christian Medical Association of India (CMAI)
A-3, Local Shopping Centre, Janakpuri
New Delhi-110058
Tel: 25599991, 25599992, 25599993
Fax: 25598150
E-mail: cmai@cmai.org, cmaidel@vsnl.com

xv)Jagruti
57, Tejaswinagar,
Dharwad 580 002
Tel: 0836-2461722

xvi)AIDWA
121, Vithal Bhai Patel House, Rafi Marg
New Delhi – 110 001
Tel: +91 11 23710476 / +91 11 23319566
Fax: +91 11 23710476
E-mail: aidwa@ndb.vsnl.net.in /
aidwa@rediffmail.com

xvii)Saheli
Saheli Women's Resource Centre
Above Shop No. 105-108
Under Defence Colony Flyover
North Jangpura Side
New Delhi-110014
Tel: 011-24616485
E-mail: saheliwomen@hotmail.com

CUTS International
D–217, Bhaskar Marg, Bani Park
Jaipur 302 016
Tel: +91(0)141-228 2821
Fax: +91(0)141-2282485
E-mail: cuts@cuts.org

c)Consumer Organisations

Consumer Guidance Society of India (CGSI)
E-mail: drarshenoy@gmail.com

Consumer Online Resource and Empowerment Centre (CORE Centre)
CORE Centre
Delhi
E-mail: cccdel@del3.vsnl.net.in

Consumer Voice
441, Jangpura, Mathura Road
New Delhi-110 014
Tel:011-24379078-80 Fax:011-24379081
E-mail: consumeralert@eth.net

Consumer Online Foundation
C-128, IInd Floor, Defence Colony
New Delhi – 110024
Tel: 24339339
Fax: 91-11-24332339
E-mail:director@consumeronline.org

d)Others

Delhi Society for Promotion of Rational Use of Drugs
Delhi Government Dispensary, Vasundhara Enclave
Delhi – 110 096.
Tel: 2261 2669
Fax: 2261 2558
E-mail:dsprud2005@yahoo.com;
dsprud@satyam.net.in

Gujarat State AIDS Control Society (Dr. Rajesh Gopal, MD, Joint Director)
O/1 Block, New Mental Hospital Complex
Meghaninagar
Ahmedabad-380016
Tel: (O) 079-22680211–12–13, 22685210
Fax: 079-22680214

LOCOST
1st Floor, Premananda Sahitya Sabha
Opposite Lakadi pool, Dandia Bazar
Baroda 390 001
Tel: 0265- 2340223, 2333438
E-mail: sahajbrc@icenet.co.in,
locostbrd@satyam.net.in

Indian Pharmaceutical Association (IPA)
Kalina
Santacruz (E)
Mumbai - 400 098.
Tel : 91-22-2667 1072
Fax : 91-22-2667 0744
E-mail: ipacentre@ipapharma.org

Bulk Drug Manufacturers Association
C-25, Industrial Estate, Near SBH, Sanathnagar
Hyderabad 500038
Tel: +91-40-23703910/23706718
Fax: +91-40-23704804
E-mail: info@bdm-assn.org;
hyd2_bdmahyd@sancharnet.in

Organization of Pharmaceutical Producers of India
Peninsula Corporate Park, Peninsula Chambers
Ground Floor, Ganpatrao Kadam Marg
Lower Parel, Mumbai – 400 013
Tel: 91 22 2491 8123, 2491 2486, 6662 7007
Fax: 91 22 2491 5168

Lawyers Collective
63/2 Masjid Road, 1st Floor
Jangpura
New Delhi – 110014
Tel: 011-24377101/2, 24373904, 23372923, 24376925
E-mail: aidslaw1@lawyerscollective.org

Cancer Patients Aid Association
5, Malhotra House
Opp. G.P.O. Mumbai – 400001
Tel: 2269 7255/ 8964

Delhi Science Forum
Tel: (011) 26524323

All India Drugs and Chemists Association (Mr. Ashwini Kumar)

Online Forum: india-drug@healthnet.org

Online Forum: aids-india@yahoogroups.com

e)Educational Institutions

National Institute of Pharmaceutical Education and Research (NIPER)
Sector 67, Phase X, S.A.S. Nagar
Punjab -160062
Tel: +91-172-2214682-87
Fax-+91-172-2214692
E-mail: medinfo@niper.ac.in

Jawaharlal Institute of Postgraduate Medical Education & Research (JIPMER)
Dhanvantri Nagar, Gorimedu
Pondicherry - 605 006, India

Indian Council of Medical Research (ICMR)
V. Ramalingaswami Bhawan
Ansari Nagar
New Delhi - 110029
Tel: 26588895, 26588980, 26589794, 26589336, 26588707
Fax: 26588662, 26588713
E-mail:headquarters@icmr.org.in, icmrhqds@sansad.nic.in

Vallabhbhai Patel Chest Institute
University of Delhi
Delhi – 110007

B. J. Medical College
Ahmedabad

Institute of Pharmacology
Madras Medical College
Chennai – 600003
E-mail: drcbtharani@yahoo.com

JSS College of Pharmacy
Mysore
Karnataka

f)Medical Professionals and Other Individuals

Dr. Amit Sen Gupta
Tel: (011) 26524323

Ms. Padma Prakash
Tel: 022 2781 4436
E-mail: padmaprakash@esocialsciences.com

Mr. Pranay Lal
E-mail: plal@iavi.org, pranaylal@gmail.com

Dr. Raj Vaidya
E-mail: hindupharmacy@gmail.com, pharmhin@sancharnet.in

Dr. Guru Prasad Mohanta
Department of Pharmacy
Annamalai University
E-mail: gpmohanta@hotmail.com

Dr. Gopal Dabade
Drug Action Forum
Karnataka
E-mail: drdabade@sancharnet.in,
drdabade@gmail.com

Dr. Suresh Saravadekar
Chief Pharmacist
J. J. Hospital
Mumbai
E-mail: sureshsaravdekar@rediffmail.com

Mr. Naveen I. Thomas
Community Health Cell
Bangalore
E-mail: navthom@gmail.com

Mr. Amitava Guha
E-mail: guhaamitava_@hotmail.com

Mrs. Manjiri Gharat
Vice-Principal
K.M.Kundnani Pharmacy Polytechnic
E-mail:symghar@yahoo.com

Dr.Nabeel.M.K.
Alliance for Social Health Action
E-mail: drnabeelmk@yahoo.com

Ranbaxy Laboratories Limited
http://www.ranbaxy.com

Dr. Reddy's Laboratories Ltd.
http://www.drreddys.com

Cipla Ltd.
http://www.cipla.com

Sun Pharmaceutical Industries Limited
http://www.sunpharma.com

Ms. Rukshana Zaman
IPEN
E-mail: rukshana@ipen.org.in

Dr. Ravi Saini
AIDS Awareness Group
E-mail: ravisaini@vsnl.com

Prof. B. N. Dhawan
Former Director
Central Drug Research Institute
E-mail: bndhawan@hotmail.com

Mr. Joe Mathew
Pharmabiz
E-mail:joecmathew@gmail.com

g)Pharmaceutical Companies

Aurobindo Pharma
http://www.aurobindo.com

Wockhardt Limited
http://www.wockhardt.com

Zydus Cadila
http://www.zyduscadila.com

Lupin Limited
http://www.lupinworld.com

Nicholas Piramal India Limited
http://www.nicholaspiramal.com

Orchid Chemicals & Pharmaceuticals Limited
http://www.orchidpharma.com

Pfizer Limited
http://www.pfizerindia.com

GlaxoSmithKline
http://www.gsk-ch.in

Annexure II

Sources of Information and Contents

Index to columns:

1 = Drug Composition

2 = Brand and/or Generic names

3 = Price

4 = Dosage

5 = Side Effects

6 = Precautions

7 = Storage

8 = Indications and Contraindications

9 = Expiry Date

10 = Special situations

11 = Alternatives to the drug

12 = Food to be consumed/avoided

Source	1	2	3	4	5	6	7	8	9	10	11	12
Individual doctors: posters						Y						Y
Individual doctors: Newspaper columns		Y		Y	Y	Y		Y		Y		Y
Individual doctors[119]:					Y			Y				
Pharmaceutical companies	Y	Y	Y	Y		Y	Y	Y	Y	Y		Y
Drug Companies	Y	Y										
Ministry of Health & Family Welfare (MoHFW) – National Health Programmes		Y		Y						Y		
MoHFW IEC Resource Centre (ayurvedic treatment)				Y	Y						Y	Y
MoHFW AYUSH Deptt.	Y			Y								Y

[119] Dr. C. Sathyamala, An Epidemiological Review of the Injectable Contraceptive, Depo-Provera (Medico Friend Circle & Forum for Women's Health India) (2001).

MoHFW website						Y						Y
NACO Ads						Y						
NACO online												
Ad by NACO and National Rural Health Mission			Y	(Y)								
Ad by NACO and National Rural Health Mission(Hindi)												
CDSCO		Y		Y		Y						
Drugs Control Department - advertisement												
Ministry of Consumer Affairs												
Ad by Northern Railway in the Indian Express on dengue												
NPPA		Y	Y									
US FDA	Y	Y		Y	Y	Y	Y	Y		Y		
Medline Plus		Y		Y	Y	Y	Y	Y		Y		
NPPA		Y (list of controlled bulk drugs)		Y (for certain scheduled drugs)								
Karnataka State Pharmacy Council (KSPC) website		Y		Y	Y	Y		Y				
KSPC newsletter		Y		Y	Y	Y		Y		Y		
KSPC Handbook for pharmacists		Y		Y	Y	Y	Y	Y		Y		Y
Maharashtra State Pharmacy Council (MSPC): Drug Interactions Manual		Y			Y							Y
MSPC Harmful Drugs in Pregnancy Manual (2006 Edition)		Y			Y	Y		Y		Y		Y
MSPC Drug Information Bulletin (July-Sept 2006)		Y		Y	Y	Y		Y		Y		
LOCOST Book: Lay Person's Guide to Medicines		Y				Y	Y			Y		Y
DSPRUD book: Prof. Usha Gupta and Dr. Sangeeta Sharma, *Use Your Medicines Correctly – A User's Guide*		Y		Y	Y	Y	Y	Y		Y		Y

CPAA	Y				Y							
DNP+	Y	Y		Y	Y			Y		Y		
Drug Action Forum – Karnataka (DAFK): booklet on anaemia	Y	Y	Y	Y				Y				Y
DAFK booklet: Study of Pain Killers Listed in a Commercial Publication for Doctor's Use		Y	Y									
DAFK booklet: Hepatitis B Vaccination Misleading Policy & Promotion												
JIPMER website (Drug Alert newsletter)		Y			Y	Y						
MIMS India book: MIMS India Monthly Index of Medical Specialties	Y	Y	Y	Y	Y	Y		Y		Y		
Indian Drug Review (IDR)	Y	Y	Y	Y	Y	Y		Y		Y		
CHAI – CMAI (Catholic Hospital Association of India and Christian Medical Association of India); Book: CHAI-CMAI Joint Formulary, 1994	Y	Y	Y	Y	Y	Y		Y		Y		
Christian Medical Association of India (CMAI): booklet by the Policy Advocacy group - 'Understanding the Thief Who Comes to Kill and Destroy' (2005)		Y	Y									
CMAI newsletter: *Rational Drugs*		Y		Y		Y		Y		Y		
Medicins Sans Frontiers (MSF): Fact Sheet on Tuberculosis			Y									
MSF booklet: 'ACT NOW for all of the Asia Pacific to get malaria treatment that works' (2004)		Y						Y				
Population Council; International Centre for Reproductive Health et al., *Adherence to Antiretroviral Therapy in Adults – A Guide for Trainers* (booklet)		Y			Y							

WHO book: *Essential Drugs for Primary Health Care – A Manual for Health Care Workers*, SEARO Regional Health Papers No. 16 (WHO, New Delhi, 2000)		Y		Y	Y	Y		Y				
Population Council, UNFPA: Manual on *District Quality Assurance Program for Reproductive Health Services An Operational Manual* (August 2006)												
Population Council website	Y	Y										
Population Council calendar on emergency contraceptive pills		Y			Y							
Population Council brochures /Flyers												
VHAI book: *Banned & Bannable Drugs*	Y	Y	Y					Y		Y	Y	
VHAI booklet: *Dengue and Dengue Haemorrhagic Fever Prevention and Control at Community Level* (2000)		Y				Y						
VHAI booklet: *Arthritis & Joint Pain*(2000)	Y	Y				Y					Y	Y
VHAI booklet: *Better Eye Care* (2003)						Y		Y		Y	Y	Y
VHAI booklet: *Immunization* (2003)		Y	Y	Y	Y	Y	Y	Y		Y		Y
VHAI booklet: *Diabetes* (1997)											Y	Y
VHAI booklet: *Care in Leprosy* (2001)		Y		Y	Y	Y				Y		
VHAI booklet: *Better Care of T.B.* (1998)		Y	Y	Y	Y	Y		Y				Y
VHAI booklet: *Cancer* (1998)											Y	Y
CIMS booklet: *Doxofylline Redefining the Role of Methylxanthin-es in Asthma & COPD* (2006)	Y	Y			Y							
CIMS booklet: *Loratadine in allergic disorders* (2006)	Y	Y			Y	Y		Y		Y		
CIMS booklet: *Biotin the Golden Molecule* (2006)	Y	Y										

Medico Friend Circle book: *In Search of Diagnosis – Analysis of Present System of Health Care*(1985)												
CGSI magazine: *Keemat*		Y			Y	Y		Y		Y		Y
CERC website: test reports												
Consumer VOICE: website												
Consumer Online Foundation: website		Y			Y	Y						
Mumbai Grahak Panchayat: website												
Pharmacy Council of India: website												
Jagori: poster on contraceptives for women (awareness creation)												
Saheli book: *Aapas ki Batein – Garbh Niyantran Suraksha aur Hamara Swasthya*' (1995)		Y	Y		Y	Y		Y				
IPA: Indian Journal of Pharma-ceutical Sciences												
IPA: Pharma Times (news magazine)												
IPA publication: *Guiding Principles for Pharmacists HIV/AIDS in India*		Y	Y	Y	Y	Y	Y	Y		Y		Y
ICMR journal: Indian Journal of Medical Research												
Websites		Y		Y	Y	Y	Y	Y		Y		Y

Annexure III

Schedule to the Drugs and Magic Remedies (Objectionable Advertisements) Act

The following is the Schedule to the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, listing the diseases, disorders or conditions for which drug advertisements shall not be made [See Sections 3(d) and 14]

S.No.	Name of the disease, disorder or condition
1.	Appendicitis
2.	Arteriosclerosis
3.	Blindness
4.	Blood poisoning
5.	Bright's disease
6.	Cancer
7.	Cataract
8.	Deafness
9.	Diabetes
10.	Diseases and disorders of the brain
11.	Diseases and disorders of the optical system
12.	Diseases and disorders of the uterus
13.	Disorders or menstrual flow
14.	Disorders of the nervous system
15.	Disorders of the prostatic gland
16.	Dropsy
17.	Epilepsy
18.	Female diseases (in general)
19.	Fevers (in general)
20.	Fits
21.	Forms and structure of the female bust
22.	Gall stones, kidney stones and bladder stones
23.	Gangrene
24.	Glaucoma
25.	Goitre
26.	Heart diseases
27.	High or low blood pressure
28.	Hydrocele
29.	Hysteria
30.	Infantile paralysis
31.	Insanity
32.	Leprosy
33.	Lecuoderma
34.	Lockjaw
35.	Locomotor atoxia
36.	Lupus
37.	Nervous debility
38.	Obesity
39.	Paralysis
40.	Plague
41.	Pleurisy
42.	Pneumonia
43.	Rheumatism
44.	Ruptures
45.	Sexual impotence
46.	Small pox
47.	Stature of persons
48.	Sterility in women
49.	Trachoma
50.	Tuberculosis
51.	Tumours
52.	Typhoid fever
54.	Venereal diseases, including syphilis, gonorrhoea, soft chancre, venereal, granulima and lympho granuloma

Annexure IV

Emerging Issues

a)Parameters for Evaluating Online Information

With an increasing amount of drug information and services for diagnosis and buying drugs being made available online, consumers need to be educated about the risks of online information and need to be guided about making the correct choices.

The dangers in buying products over the internet include:[120]

- Safety and efficacy assurance may be lacking
- Instructions for use may be inadequate
- Quality may not be assured
- Products may circumvent regulatory protections
- Products may be fraudulent and harmful to your health
- Reimbursement may not be possible
- Products bought across borders may not be allowed in your country
- Products with the same name may be different in different countries

The US Food and Drug Administration (FDA) has also come up with a consumer safety guide in which the dangers of buying medicines online are stressed, and tips are given for consumers to protect themselves against these. For instance it is cautioned that[121]:

- Some websites that sell medicines are not licensed pharmacies or are not pharmacies at all
- These websites may give a diagnosis that is not correct and sell medicine that is not right for the patient
- The website may not protect the patient's personal information
- The medicines sold may be: counterfeit, too strong or too weak, have dangerous ingredients, have expired, are not approved by regulatory authorities, are not safe for use with other medicines or products being used by the patient, are not labelled, stored or shipped correctly.

The WHO has brought out guidelines on medical products and the internet[122] meant as a model for States to adopt for advising internet users to obtain "reliable, independent and comparable information on medicinal products".[123] These guidelines are available at *http://whqlibdoc.who.int/hq/1999/WHO_EDM_QSM_99.4.pdf*. The guidelines emphasise that the information available on the internet cannot replace consultation with the patient's healthcare provider, and such information is useful only when the patient has consulted their doctor. It is also stated that even information from reliable sources may require special training in order to evaluate it properly and to determine whether the information applies to the patient's disease or condition. The source of information available on the internet should be verified before it is used. Caution is advised with respect to buying medical products over the internet, and it is advised that legitimate distribution channels such as pharmacies should be used. The dangers of buying products over the internet are also pointed out such as: safety

[120] "Buying Prescription Medicine Online: A Consumer Safety Guide", U.S. Food and Drug Administration Centre for Drug Evaluation and Research, www.fda.gov.
[121] Id.
[122] "Medical Products and the Internet: A Guide to Finding Reliable Information", World Health Organization Geneva 1999, WHO/EDM/QSM/99.4. See: http://whqlibdoc.who.int/hq/1999/WHO_EDM_QSM_99.4.pdf.
[123] "Medical Products and the Internet: A Guide to Finding Reliable Information", World Health Organization Geneva 1999, WHO/EDM/QSM/99.4. See: http://whqlibdoc.who.int/hq/1999/WHO_EDM_QSM_99.4.pdf.

and efficacy assurance may be lacking; instructions for use may be inadequate; quality may not be assured; products sold through the internet may circumvent regulatory protections provided by health authorities and the government; reimbursement may not be possible; money and time may be wasted by seeking treatment over the internet as the treatments may not work; products brought over the internet may not be allowed into the country; the purchaser's personal information may not remain confidential.[124]

The guidelines give examples of the type of information being provided on websites. For instance, the topics covered include: research being conducted on a particular disease or condition; new product approvals by health authorities in national jurisdictions; general information about diseases or conditions (e.g. high blood pressure, arthritis); support groups for people with certain diseases or conditions; lists of organisations that provide support and information for a disease or condition.[125] The guidelines suggest that health authorities and organisations in each country should provide a list of sites with links to reliable sources of health and medical information. They also mention particular organisations as private organisations involved in recommending ways of ensuring the quality of information on the internet, namely the *Health on the Net Foundation*[126] and the *Internet Healthcare Coalition*[127].

The guidelines include:

Checking for the following information on the website[128]:

- Name and contact address of the website owner
- Stating which organisations contribute funding, services or other support to the website
- If advertising or sponsorship is a source of funding, is this clearly stated?
- Is this a site for consumers, health professionals, or some other audience?
- When was the information displayed last updated?

The WHO Guidelines suggest some practical ways to see whether the medical information on the products listed on the website is true or not by looking out for the following warning signs[129]:

- Advertisements or information that use phrases such as *scientific breakthrough, miraculous cure, exclusive product, secret formula, ancient ingredient, without risk, anti-ageing, improve sexual performance,* and *all natural;*
- Case histories from cured customers claiming amazing results
- A list of symptoms and diseases it claimed the product cures
- Claims that the product is available from only one source for a limited time
- Testimonials from *famous* medical experts
- Claims of *no risk* or lack of any risk information
- Claims that a product is *scientifically proven and absolutely safe*

Other guidelines to consumers include:[130]

- Consumers should find out whether selling and buying products from another country over the internet is illegal in that country.

[124] "Medical Products and the Internet: A Guide to Finding Reliable Information", World Health Organization Geneva 1999, WHO/EDM/QSM/99.4. See: http://whqlibdoc.who.int/hq/1999/WHO_EDM_QSM_99.4.pdf.
[125] "Medical Products and the Internet: A Guide to Finding Reliable Information", World Health Organization Geneva 1999, WHO/EDM/QSM/99.4. See: http://whqlibdoc.who.int/hq/1999/WHO_EDM_QSM_99.4.pdf.
[126] http://www.hon.ch.
[127] http://www.ihc.net.
[128] "Medical Products and the Internet: A Guide to Finding Reliable Information", World Health Organization Geneva 1999, WHO/EDM/QSM/99.4. See: http://whqlibdoc.who.int/hq/1999/WHO_EDM_QSM_99.4.pdf.
[129] "Medical Products and the Internet: A Guide to Finding Reliable Information", World Health Organization Geneva 1999, WHO/EDM/QSM/99.4. See: http://whqlibdoc.who.int/hq/1999/WHO_EDM_QSM_99.4.pdf. Organization Geneva 1999, WHO/EDM/QSM/99.4. See: http://whqlibdoc.who.int/hq/1999/WHO_EDM_QSM_99.4.pdf.
[130] "Medical Products and the Internet: A Guide to Finding Reliable Information", World Health

- While searching for information consumers should look for the International Nonproprietary Name (INN) as products with the same name may contain different ingredients in different countries.
- Product information should include: product name; active ingredient(s); name of other ingredients known to cause problems to some people; what to use the product for; situations when the product should not be used; how to use the product; possible undesired effects; how to store the product; manufacturer's name and contact information; last update of the information.

The tips given by the US FDA to patients to ensure their safety are:

- Talking with your doctor and having a physical exam before getting any new medicine for the first time
- Use only medicine that has been prescribed by your doctor or another trusted professional who is licensed in the US to write prescriptions for medicine
- Ask your doctor if there are any special steps you need to take to fill your prescription
- Make sure the website is of a licensed pharmacy
- The website has a licensed pharmacist to answer any questions
- The website should require a prescription from your doctor or other healthcare professional who is licensed in the US to write prescriptions for medicine
- The website should have a way for you to talk to a person if you have problems
- The patient should make sure their privacy is protected by checking for privacy and security policies, not giving personal information, making sure the site will not sell the patient's information and so on.

The 'Health On the Net Foundation' has established a HON Code of Conduct (HONcode) for medical and health websites. This Code is intended for webmasters, information providers, or other persons responsible for a site that is applying for HONcode accreditation. The principles as per this code are:[131]

1. Authority

Any medical or health advice provided and hosted on this site will only be given by medically trained and qualified professionals unless a clear statement is made that a piece of advice offered is from a non-medically qualified individual or organisation.

2. Complementarity

The information provided on this site is designed to support, not replace, the relationship that exists between a patient/site visitor and his/her existing physician.

3. Confidentiality

Confidentiality of data relating to individual patients and visitors to a medical/health website, including their identity, is respected by this website. The website owners undertake to honour or exceed the legal requirements of medical/health information privacy that apply in the country and state where the website and mirror sites are located.

4. Attribution

Where appropriate, information contained on this site will be supported by clear references to source data and, where possible, have specific HTML links to that data. The date when a clinical page was last modified will be clearly displayed (e.g. at the bottom of the page).

[131] http://www.hon.ch

5. Justifiability

Any claims relating to the benefits/performance of a specific treatment, commercial product or service will be supported by appropriate, balanced evidence in the manner outlined above in Principle 4.

6. Transparency of authorship

The designers of this website will seek to provide information in the clearest possible manner and provide contact addresses for visitors that seek further information or support. The webmaster will display his/her E-mail address clearly throughout the website.

7. Transparency of sponsorship

Support for this website will be clearly identified, including the identities of commercial and non-commercial organisations that have contributed funding, services or material for the site.

8. Honesty in advertising and editorial policy

If advertising is a source of funding it will be clearly stated. A brief description of the advertising policy adopted by the website owners will be displayed on the site. Advertising and other promotional material will be presented to viewers in a manner and context that facilitates differentiation between it and the original material created by the institution operating the site.

b)An Analysis of Information Provided on the Internet

i)Websites with information on drug products

There are different categories of websites marketing and prescribing drugs to consumers. The first category delivers medicines after first obtaining a valid prescription, while the second category is prescribing-based sites, i.e. they have a physician in their panel who initiates the prescription, getting a commission of sales. The third category is online drug shops, which are not concerned with prescriptions and other issues. A variety of prescription and non-prescription drugs can be obtained from these sites.[132] There are also sites providing information from the perspective of creating awareness and educating consumers about drugs, even though there is no online marketing of drugs on these sites. On a number of sites, information is directed to medical professionals and not consumers.

Apart from the websites seen in the course of this project, there have been a few surveys conducted to analyse the phenomenon of cyber pharmacies. For instance, in an article published in 2003 in the BMJ, discussing the results of a survey done on buying medicines via the internet, it was noted that of 104 e-pharmacies from at least 13 different countries, 63 websites provided some health information but overall the quality of the information was poor. Only three website operators provided adequate advice to consumers to avoid a potential drug interaction. It was concluded that consumers who self-select medicines from websites have insufficient access to information and advice at the point of ordering and on delivery to make informed decisions about their safe and appropriate use.[133]

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[132] Dr. Vinod Scaria, "Cyber-pharmacies and emerging concerns on marketing drugs online", OJHAS: Vol. 2, Issue 2: (2003 Apr-Jun), http://ojhas.org/issue6/2003-2-1.htm.

[133] T. L. Bessell, J. N. Anderson, C. A. Silagy, L. N. Sansom and J. E. Hiller, "Surfing, self-medicating and safety: buying non-prescription and complementary medicines via the internet", Qual Saf Health Care 2003; 12 :88-92, http://qhc.bmjjournals.com/cgi/content/abstract/12/2/88.

[134] See: Vinod Scaria, "Buying Sildenafil Citrate (Viagra®) Online: Are prospective buyers informed of Contraindications? www.calicutmedicaljournal.org. Here a survey was done of websites selling the drug Sildenafil citrate (Viagra®), which is one of the most widely advertised drugs on the internet. The study is aimed at assessing the extent to which information is provided to prospective customers who visit the website before actually buying the drug. 100 top scoring URLs were analysed and cyber pharmacies that actually sold the drug were analysed. 43 websites were identified and analysed, out of which 32 websites provided information that the drug was con traindicated in people taking Nitrates, while only 7 provided information that it was contraindicated in women and 6 websites provided information that the drug was not to be used in children. Out of the websites that provided information that taking Nitrates was a contraindication, 8 websites provided vital information that 'poppers' contained nitrates. The conclusion taken was that though most of the websites provided information on contraindications, the information was often incomplete.

Similar findings have been made in other such surveys as well.[134]

Among the websites seen in the course of this project, a useful and authoritative site was http://www.hon.ch set up by the 'Health On the Net Foundation' (HON). The site describes itself as 'a non-commercial overview of health resources on the net, with guidelines for content' and as 'one of the very first URLs to guide both lay users and medical professionals to reliable sources of healthcare information in cyberspace'. As seen earlier, HON has developed certain principles, which must be abided by before a site can get approval from HON.

The HON website itself has named certain drugs for different medical conditions, but these are not described in detail in terms of dosage, side effects, and so on. However, each of the names of the drugs are links in themselves; in some of which details are given regarding the ongoing testing and trials of the drugs or the results of tests using these drugs.

With respect to sites that did provide information on health and medicines, in some, clear disclaimers were given. For instance for the site, http://www.diagnosishealth.com, it was clearly stated that the site must not be used for the diagnosis or treatment of a disease or disorder. It was clarified that the site was meant for educational and discussion purposes only. The information provided would not substitute for medical consultation and it was clearly mentioned that only the doctor is the best person who can give the patient medical advice. In addition, it was stated that the site does not accept any responsibility or liability for information on the site or its use/misuse. It was also pointed out that inclusion of information on this site does not imply any endorsement for a particular organisation, products and/or persons and their work.

It can be inferred that such disclaimers work to the benefit of both the consumer or browser and the site-owner. Consumers are clearly warned that the information provided is only for furthering their own understanding and that they must not act upon information without consulting their doctor. For the site-owner and also those who put their content on the site, the disclaimer has the function of exempting them from any liability and clarifies their role in merely providing information for educational and awareness-creation purposes only.

In other sites, specific information is provided. For instance in the site, http://www.doctorndtv.com, information on drugs is provided under the following categories: list of reputed pharmaceutical companies; list of discarded drugs; list of irrational combinations; lists and description of single-ingredient drugs (generic names) and of multi-ingredient drugs (brand names). With respect to single-ingredient drugs, information is given under the following heads: brand names; available as (eg. tablet, etc); uses (eg. glaucoma, epilepsy); side effects; conditions in which it is to be used with care; conditions where it is not used.

With respect to multi-ingredient drugs (brand names), information is given under the following headings: composition; uses; side effects; conditions in which it is to be used with care; conditions where it is not used. The site also points to other sources of information, such as the MIMS database on drugs being sold in India. This site too advises that medicines should be taken only as directed by the doctor and cautions that self-prescription can be dangerous. It also cautions that although by law manufacturers and drug stores are obliged to give a product information leaflet with the purchase of every medicine, in practice, this not being done.

In the site, http://www.healthlibrary.com, which describes itself as India's largest consumer health library for patients as well as doctors, there was also a section which provided the service of researching the user's (i.e. patient's) topic and providing customised and detailed health information. Here too there was a disclaimer stating that the purpose of this site was to provide information so that patients and their doctors can make informed decisions. It was described that this system of retrieving information for the patient would be

more beneficial than searches performed by laypersons, as here the search would be done by a trained and experienced information researcher.

It is to be noted that this site mentions the provision of information on topics that are not usually stressed upon in other sites such as: leading researchers, recent advances, support groups, mailing lists, and newsgroups. Although all of this may not relate directly to medicines, it is useful in terms of educating the patient and providing a continuous and updated channel of information. It is suggested that these aspects of information be provided on other sites as well.

In some sites, though there is provision for the public to post queries about medical conditions, and responses are provided to these, what it is not mentioned is who is giving these responses. Thus it cannot be determined whether the responses are being given by qualified and authentic sources. This was the case in sites such as http://www.indmedica.com (although it is to be noted that the site is directed to professionals and not consumers).

In some sites it was noticed that there was strong support for the site through advertisements put out by companies for their medical products. For instance in http://www.medicalonline.com, a non-Indian URL, the site advertised an offering of allowing medical products companies to list their business and products online for free, for a limited time. In order to do this details would have to be disclosed by the company about itself, through the filling of an online form requiring details such as contact information, website, product listing, and so on of the company. This in itself could act as a check to make sure that the company and the information it was providing was authentic. However the fact of product advertisements, as well as the fact that in the site's section on 'Product Categories', links are often given to various companies; could raise doubts regarding the objectivity of the information provided with respect to drug products.

Sites such as http://www.medguideindia.com provided the following information on a number of drugs: brand name, generic name, company manufacturing the medicine, form in which the medicine was available (e.g. tablet), quantity and measurement according to which the medicine was available, active ingredients, and price. Drugs are classified according to either the brand name or generic name. Where the generic drug was described, the information was displayed as a comparative chart showing the different brands under which the drug was marketed and for each brand, the information as described above was available, including information on prices.

Well-known sites include the sites of the US FDA, the British National Formulary[135] (BNF) and Medline Plus (a service of the US National Library of Medicine and the National Institutes of Health). The US FDA site, which is targeted to consumers and specifically to medical professionals, has been discussed earlier in this paper. The online information provided by the BNF includes the entire content of the BNF, which is targeted at healthcare professionals such as doctors and pharmacists. The information includes information on labels for dispensed medicines, the BNF procedure for constructing non-proprietary names for medicinal products, name changes and an index of manufacturers. For instance in the context of labelling, the BNF advises that pharmacists counsel patients when necessary about the labelling and the usage of the drug. Such counselling should be related to the age, experience, background and understanding of the individual patient. Specific points to be discussed include the effects of the medicine, foods to be avoided, what to do if a dose is missed, specific methods or times of administration, and so on.[136] The site gives guidance

[135] http://www.bnf.org

[136] *Cautionary and advisory labels for dispensed medicines,* http://www.bnf.org/bnf/extra/current/450051.htm.

to pharmacists for putting labels on drugs and for counselling patients. Medline Plus[137] provides information to consumers on drugs. Information is organised in terms of the generic or brand name for each drug. For each drug, information is provided on why the medication is prescribed, how it should be used, other uses for the medicine, special precautions, special dietary instructions, side effects, storage conditions, what do in case of an emergency/overdose, brand names and advice to patients to consult their doctors and pharmacists. The information is thus specifically targeted to consumers and is provided in a concise and easy to understand manner.

ii)US FDA website

The website of the US FDA is useful in terms of both the content and format in which information is provided to consumers. It is suggested that the website can be a useful reference point for developing a similar website by Indian authorities. The site has a separate section on 'FDA Information for Consumers' where the topics range from information on specific diseases and medical conditions, specific drugs, adverse reaction reporting, links to consumer publications, drug interactions, guidelines for usage of various devices and tests, guidelines for buying medicines online, and so on.[138] Through the comprehensive information provided on a range of drug-related topics for consumers, the FDA site represents a comprehensive source of information for consumers. The FDA has also proposed to undertake more initiatives for improving healthcare through better information to consumers. It envisages doing this through measures such as encouraging better guidance to patients in pharmacy labels, giving clearer guidance on communicating risk and benefit information in direct-to-consumer advertising, launching new enforcement initiatives against dietary supplement manufacturers who make health claims without scientific foundation.[139] Even in the opinion of medical professionals, the FDA website is more comprehensive than the Indian sources of information. There is a section for consumers and even if information cannot be located in this section, it can be looked up in the 'doctors page'.[140]

The FDA site also provides a useful illustration of what information all non-prescription, over-the-counter drug labels must contain. This includes information under the heads of active ingredient, purpose, uses, warnings, side effects, highlighting special conditions (eg. pregnancy) when a health professional should be consulted before using the drug, directions for dosage, storage, and inactive ingredients. The information provided is brief and in simple language so that it can be easily understood by the consumer.[141]The regulatory roles of the FDA for fulfilling these objectives are through ensuring that information supplied by the product's sponsors is accurate and through directly communicating information to the public.[142]

[137] http://www.nlm.nih.gov/medlineplus/druginformation.html.
[138] http://www.fda.gov/opacom/morecons.html
[139] http://www.fda.gov/oc/mcclellan/strategic_consumer.html
[140] Interview with Dr. Anant Phadke.
[141] http://www.fda.gov/oc/mcclellan/strategic_consumer.html.
[142] http://www.fda.gov/oc/mcclellan/strategic_consumer.html.

Annexure V

Guidelines for Information on Traditional Medicines

The World Health Assembly Resolution on Traditional Medicine in 2003 urged Member States of the WHO to provide reliable information on traditional medicine (TM) and complementary and alternative medicine (CAM) to consumers and providers in order to promote proper use.[143]

The WHO has provided a checklist of basic questions, which may be used by consumers to help facilitate proper use of TM/CAM:[144]

- Is the therapy suitable for treating the condition?
- Does the therapy have the potential to prevent, alleviate and/or cure symptoms or in other ways contribute to improved health and well-being?
- Is the therapy or herbal medicines provided by a qualified (preferably registered and certified) TM/CAM or healthcare practitioner with adequate training background, good skills and knowledge?
- Are the herbal medicinal products or materials of assured quality and what are the contraindications and precautions?
- Are the therapies or herbal medicinal products available at a competitive price?

A model for guidelines to be used for developing consumer information and also for highlighting consumers the important factors to be considered by them is as follows[145]:

1. General information

- Being an informed consumer
- Informing healthcare providers and TM/CAM practitioners about therapies being used
- Engaging qualified TM/CAM practitioners and utilising quality assured TM/CAM medication therapies
- Where relevant, information regarding health insurance coverage

2. Where to find reliable information

- Institutions and authorities representing TM/CAM and/or conventional medicine
- Registered TM/CAM providers, conventional healthcare providers
- Certain publications and websites

3. How to identify reliable information

- Purpose
- Relevance/accuracy
- Sources
- Updated information
- Objectivity

4. TM/CAM medication therapies

- Therapeutic claims and corresponding level of evidence
- Quality
- Precautions

[143] Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine (World Health Organization, Geneva, 2004) at v.

[144] Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine (World Health Organization, Geneva, 2004) at 6.

[145] Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine (World Health Organization, Geneva, 2004) at 29.

- Adverse events
- Potent and/or toxic therapies
- Interactions and contraindications
- Methods of administration
- Self-medication
- Preparation
- Children, pregnant or lactating women and the elderly

5. Procedure-based therapies

- Therapeutic claims and corresponding level of evidence
- Precautions

6. Practitioners

- How to identify qualified practitioners
- Certification of practitioners
- Surveillance system for malpractice

7. Pricing/health insurance coverage

- Where to access information about standard charges and health insurance coverage

Regarding the dissemination of information in a manner ensuring its greatest reach, WHO has proposed that the information provided should be in plain and simple language, if possible in each of the main languages spoken in country and with alternative forms for those unable to access the written form. Also to ensure that information is both accessible and understandable, it needs to be presented within a variety of ways and through different activities.[146]

[146] Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine (World Health Organization, Geneva, 2004) at 18.

Annexure VI

Detailed Description of Information Examined

In this section, a detailed description has been given of the information seen from various sources. The information has been arranged according to the source of information, i.e. the organisation providing the information.

a)Publications by the Karnataka and Maharashtra State Pharmacy Councils

The Karnataka State Pharmacy Council (KSPC) and Maharashtra State Pharmacy Council (MSPC) have brought out published materials through their respective Drug Information Centres (DICs), for the benefit of pharmacists.

The printed material brought out by the KSPC DIC includes newsletters and handbooks for pharmacists.[147]

The information provided in the newsletter included updates and news on vaccines, drugs and treatments, specific and detailed information on particular diseases chosen for that newsletter, investigational drugs, dispensing instructions to pharmacists, FAQs, websites of interest, and so on. It also provided detailed information on particular drugs covering topics such as drug category, what government approvals the drug has obtained and in which countries, indications, dosage, contraindications, precautions, adverse effects, mechanism of action, and so on.

With respect to the handbooks, at the outset it is stated that the book is an educational supplement to the pharmacist and other healthcare professionals and is not intended to replace the physician's decision. The publications include advice to the pharmacist on what to instruct the patient. There are also general instructions that can be given straight to patients, such as relating to storage of the medicine; dosage and what to do in case of missed doses; checking the expiry date, and so on.

Although the information was specific and often technical it was presented in a manner that would be comprehendible to even laypersons. Also though the information was not addressed particularly to consumers, the value of this information impacts them as pharmacists and others in the medical profession rely on these sources while handling and counselling on the medical conditions of their patients. Thus indirectly this information has the same effect. In fact it may have even a greater impact on patients than information they themselves seek since in the former case, the patients would feel that information is being provided by a more authentic source by a person who knows their medical condition best, i.e. the doctor or pharmacist.

Similar published materials were also seen of the MSPC.[148] The MSPC described the aim of its DIC as helping pharmacists, drug regulators, doctors and the common man get in-depth and focused drug information thus improving patient compliance. The type of information provided by them is on subjects

[147] "Handbook of Pharma SOS", (P.K. Lakshmi editor, 2nd edn., 2005); "Drugs Usage in Special Population – Paediatrics and Geriatrics", (KSPC Educational Series II, 1st edn., 2004); "Drugs Usage in Special Population – Pregnancy and Lactation", (KSPC Educational Series I, P.K. Lakshmi Editor, 1st edn., 2004); and "Pharmacist for Tobacco free Future", (KSPC Educational Series IV, P. S. Bhagavan Editor, 1st edn., 2005).

[148] The materials seen included the following: Maharashtra State Pharmacy Council Drug Information Bulletin, July – Sept. 2006; Drug Interactions Manual (2006 Edition) (English), Drugs Harmful in Pregnancy Manual (2006 Edition) (English),

of safety, efficacy, contraindications, dosage of drugs and information assisting pharmacists in updating on new drugs emerging at international level in different therapeutic areas. The MSPC has described its source of information as mainly internationally reputed databases (Micromedex's Drugdex, USA).

Similar information was observed in the MSPC and KSPC publications. In the MSPC bulletin[149] there was also an article on retail price and labelling requirements. In the bulleting, information was provided in both English and Marathi. The articles are short and in a simple language. Thus the aim is to create awareness among consumers of drugs.

In addition we also received flyers in Marathi on warnings on tobacco and gutka, information on hypertension, asthma, cancer, anemia, dengue, diabetes, AIDS, and so on. There were also posters in English and Marathi giving information on the MSPC's Drug Information Centre and welcoming drug-related queries.

b)Information Provided by Consumer Groups

One of the consumer organisations whose materials were examined was the Consumer Guidance Society of India (CGSI). The CGSI brings out a magazine, *Keemat*, which is available online as well. The volumes of *Keemat* include information on drugs, under topics such as what the drug is used for; information that the doctor must know about the patient before prescribing it; cautions in using the drugs; guidelines for safe usage of the drug; reported interactions with other drugs; and adverse effects.[150]

Some consumer organisations are involved in testing of products. For instance, the Consumer Education and Research Centre (CERC) conducts product testing on food products, pharmaceuticals, and electrical appliances. CERC has made available online its key findings on certain drugs from tests conducted by its laboratory. The testing on pharmaceutical products includes tests on national brands and generics. The results show key findings on both technical aspects as well as observations relating to whether information pertaining to dosage, storage, and labelling was provided. However this information is more technical in nature and thus would be more useful for medical professionals rather than patients.

An example of the tests done by CERC include a study of labels of 18 ayurvedic medicines made in India. It was found that none of these widely sold products declared on their labels the presence of heavy metals that they contained according to a study (based on testing) published in the Journal of the American Medical Association (JAMA) and testing by Health Canada, the Canadian government's health department. As per Rule 161 of the Drugs and Cosmetics Rules, medicines containing poisonous substances like mercury, arsenic and red oxide of lead have to carry a warning. It as found that only four of the products studied carried this warning. Follow-up action taken by CERC has brought these violations to the notice of regulatory authorities such as the Department of AYUSH (Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy) through the Ministry of Consumer Affairs, Government of India.

c)Information Provided by Health Organisations and NGOs

i)Publications by the Voluntary Health Association of India (VHAI)

The VHAI has brought out a publication, *Banned & Bannable Drugs*[151] in which specific information

[149] Maharashtra State Pharmacy Council Drug Information Bulletin, July – Sept. 2006.
[150] "Keemat", Vol. 35 Issue No. 7, July 2006, Consumer Guidance Society of India.
[151] Dr. Mira Shiva and Dr. Wishvas Rane, "Banned & Bannable Drugs *Unbiased Drug Information Essential Drugs and Rational Drug Policy"*, (Voluntary Health Association of India, New Delhi, 2004).

on medicines is provided apart from raising public awareness on aspects of a rational drug policy.

Regarding awareness creation on issues of rational drugs, there is information on topics such as when a banned drug would not be banned. The instances include: when the government decides to lift the ban, when the ban is diluted so as to leave out some drugs, when the ban in ambiguously worded, and so on. This would have practical value for consumers as it highlights important considerations for consumer safety while using drugs. The book also explains consumers what the schedules given in the Drugs & Cosmetics Act 1940, and Cosmetics Act 1945 are about.

With respect to specific information on drugs, the book gives details of banned drugs and drugs which should be banned. Here details are given on drug names, reason for banning, uses of the drug, countries where it is banned, and safer alternatives to the drug. The book also has case studies on particular drugs or classes of drugs, creating awareness about the same and discussing details such as when the drug in contraindicated. The information is brief and explained in a simple language.

The book's discussion on 'Hazardous and Irrational Drugs' is designed to educate consumers about the basics of drug use and prescription, creating awareness of what may be considered technical, medical, and scientific issues, in a simple language. Issues of dangerous drug combinations are discussed which is illustrated with a list of some of the fixed dose combinations of questionable rationality.

In the section on 'Drugs not to be Used by Pregnant and Breast feeding Mothers', a table is given of drugs that are avoided or used with caution during pregnancy in terms of in which trimesters of pregnancy the drug should be avoided or can be taken with caution. Brief comments are also given regarding warnings about the drug and possible impacts of the drug. Similar information is given regarding drugs consumed during lactation. The information is specific and easy to understand.

The publication goes on to discuss issues of drug pricing and in this price comparisons are provided between different brands and companies, comparisons of generic medicines prices and other retails prices, and so on. Apart from issues of general concerns and specific information on drugs, the book also gives contact details for different drug control organisations, and publications on relevant topics relating to drugs, brought out by different groups. This has the effect of furthering the cause of creating consumer awareness.

In another publication by VHAI[152], the issue of drug package labelling is discussed. It is emphasised that package inserts must carry unbiased information and cautions for consumers such as according to pregnancy and age and that information about serious potential side effects must be made available in a comprehensive language that people of the area can understand.

ii)Publications by LOCOST

Low Cost Standard Therapeutics (LOCOST) has recently published a book *A Lay Person's Guide to Medicines*, which is a guide for consumers on the use of pharmaceutical drugs and also is about the political economy of the pharmaceutical industry. The drug details given include drug classification, forms of drugs and administration, drug action and effects, drug dependence, drug storage and poisoning, drug interactions with food, alcohol and dangerous drug interactions as well as special considerations in drug usage in special circumstances (eg. pregnancy) and categories such as by children and the elderly. It guides patients on the management of drug treatment with their doctors and suggests precautions to be taken while on drug therapy. Information is given on combinations of drugs, as

[152] Mira Shiva, "Medicines, Medical Care and Drug Policy", (Voluntary Health Association of India, New Delhi, 2000).

well as pointing out which combinations are irrational, with a list of combination drugs that are hazardous.

There is also a discussion on the action that needs to be taken by consumers themselves. For instance it advises points which patients must discuss with their doctors, such as:

- Drugs being taken already
- If patient is pregnant or intending to become pregnant
- If patient is breast feeding
- If the patient has had in the past any specific health problem such as liver or kidney disease or any other severe disease/disorder
- If patient has to undergo any kind of surgery in the near future
- If the patient is on any kind of special diet, eg. low sugar or low salt
- If patient has had any allergic reactions to any past treatment.

There are also specific points which women patients are advised to discuss with doctors, as it is emphasised that drugs affect women differently from men. These points included:

- Is the drug really necessary?
- Are there any non-drug alternatives?
- What are the benefits of the drug?
- What are the common, rare and serious side effects of this medicine?
- How is it likely to affect pregnancy and lactation?
- Will it interfere with any contraceptive method being used?
- Are there any safer alternatives to the drug?
- Can a small overdose, such as an extra pill, be dangerous?
- Can the prescription interfere with other medications being taken?
- Does the drug have any serious interactions with other drugs or with a large number of other medications?
- Are there any known or suspected long-term effects of this drug?
- Does the drug require laboratory monitoring to ensure that I (patient) am not being harmed?
- If any side effects are experienced these should be reported to a doctor.

The book gives detailed profiles on 50 of the more commonly used medicines. The information given includes the drug group; principal uses; how the drug works; dosage and usage information; precautions; possible adverse effects; interactions; and effects of long-term use. Briefer information on some 100 other commonly used medicines is also given in a simple style. Regarding precautions, drawings are used as symbols (eg. drawing of a small child for symbolising 'infants and children'). This makes for easy comprehension by the patients.

The book also gives references and links to sources of information, such as pharmaceutical website links; pharma business; US FDA and EU-related; TRIPS/WTO/IPR; guidelines; medical journals, and so on.

The book thus manages to combine awareness creation on general issues regarding rational drugs and the state of play in the pharmaceutical sector today vis-à-vis patients, practical guidelines for consumers to follow, as well as technical details of drugs and combinations which can be understood by patients. It is suggested that this can be used as a model for development of consumer drug information.

iii)Information provided by the Christian Medical Association of India (CMAI)

The Christian Medical Association of India (CMAI) is an association and fellowship of doctors, nurses, administrators, chaplains and allied health professionals and its work includes providing nursing, diagnostic, and other healthcare services.

Its publications include the *CHAI-CMAI Joint Formulary,*[153] which is aimed at sensitising health professionals as well as the public about the dangers of irrational drug use. The information seems not to be directed to consumers directly but to medical professionals and organisations who would be in a position of providing such information to consumers.

Technical information is given as well as general guidelines such as how to choose a particular drug, procedures for reducing adverse drug reactions, prescribing drugs, dispensing medicines, storage of medicines, and so on.

iv)Publication by the Delhi Society for Promotion of Rational Use of Drugs

The Delhi Society for the Promotion of Rational Use of Drugs (DSPRUD) was formed in 1996 to implement the programme of rational use of drugs in India.[154] Among the materials distributed by DSPRUD is the *DSPRUD Medical Newsletter*, initially released in July 1999, and which has the objective of providing unbiased and updated information on therapeutics and drugs to doctors. The newsletter is distributed also to all the Delhi government hospitals. In addition to this newsletter, *Standard Treatment Guidelines for Primary Healthcare in Delhi* and the *Delhi State Formulary* have been published to provide objective information to doctors.[155]

DSPRUD has also brought out a booklet,[156] which has been compiled and published with the support of India-WHO Essential Drugs Programme. The booklet emphasises that knowledge of patients of drugs is a key component of any rational use of drugs programme. The information provided in the booklet includes the purpose of the medication, the dose, the frequency of drug administration, duration of treatment, precautions, guidelines to deal with side effects, how to withdraw, cautions regarding storage, and so on. Advice on drug devices and techniques has also been given, such as guidelines for using inhalers, along with diagrams for the same. Some commonly occurring problems encountered during the treatment have been incorporated. The booklet describes 52 medicines/drugs, each being described in about a page in Hindi and English.

v)Publications by Drug Action Forum – Karnataka

The Drug Action Forum – Karnataka is a non-governmental organisation campaigning for rational drug therapy and policies. A description of some sample publications is given below.

1. "Study of Pain Killers – (Analgesics & Antipyretics and NSAIDS) Listed in a Commercial Publication for Doctor's Use" (by Dr. Gopal Dabade, Drug Action Forum - Karnataka)

The study is an attempt to bring to the notice of consumer action groups the type of painkillers that are available for a doctor to prescribe to the patient. The questions for consideration are whether the drugs promoted to doctors are from the list of essential drugs by WHO, whether the drugs are scientific, and whether the pricing of drugs are justified.

The study is mainly under two heads:

i. Rationality: Does the drug listed in the commercial publication (MIMS), match with the Essential Drug list by WHO? Is the drug rational?

ii. The drug prices – Comparing the essential drug prices set by different companies.

To assess whether the drug was essential and rational, the following publications were used:

1. WHO Model List of Essential Drugs 2003: The list was first published in 1977. It contains about 375 drugs in 500 formulations. Essential Drugs should be the drugs of first choice. All 235 drugs in this study were checked to see whether they are included as essential drugs or not.

[153] "CHAI-CMAI Joint Formulary 1994" (2nd edn., 1994).

2. Monthly Index of Medical Specialities (MIMS): totally 235 formulations from here were scrutinised with reference to the World Health Organization (WHO) Model List and a standard textbook of pharmacology.
3. Goodman & Gilman's "The Pharmacological Basis of Therapeutics". This is a standard textbook of pharmacology.

The criteria for rational drugs in the study were taken as: (1) firstly if the formulation is not mentioned in the standard text book then it is considered irrational, (2) secondly if the formulation is described but the text book does not advocate it, the formulation is considered as irrational.

Summary of the Study:

Of the total 235 formulations that were screened only 22 (9%) conformed to the Essential Drug list of WHO, 140 (60%) were rational drugs and remaining 95 (40%) were irrational.

Cost Analysis of Essential Drugs:

A comparison of prices of the same drug being sold by different pharmaceutical companies and under different brand names is given. In some cases it was observed that the same manufacturing company sold the same drug under different brand names and with differential prices. There was no scientific justification for this.

It was also found that there are sometimes large differences in prices for the same drug. The explanation given for this was that drug companies spend a lot of money in promoting a drug to the doctor and this cost is recovered by hiking the price of the drug. Also doctors are neither taught during their student days and nor do the drug companies mention its price when they promote drugs to doctors. Thus doctors tend to prescribe the costliest drugs.

The study concludes that drug prices need to be regulated by the government.

2. "Hepatitis B Vaccination – Misleading Policy & Promotion" [Drug Action Forum – Karnataka (Dharwad) and TEST Foundation (Chennai)]

In the section on misleading promotion certain misleading advertisements were pointed out. The criticism raised against these advertisements was that they have instilled fear among the general public regarding how important it is for one to get vaccinated or else die of cancer of the liver.

For instance in an advertisement by SFK (now known as Glaxo Smith Kline or GSK) it was stated that hepatitis B kills more people in a day than AIDS in a year. However this was criticised as being totally unscientific and misleading.

vi)Information provided by the Population Council

The Population Council conducts research on reproductive and immunological processes, which serves as the basis for the development of new contraceptive methods, hormone therapies, and AIDS-prevention products.[157]

Their website gives details of the research projects in terms of drugs and devices that they are working on at an international level. For instance, they have already delivered to the market certain models of contraceptive devices. The descriptions of their research projects, though on technical subjects, are written in a manner that is easily understood by laypersons.

Apart from this the Council also provides printed information such as training manuals, calendars, brochures, and flyers. The printed materials provided were largely directed to medical professionals and not consumers, such as the materials included training manuals for medical practitioners.

[154] http://www.dsprud.org/aboutus.htm.
[155] http://www.dsprud.org/aboutus.htm.
[156] Prof. Usha Gupta and Dr. Sangeeta Sharma, "Use Your Medicines Correctly – A User 's Guide"
[157] http://www.popcouncil.org/biomed/index.html

1.Training manuals

In some of the training manuals, such as concerning emergency contraceptive pills, the information given was easy to understand and not very technical and was similar to a guide for those uninitiated in the subject. However, the manuals were directed to trainers and not consumers. In fact, even though these training manuals were directed to trainers entrusted with the task of training service providers and workers on emergency contraceptive pills, the technicalities of different drugs available were not discussed. Usually topics such as side effects and so on were discussed regarding common side effects of all emergency contraceptive pills, and individualised information for each type of drug was not available.

2.Calendar

Population Council has provided a calendar with information on emergency contraceptive pills. The information was brief and precise in simple language. The information includes brands available, their safety, effectiveness, side effects and how to manage them, how to return to regular family planning methods after using ECPs, and so on.

Although this information may be very useful in raising awareness about the basics of ECPs, it would be effective only if the message it conveys actually reach consumers. However, keeping in mind that most of the information published was for trainers and not consumers, it can be assumed that the calendar too is directed to trainers. Thus the reach of the information is indirect, as it is not directed to consumers but to trainers.

3.Brochures/Flyers

Population Council also distributes brochures and flyers on issues such as maternal care or care to be taken during pregnancy. We have seen such materials in both Hindi and English. The information provided is brief, non-technical and is often general advise. For instance, while dealing with maternal care advise is given regarding how often testing must be done, etc. Information on drugs is not provided. There were also brochures dealing with contraceptive techniques for both men and women.

vii)Additional information provided by WHO

The WHO has published (in 2000) a manual for healthcare workers on 'Essential Drugs for Primary Health Care'. The book is divided into two parts; 'Part I – Essential Drugs: How and when to use them'; and 'Part II – Common Medical Problems: How to treat and when to refer cases to the doctor'. A description of these parts is done below.

Part I – Essential Drugs: How and when to use them

For each drug, information is given over a couple of pages according to the following headings:

1. How does it help?
2. When should it be used?
3. How is it supplied and given to patients?
4. What are its side effects?
5. What precautions should be taken?

In some cases a diagram is also given of the human body and the parts affected in the particular disease or medical condition. The language is simple and easy to understand. It is not technical and thus can be understood by laypersons as well.

In the section '*How does it help?*' the information given relates to how the drug acts and is useful. '*When should it be used?*' provides information on the medical conditions or diseases in relation to which the drug should be used. This information is usually given in terms of the physical symptoms of the disease. The section on '*How is it supplied and given to patients?*' gives information on whether the drug is available as a solution or powder, concentration and dilutions and the required measurements for the drug's preparation and application, how it is used or applied. The section, '*What precautions should be taken?*' gives precautions such as what the drug should not be mixed with, what sort of containers it should not be stored in, storage conditions, duration of storage and so on.

Part II – Common Medical Problems: How to treat and when to refer cases to the doctor

In this section, information is given on 22 common medical problems, ranging from anaemia, HIV/AIDS, tuberculosis, eye and ear problems, breathlessness, poisoning, vomiting, and so on.

For each medical condition a brief write-up is given on the causes of the condition and symptoms. The rest of the information is organised under the heads of:

1.General guidelines

Here the symptoms and conditions under which the particular condition may be suspected is given. The enquiries that should be made to the patient are also described. Recommendations on the type of food and medicines that should be given to the patient are also described. Here, particular drugs are not named.

2.How to treat?

In a few phrases and points, information is given on the kind of treatment that should be given depending on the cause for the medical condition. It also includes advise on when the patient should be referred to a doctor.

When to refer to a doctor?

This includes a description of physical symptoms suggesting when a patient be shown to a doctor and also whether the patient is not responding to treatment.

3.What precautions should be taken?

This includes information and instructions to be given to the patient; conditions and symptoms which suggest that dosage should be reduced; duration over which the medication must continue; instances when the patient should be referred to a doctor; instances when medication should be kept out of reach of children.

viii) Online information provided by pharmaceutical companies

In the course of this project, the details of information provided on the websites of certain pharmaceutical companies are described below. Although the information provided is often targeted at medical professionals and not patients (as this may not always be permissible), the information is available online and patients can educate themselves about the drug products in the market. By looking at the style of presentation of information to professionals, models can be developed for consumer drug information as well. For instance in addition to written descriptions, pictorial representations, as was done on the Cipla site, would be useful as well.

1.Aurobindo products

The section on 'Product Profile' is divided into two parts: API (Active Pharmaceutical Ingredients); Organic Intermediates. On APIs a list is given under different categories and sub-categories. Regarding organic intermediates, a table is given with very technical information such as on chemical structures (with diagrammatic representation). No links are given for further information on each drug. Thus the information, though brief, is technical in nature.

2.Cipla

On its website, information is given on drugs under a number of categories including prescription and OTC drugs. The information includes details of active ingredients, product type (eg. capsules), pack type, pack size, and product brand. Thus though some of the information is technical in nature, it can be understood by patients as well. In the OTC category, pictures are given of each packaged product. There are no details given and the information that has been provided is very brief.

Apart from websites, information on company products is also available through press releases and news reports. For instance in the case of Cipla, it announced the launch of Viraday, described as a

breakthrough combination of anti-HIV drugs in a single pill, which can be taken just once a day, through a press release which was also circulated online. As it is a press release, not too many technical details were given about the drug, except for the anti-HIV combination of drugs that constituted it. Another piece of important information given about the drug was its price. Press releases would also cover the launch of diagnostic products, devices, test kits, and so on. The kind of information provided through press releases is essentially about how the new launch is better than what is provided in the existing market, the brand names under which the product is marketed, prices, and details of the companies developing the products.

3.Dr. Reddy's, Lupin, Orchid, Pfizer, Sun

Technical information is given on the sites of these companies. Such information would be better understood by medical professionals than patients.

For herbal products, in the website of Lupin, a picture of the packaged product is also given. In the Ranbaxy site, there is a section directed to patients under the 'HIV/AIDS Product Portfolio'. Technical information is not provided in this section. Advise is given to patients regarding adherence to their therapy by ensuring that the medication is taken regularly at the right time, in the right doses and in the right way. The negative consequences of non-adherence to doses are also stated. Tips are given for adhering to doses.

4.GlaxoSmithKline

The information provided for drugs is not technical. It is general, non-technical, and is more from the perspective of marketing. Also under the OTC category only 3 drugs are described. It is not known from the website whether there are more drugs manufactured and/or sold by GSK which are OTC drugs. There is no information given on prescription drugs, if any, which are manufactured by GSK.

Also the site gives information on other products and brands that have nutritional value but are not strictly classified as drugs, such as Horlicks. It is suggested that a greater range of drugs should be covered on the website and in more detail.

5.Nicholas Piramal

A different feature of this site is that it has information not only on drugs but also on diagnostics and devices (such as devices for measuring blood sugar for diabetic patients). The information is styled from the perspective of promoting the marketing of these diagnostic instruments and kits. Pictures and technical descriptions of the products are given, which would be best understood and be of interest to medical professionals and not patients.

6.Wockhardt

The site does not offer information on drugs produced. However, there is a list of Wockhardt's 'Power Brands'.

7.Zydus Cadila

In the Consumer Division section of this site, it is stated that the consumer business of the company spans over food and skincare products. Brief descriptions are given of these products in layman terms. No technical information is provided. Pictures of the products are also displayed. This information seems to be directed to consumers directly from a marketing perspective.

ix)Advertisements issued by NACO in print media

An advertisement issued by NACO and the National Rural Health Mission in October 2006 in the Hindi newspaper *Jansatta* and the English newspaper *The Indian Express*, on the subject of ART treatment for AIDS, contained the following information:

The ad stated that antiretroviral (ART) treatment was available for free at select government hospitals. It was pointed out that till date there exists no treatment for AIDS, but the benefit of regular intake of Antiretroviral Drugs is that it

improves the quality of life and increases the life span of people living with AIDS. It was cautioned in the ad that the medicines must be taken on time, even a single dose cannot be missed as if this was done then the effect of the medicine can be lost and next time the patient may need to take more powerful and expensive medicines. A list of ART centres in the northern India was also given.

x)Indian Drug Review

As a sample of the *Indian Drug Review*, the November—December 2005 issue was seen (Vol. XI No.6). The type of information provided in the IDR included *Brand Review* (a few brands were examined)*; New Brands* (about new products introduced in the Indian market in the last two months); *Therapy* (this section was a feature on 'Peripheral Neuropathy'); *Drug Index* (an index of generics and brands); *Directory of Manufacturers; Therapeutic Index* (diseases indexed alphabetically mentioning the drugs used in these diseases); *Generic Index* (an alphabetical index of all generic products covered in IDR); *Brand Name Index* (an alphabetical index of all brands covered in IDR).

The information provided is very technical and comprehensive and cannot be easily comprehended by laypersons, as the information is directed to medical professionals. For instance in the *Brand Review* section, technical information is given on topics such as clinical pharmacology, mechanism of action, pharmacokinetics, indications, contraindications, adverse effects, dosage and administration, precautions, composition, and so on.

In the *New Brands* section, prices are also given. In the *Drug Index* section, brief, technical information is given regarding the features of the drugs. This includes details such as onset of action; duration of action; adverse effects; contraindications; special precautions, and so on.

Annexure VII

Analysis of Information According to the Form of Materials

The following is an analysis of materials according to the form in which the information was presented, such as by books and booklets, pamphlets, magazines, newspapers, posters, CDs, online information, and so on. A more detailed presentation of the information has been done in Annexure I where the information has been classified according to the source of information, i.e. the actor providing it.

a)Books and Booklets

The books and booklets seen provided information ranging from basic to comprehensive and detailed information. Some information was specifically directed to medical professionals such as pharmacists while some to patients. Many publications focused on rational drug use and in this context, provided information on banned drugs, irrational drug combinations, safer alternatives to currently used drugs, and so on. Some publications were specific to particular diseases and medical conditions such as hepatitis, anaemia, HIV/AIDS, and so on. A few of the publications seen were in the nature of reports on the prevailing health situation with respect to a particular disease and its treatment in terms of implementation of health policies targeted at it.

Materials directed to patients were published in a simple and brief manner. On particular diseases, the nature of the disease was explained in terms of what it is, how it occurs, symptoms, transmission, and so on. In addition practical advice was often given on the treatment of the disease, medications required, how the drugs work, side effects, precautions, food habits, special precautions in conditions of pregnancy, and so on. Often there was emphasis on the fact that patients must rely on and strictly adhere to the advice given by their doctors in taking medication. Guidance was also given to patients for asking questions to doctors.

Books directed to medical professionals such as pharmacists were sometimes meant as educational supplements to them. These included advice on instructions to be given to patients. With respect to the information provided in the handbooks published by the Drug Information Centres surveyed in the course of this project, it was seen that such information was provided in a simple manner and thus can be understood by laypersons as well, even though it is directed to pharmacists. Other books were more technical, with detailed medical and scientific information, such as formularies published with the aim of sensitising medical professionals about irrational drug use. Some books were meant specifically as training manuals to health and medical workers.

The information provided sometimes included discussions on existing policy and its shortfalls and instances of misleading promotions.[158] Not all publications were brought out in local languages. Also only some publications had information on price comparisons of different brands of drugs.

b)Posters and Flyers

The flyers or leaflets seen in the course of this project were in the nature of brief information on

[158] "Hepatitis B Vaccination Misleading Policy & Promotion", Drug Action Forum Karnataka and TEST Foundation Chennai., 2004. See also LOCOST publication.

specific diseases such as AIDS, cancer, anemia, dengue, diabetes, and so on, and also warnings on tobacco and gutka use. Some brochures seen were related to contraceptive techniques and maternal care during pregnancy. These were given in local languages as well.

The posters seen were aimed at awareness creation on specific diseases and medical conditions. They provided brief messages on what the disease is, how it is caused, how it can be prevented, and symptoms and treatments for cure. In relation to treatment and medication, information was given on the number of drugs required to be taken, duration of treatment, how many times a day medicines are to be taken, and the importance of adhering to the schedule. In one instance, we came across posters provided by a doctor on issues of what drugs are, how they are manufactured, when they are used, the ways in which they can be consumed, what questions patients must ask their doctors, information that doctors should know prior to making prescriptions, cautionary advice on what food and drinks can and cannot be consumed alongside medication.

c)Newsletter and Magazines

The newsletters brought out by organisations working on health and consumer issues often included information on specific drugs, such as updates on drug approvals, treatments, indications, dosage, storage, precautions, adverse effects, and so on. Brief information would be provided on particular diseases as brief points of FAQs.

Magazines brought out by some organisations such as consumer organisations were seen. Among the drug-related information, the topics included what drugs are used for treatments, information necessary to be known to doctors, cautions and safety advice for using the drugs and adverse effects. News magazines also sometimes carry articles on health issues where treatment is discussed in a non-technical manner, such as debates on the efficacy of the polio treatment programme and vaccine.

d)Advertisements

Advertisements seen covered a range of topics such as treatment for AIDS, weight loss and obesity, contraceptives, baldness, and so on. Those seen on AIDS treatment were issued by NACO on ART treatment, in which it was highlighted that ART treatment was available for free at select government hospitals and the importance of adherence was highlighted.

e)Online Information

This has been discussed in detail in Annexures I and V. Also for the different actors providing information, their websites were also studied in the course of this project.

An overview of some of the sources of information seen in the course of this project, and the form in which they were provided can be seen in the table below:

Table: Sources of information and forms in which information was provided

Source	Forms of information seen
Individual doctors and healthcare professionals	Posters: *These contained advise on what sort of information should be asked for and provided* Newspaper columns by doctors.[159] Books: *An Epidemiological Review of the Injectable Contraceptive, Depo-Provera* (Medico Friend Circle & Forum for Women's Health India, 2001).[160] Journals: Articles by medical professionals in medical journals available in print and online.
Pharmaceutical companies -Leaflets and labels	Websites
Ministry of Health – National Health Programmes	Online
Ministry of Health	IEC Resource Centre Online, print, audio, video
Ministry of Health	AYUSH Department Online
Ministry of Heath – general	Advertisements
NACO	Advertisements
NACO	Online site
Ad by NACO and National Rural Health Mission	Ad for antiretroviral treatment (ART) on importance of adherence; free ART treatment is available at select govt. hospitals.Ad in Indian Express, New Delhi, Oct 27 2006.
Ad by NACO and National Rural Health	Ad same as above – in Hindi, *Jansatta*, 27
Mission (Hindi)	Oct 06, New Delhi
CDSCO	Website
Drugs Control Department	Newspaper ad against fake drugs; gives guidelines to consumers while buying drugs; encouraging consumers to report any suspicion of illegal trade in drugs.
Ministry of Consumer Affairs	Website
Northern Railway	Advertisement in *The Indian Express*, New Delhi, October 5, 2006 on *Dengue* with information on symptoms; treatment (*specification that there is no specific medicine or vaccine*); precautions
NPPA	Online
US FDA	Website

[159] See for instance articles available online at www.newindpress.com by Dr. G. P. Mohanta.
[160] Author: Dr. C. Sathyamala.

Medline Plus	Website (a service of the US National Library of Medicine and the National Institutes of Health)
Karnataka State Pharmacy Council (KSPC)	Website. This includes uploads of newsletters, etc.
KSPC	Newsletter
KSPC	Handbooks for pharmacists
Maharashtra State Pharmacy Council (MSPC)	Booklet: Drug Interactions Manual (2006 edn.)
MSPC	Drugs Harmful in Pregnancy Manual (2006 Edn.)
MSPC	MSPC Drug Information Bulletin (July—Sept 2006)
LOCOST	Books: Lay Person's Guide to Medicines Impoverishing the Poor: Pharmaceuticals and Drug Pricing in India
DSPRUD	Book: 'Use Your Medicines Correctly – A User's Guide' by Prof. Usha Gupta and Dr. Sangeeta Sharma
CPAA	Website
DNP+	Booklet: 'Antiretroviral ARV Information Booklet for People Living with HIV and AIDS'
Drug Action Forum – Karnataka (DAFK)	Booklet: Study on Anaemia
DAFK	Booklet: 'Study of Pain Killers Listed in a Commercial Publication for Doctor's Use'
DAFK	Booklet: 'Hepatitis B Vaccination Misleading Policy & Promotion'
JIPMER	Website: volumes of 'Drug Alert' newsletter.[161]
MIMS India	Book: MIMS India Monthly Index of Medical Specialties
Indian Drug Review (IDR)	Book: IDR (Nov-Dec 2005)
CHAI – CMAI (Catholic Hospital Association of India and Christian Medical Association of India)	Book: CHAI-CMAI Joint Formulary, 1994.
Christian Medical Association of India (CMAI)	Booklet: 'Understanding the Thief Who Comes to Kill and Destroy'. By the Policy Advocacy Group, CMAI; October 2005
CMAI	Newsletter: 'Rational Drugs' (Issue 11, January—March 2003. Topic focus: Control of Tuberculosis in India) and other editions of the newsletter.

[161] http://www.jipmer.edu/charu/drug_alert.htm

Medicins Sans Frontiers (MSF)	MSF Fact Sheet on Tuberculosis
MSF	Booklet: 'ACT NOW for all of the Asia Pacific to get malaria treatment that works' (2004)
Population Council International	Booklet: Adherence to Antiretroviral
Centre for Reproductive Health	Therapy in Adults – A Guide For Trainers
WHO	Book: *Essential Drugs for Primary Health Care – A Manual for Health Care Workers*, SEARO Regional Health Papers No. 16 (WHO, New Delhi, 2000)
Population Council, UNFPA	Manual: *District Quality Assurance Program for Reproductive Health Services An Operational Manual* (August, 2006).
Population Council	Website
Population Council	Calendar on emergency contraceptive pills
Population Council	Brochures/Flyers
VHAI	Book: *Banned & Bannable Drugs*
VHAI	Booklet: *Dengue and Dengue Haemorrhagic Fever Prevention and Control at Community Level* (2000)
VHAI	Booklet: *Arthritis & Joint Pain*(2000): limited info on drugs
VHAI	Booklet: *Better Eye Care* (2003)
VHAI	Booklet: *Immunization* (2003)
VHAI	Booklet: *Diabetes* (1997)
VHAI	Booklet: *Care in Leprosy* (2001)
VHAI	Booklet: *Better Care of T.B.* (1998)
VHAI	Booklet: *Cancer* (1998)
CIMS	Booklet: *Doxofylline Redefining the Role of Methylxanthines in Asthma & COPD* (2006)
CIMS	Booklet: *Loratadine in allergic disorders* (2006)
CIMS	Booklet: *Biotin the Golden Molecule* (2006)
Medico Friend Circle	Book: *In Search of Diagnosis – Analysis of Present System of Health Care*(1985)
CGSI	Magazine: *Keemat*
CERC	Website: Test reports
Consumer VOICE	Website
Consumer Online Foundation	Website
Mumbai Grahak Panchayat	Website

Pharmacy Council of India	Website
Jagori	Poster on contraceptives for women.
Saheli	Book: '*Aapas ki Batein – Garbh Niyantran Suraksha aur Hamara Swasthya*' (1995)
IPA	Indian Journal of Pharmaceutical Sciences.*Technical and scientific articles*
IPA	Pharma Times *News magazine for professionals; scientific journal*
IPA	Publication: *Guiding Principles for Pharmacists HIV/AIDS in India*
ICMR	Indian Journal of Medical Research*Technical and scientific journal directed at professionals*
Websites	Online

Notes: The above table does not mention other information received from various sources pertaining to health issues, but they were not relevant to the topic of this paper.

Annexure VIII

National Consultation on Consumer Drug Information in India: A Situational Analysis

A national consultation on 'Consumer Drug Information in India: A Situational Analysis' was organised by the Centre for Trade and Development (Centad) in collaboration with the Office of World Health Organization (WHO) Representative to India in New Delhi on March 29, 2007.

a)Objectives

- To share and discuss the findings of a background study carried out by Centad examining the current situation of consumer drug information in India.
- To critically examine the study and seek inputs for improvements.
- To hold an informed discussion on the current situation of consumer drug information in India.
- To deliberate on recommendations to address the problems identified on issues of consumer drug information.
- To formulate an action plan to implement the recommendations.
- To bring together various stakeholders involved with the subject, including medical professionals, pharmaceutical associations, pharmaceutical companies, civil society organisations working on health and consumer issues, WHO experts, and concerned ministries of the Government of India.

As a background to the consultation, Centad undertook a study analysing the current scenario regarding consumer drug information in India, and its nature and reach. This involved a survey on information being provided to consumers, channels through which this is being done and the actors responsible for providing the information.

The consultation was attended by various actors in the drugs and pharmaceuticals sectors including academicians, Government of India policymakers, medical representatives and practitioners, and civil society organisations. It featured three sessions:

- Session I: Presentation of approach paper.
- Session II: Experience-sharing by representatives from the government, civil society and pharmacy sectors.
- Session III: Panel discussion and open discussions on experiences, recommendations and formulating a plan of action.

Session I: Presentation of approach paper

This session began after a welcome speech to participants and a round of introductions. The context and background of the study on consumer drug information was presented. Centad then presented the paper *'Consumer Drug Information: A Situational Analysis'*. After the presentation, critical comments on the study were made by the panel members. This was followed by discussions and comments on the paper by the rest of the participants.

The presentation discussed the following subjects:

- Need for and nature of consumer drug information.
- Law and policy regime.
- Survey of information gathered during the course of the study.
- Conclusions and recommendations.

The importance of providing information on drugs

to consumers was discussed, and what the information should consist of. The essentials of information that must be provided to consumers were listed, as well as other types of information that may prove useful to consumers. The parameters of the manner in which this information should be communicated were also discussed.

At the outset, the importance of providing drug information to consumers was established — to enable consumers to become more involved in informed decision-making and safeguard their right to health and right to information.

The essential components of drug information are:

- Whether or not the drug is a prescription drug.
- Details of its composition.
- Brand and generic names.
- Comparative lists of branded and generic drug prices.
- Dosage.
- Side-effects.
- Precautions and risks.
- Storage conditions.
- Approved indications and contraindications.
- Information on alternatives for prescribed drugs.
- Dietary requirements.

Other information that would be useful to consumers is whether a particular drug is a banned or hazardous drug, or its combination useless and irrational, and advice regarding traditional remedies. The manner in which information is communicated is as important as the substance of the information. For information to be effective it must be accurate, reliable, accessible, user-friendly and provided at a basic and comprehensive level depending on the consumer's requirements.

The applicable law and policy regime in India, governing different aspects of consumer drug information, was also discussed. The analysis was presented in a critique of the shortcomings of various laws and policies. Gaps in law and policy were pointed out; it was concluded that they do not deal comprehensively or exclusively with the issue of consumer drug information. There is lack of clarity on the legal requirements for providing drug information to consumers.

The survey on drug information was discussed through an analysis of the information and material being provided by various categories of actors. These include government and quasi-government authorities, healthcare professionals, civil society and non-government organisations, pharmaceutical companies and other associations. A broad analysis of the nature, content, and form of the information was made.

The issue of information required from a consumer perspective was also raised; whether or not the information currently being directed at consumers is indeed useful to them. Following the discussion on the survey, broad conclusions and recommendations made in the study were presented.

After the presentation in Session I panel members offered their comments, criticisms and suggestions on the study. Some of these include:

- There should be greater emphasis on connections between the pharmaceuticals industry and doctors. This affects the medication being given to patients, as information from the industry is often biased.
- The study needs to include the consumer perspective and focus on the actual consumer, or patient, rather than the other stakeholders. It was also recommended that the consumers should be surveyed. The impact of material directed at consumers should be assessed.
- Other categories, such as doctors and pharmacists, should be included as consumers.
- The study needs to be more critical of the government.

- The study should survey write-ups in newspapers and advertisements given in publications that are often misleading.
- The survey should determine the quality and sort of information being given out. In an assessment of quality, there should be clear parameters for evaluating material.
- The material should be checked to see how updated it is and how many times it has been revised. There should also be an analysis of the actors providing the material, in terms of why a particular material was produced.
- The study should mention the efforts of actors in various states.
- Best practices in other countries should be reviewed.
- There should be a focus on the role of pharmacists in providing information on drugs.

Session II: Sharing of experiences

This session incorporated five presentations where experiences were shared by the panel members, who were representatives of civil society organisations working with health and consumer issues, pharmacy councils, medical professionals, AIDS patient groups, etc.

A representative from an AIDS patient organisation presented a booklet, published by the organisation for HIV/AIDS patients on ARV (antiretroviral) treatment, which should improve communication between patients and doctors.

In another presentation, examples were given of the type and format in which information should be provided to consumers. The need for a prescription guidance service for patients was pointed out. Also, that information should be provided not only to consumers but to doctors and health activists as well.

A pharmacist from a state Drug Information Centre (DIC) discussed the experiences of the DIC with patient queries, efforts at educating patients about treatment options, and guidance on prescriptions.

A representative from a consumer organisation spoke about the need for technical education at consumer organisations and efforts being made to educate consumers on drug issues.

In a presentation by a representative from an organisation that provides information to pharmacists and answers their queries, the type of data being provided (such as data on brands and drug prices) by the organisation was discussed. It was noted that community pharmacists are one of the best sources of information for patients and that by providing information to pharmacists, patients too were being educated. It was also pointed out that there is no official list of Over The Counter (OTC) drugs in India.

Session III: Discussions on experiences and recommendations, and formulating a plan of action

a)Open Discussion by Participants

In the open discussion in this session, participants discussed specific issues and recommendations for all actors engaged in providing drug information to consumers. The recommendations made to the Ministry of Consumer Affairs by a taskforce (2004), which worked on examining drugs and pharmaceutical devices from a consumer perspective, were discussed.

On the issue of drug prices, the taskforce recommended that as attempts to control prices through regulatory mechanisms had failed, competitive pressures should be used. There is a need for greater regulation of traditional medicines such as ayurvedic and unani drugs. The taskforce also recommended that the resources of the Drug Controller General of India (DCGI) and state authorities for drug testing should be augmented. The need to set up a website with information for consumers on identical drugs and their manufacturers was stressed. Another recommendation of the taskforce was that the current package leaflet should be replaced by a patient package insert.

In discussions on the issue of patient package inserts by participants at the national consultation, it was stated that the provision of information can never be harmful and that the fear that patients self-medicate when they are provided information is misplaced. It was suggested that drug manufacturers submit the text of patient package inserts themselves; this would prove beneficial to them too as it would allow them to safeguard their interests.

The importance of the role of information in lowering drug prices was reiterated; it was noted that the reason why market forces have failed to do this is because the consumer does not have the requisite information. Once consumers have the information they will demand the prescription of cheaper and generic drugs.

b)Discussion by Panel Members

In this session, the initiatives taken by various organisations and authorities dealing with health and consumer issues were discussed. The application and workings of the Consumer Protection Act were studied. It was stated that the Act applies to drug commodities as well, and that it gives certain rights to consumers. Even where the manufacture of a particular drug has been licensed under law, consumers can seek redressal under the Act if they have problems with that particular drug.

Initiatives taken by the World Health Organization (WHO) were also discussed in this session. These include the development of norms and guidelines, finding gaps in the available information and determining how to fill them, building databases of information, disseminating information, supporting the Karnataka State Pharmacy Council (KSPC) in the development of drug information centres in north India, etc.

The types of inputs that the WHO could provide include norm-setting, helping build databases, looking at prescription audits, pushing for changes in legislation, and identifying areas where information is unavailable.

Issues discussed in detail included drug package inserts and the role of pharmacists in providing information. On the issue of package inserts, it was pointed out that package inserts should not be made too non-technical and simple, as there could then be legal problems. The industry believes information should be provided in medical language so that it is precise. It was also stressed that patients cannot rely solely on package inserts; the doctor's advice must always be taken, as there could be conditions specific to a particular patient. Problems relating to the type and format of information to be provided in package inserts were also discussed. It was noted that information like price comparisons and facts about the disease could not be provided by the producer, as he would be able to give information only on the product. The problem with providing information in local languages is that once the product leaves the factory it ends up all over the country; the manufacturer cannot monitor its distribution.

One speaker spoke of the important but under-utilised role of community pharmacists in providing consumers with information. The need to provide cost-effective and reliable information to pharmacists was highlighted.

c)Conclusion

In the course of the presentations and discussions at the consultation, it emerged that the drug information being provided to consumers is scattered and from a variety of sources. It also differs in terms of both quality and reach.

Overall, the quality of information available, including that from the government, is poor. Though there are a number of legislations and policy provisions that cover different aspects of consumer drug information, there is the need for greater clarity and a more comprehensive approach.

The Centad study reiterates the need for coordination and cooperation among the various stakeholders. Click here to view details of conclusions and recommendations reached at the consultation.

Conclusions and recommendations in the Centad study

d) Conclusions and Recommendations in the Centad Study

i) Conclusions

Some broad conclusions drawn from the survey on materials and law and policy frameworks are:

- The availability of consumer drug information in India is very limited, particularly in terms of quantity.
- There is no single dedicated actor concentrating only on consumer drug information.
- The multiplicity of actors makes it possible for the range and reach of information to be as broad as possible, thereby reaching out to a large number of consumers. At the same time, efforts differ in their standards and content. The consumer may, in some cases, be unable to decide which source of information is the best.
- There is no level of consistency with respect to the information supplied.
- Information directed at consumers is largely aimed at awareness creation about preventive strategies and is not very technical.
- Most technical information on drugs is directed at medical professionals and not at consumers.
- In most cases, the information is not given in a user-friendly manner. It is usually neither comprehensive nor brief, and is not presented in a manner that is understood by laypersons and also has all the information on the drug and treatment.
- There is particular lack of information about drug prices, for which there is no comprehensive database. Only some actors engaged in providing consumer drug information provide information on prices. In the course of this study there was found to be no information on clinical trials, which is another neglected area.
- Efforts have been made by a number of organisations to provide comprehensive information to consumers in a simple manner, however, they are usually done through the publication of books, booklets or CDs or in formats that are not normally accessed by the common consumer.
- Although considerable information is available in journals and academic papers, particularly on issues of rational drug use, such sources of information are not accessed by laypersons. Though there may be the chance that the information percolates down to the layperson from technical people accessing the information, the common consumer cannot access the information directly. These are therefore secondary and indirect sources of information.
- Information is sometimes provided both in English and the local language, though, for some sources of information, such as labels on medicines and the internet, the information is primarily in English. Another limitation is that information provided in local languages is usually basic, not very comprehensive, and too technical.
- Information is provided mostly on allopathic drugs. There is limited information on traditional medicines, medical technologies and equipment, and diagnostics.

ii)Recommendations

Recommendations made in the study were categorised into those for immediate implementation, those for consideration at a broader level, and recommendations for various categories of actors.

Recommendations that need to be immediately implemented to address the pressing issues of consumer drug information availability are:

- There should be bigger packs of medicines, leaflets and printed material. This should be made compulsory for all drug companies, and should be regularly reviewed. Also, the print

on medicine labels should be larger.

- There should be a team of pharmacologists, clinical professionals and consumers reviewing all information and material provided by pharmaceutical companies. Drug companies should be compulsorily made to use part of their profits to provide drug information to consumers.
- Information on the prices of drugs and comparisons between the prices of various branded and generic versions of the drug should be more readily available to consumers.
- Detailed information on drugs should be disseminated in a simple, easy-to-understand manner.
- Dissemination of information should also be carried out in local languages.
- A forum should be set up where the actors involved in disseminating information can meet and deliberate on common steps to take the movement for advocating rational drug use forward, particularly regarding consumer drug information.
- Consumers should be encouraged to be more proactive in seeking information on drugs. Patients are usually more proactive about obtaining information on how to treat medical conditions that require continuous or lifelong monitoring, such as diabetes. In such situations, patients are more demanding about information on the drugs and treatment required, including such details as drug prices.

iii)Other recommendations to be implemented

- There should be a single, comprehensive source of information that can be readily accessed by the consumer. This could be provided by the government as a source of verified and authentic information.
- Comprehensive regulations and guidelines should be developed and their implementation ensured, governing all possible sources of consumer information and the actors providing the information. This involves setting up guidelines for providing consumer drug information that act as a common standard for all those involved in dispensing such information. It also involves examining current law and policy in greater detail.
- Coordination among the various actors is necessary so that a common approach may be developed with respect to the standards and guidelines to be evolved.
- There should be an authority to assess the information being provided. The assessment should be done in a manner that involves the inputs and efforts of different actors including NGOs.
- Guidelines and checks must be evolved for information provided online.
- There should be a range of journals and websites to cater to different levels of understanding among various sections of the public.
- Current efforts at providing consumer drug information must be continued, as also efforts at providing information to medical practitioners.
- There should be a focus on subjects where there is greater lack of information, such as traditional medicine.
- Further analysis is required to determine current obstacles in the development of comprehensive consumer drug information. This includes determining what prevents the government from setting up a centralised information database and what can be done to address this.
- As patients consider doctors their primary and most trusted source of information, doctors must provide them at least basic and comprehensible information, according to the standards prescribed for the provision of drug information to consumers.
- It is important to keep in mind similar recommendations regarding sources of

information for doctors.

The study also mentions certain issues to be considered as future research questions and areas for examination:

- Issues of consumer drug information must be understood from the demand side as well. This means that the information expected and demanded by consumers and organisations representing and protecting consumer interests must be understood. The provision of consumer drug information can be effective only if it meets the needs of consumers.
- Considering the level and type of information available to consumers at present, the major legal, ethical and other reasons behind the current state of play need to be identified.
- There is a need to link research done on the marketing and drug-promotion strategies pursued by the pharmaceutical industry with mechanisms for the provision of consumer drug information and the quality of the information.
- Doctors and other medical professionals should be asked their views on the promotional activities being pursued by pharmaceutical companies, and how this impacts them.
- Advertisements should be studied in greater detail, as they are a direct and predominant source of information for consumers. The issue of monitoring drug advertisements also needs to be examined as, for certain diseases and medical conditions, advertisements are prohibited. The level of actual compliance with the law should be assessed. Instances of false and misleading advertisements must also be determined; the issue of how such advertisements can be prevented and monitored must be considered.

iv)Recommendations made in the course of the consultation

Apart from the recommendations, important issues for consideration were highlighted at the consultation. These are provided below according to the topics they broadly relate to:

- Recommendations on type and form of information required
- There is a need for greater information, particularly on prices and brands. Catalogues with this information should be readily available.
- A brand name registry should be created.
- Consumer information on medical technology and devices needs to be examined in greater detail. A large portion of out-of-pocket expenditure is on testing and medical technology and devices. There is also an absence of regulation on technology.
- There is a need to create awareness about clinical trial registration.

v)Recommendations on effective communication of information

- Media should be used to disseminate information to laypersons.

vi)Recommendations concerning the government

- There must be a focus on the government's responsibility to take action. There is need for greater regulation in this area and for the enforcement of such regulation.
- The government should set up a registry to which any information published on consumer drug information is sent. This should be put up on a website.
- The government should frame requirements for registering clinical trials in India.
- The government should establish drug information centres in hospitals catering to healthcare professionals and patients.
- There is a need to determine a final authority that decides what information is to be passed on to the public and who should provide the information.
- More stringent licensing conditions are required in the manufacturing and quality control of drugs.

- A drug price system should be institutionalised.
- Drug information centres should network and carry out need assessments, instead of being prescriptive. Need assessments should be conducted throughout the country.
- Regulatory capacity should be increased in terms of personnel.
- Alternative mechanisms to regulation should be examined.
- Regulatory structures should be publicly examined.
- The drug policy must include a component on rational use of drugs. There is a need to assess how medicines are being sold, prescribed and used.
- Amendments to legislations are needed.

vii)Recommendations related to healthcare professionals

- Doctors/healthcare-providers should be held primarily responsible for providing accurate and comprehensive information to consumers in a manner that is easily understood.
- The Indian Medical Association, Medical Council of India, etc, should be approached to bring out a code of conduct for information dissemination to patients. Healthcare professionals should be sensitised.
- Healthcare professionals must ensure that they refer to updated information. There is the need for updated national and state formularies, and for a Prescriber's Journal of India. Continuing medical education of healthcare professionals must be ensured through updated sources of information.
- Prescriptions should be made out using generic names.
- People specialising in pharmacogenics should also be recognised, apart from doctors and pharmacists.
- Irrational combinations of drugs need to be weeded out.

viii)Recommendations related to pharmaceutical companies

- Production of irrational drug combinations must be stopped.
- The marketing strategies used by pharmaceutical companies to promote their products among the medical fraternity must be examined.
- The issue of outsourcing drug manufacturing must be addressed in order to determine how quality control needs to be done.

ix)Recommendations for civil society

- There is a need for coordination among civil society organisations.
- The RTI (Right to Information) Act must be used to obtain information, particularly on irrational drugs.
- There should be greater sharing of information between civil society organisations.

List of Participants

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4. Padma Prakash (E-Social Sciences, Mumbai)
5. Dr Rekha V Ganachari (Bangalore)
6. Dr Prakash C Rao (Bangalore)
7. Amitava Guha (Federation of Medical & Sales Representatives' Associations of India, Kolkata)
8. Professor G P Mohanta (Department of Pharmacy, Annamalai University, Annamalai Nagar)
9. Dr Raj Vaidya (Indian Pharmaceutical Association — Community Pharmacy Division, Goa)
10. Rajan R Gandhi (Safety Action Group, New

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11. S Swarna Latha (Research Scholar, Centre for International Legal Studies, JNU)
12. D Jameel Zamir (International Planned Parenthood Federation, South Asia Regional Office, New Delhi)
13. Dr Mira Shiva (All-India Drug Action Network, New Delhi)
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15. Rukmini Pillai (Torchbearers, New Delhi)
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17. Dr M M Mittal (Medguideindiacom, Delhi)
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23. G Mahesh (AIDS Healthcare Foundation)
24. Terri Ford (AIDS Healthcare Foundation)
25. Reji K Joseph (Research Scholar, JNU)
26. Deepu M (Research Scholar, JNU)
27. Vinod Bhanu (Centre for Legislative Research and Advocacy, New Delhi)
28. Gajanan Wakankar (Indian Drug Manufacturers' Association)
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32. Meghendra Banerjee (World Health Organization)
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