LAW AND ETHICS IN PUBLIC HEALTH – THE CASE OF PHARMACEUTICAL POLICY 2002

PROJECT ASSIGNMENT
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… to all those people
who have been
denied access to health care …

ACKNOWLEDGEMENTS

To be convicted can often be demoralising, but in same cases it can be challenging and lead the person to begin a new journey and reach new heights. I felt deeply troubled by the fact that all my efforts in life were aimed at making a better life for myself. The studies, the ambitions, the goal and the purpose was to have a comfortable tomorrow for myself. But the message of Christ convicted me and made me question the path that I was to take; and that has brought me to where I am today. To my Convictor and Redeemer, is my first offer of gratitude.

I am ever grateful to my parents, grandmother and sister who encouraged me to do the Medical Law and Ethics Course and persevere in it, in spite of my laziness. Savio from Oxfam GB was very encouraging about the course. Thanks to him too.

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For me, this course was a means to learn about how people could be helped to access healthcare as a right. I gratefully acknowledge all those people who have been denied access to health care for whatever reason. They have been my motivation and inspiration to do this course, and their project report is dedicated to them.

Naveen i. thomas

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INTRODUCTION

"At the door stood Death. She said 'I smelled your rooster
and I came along to help you eat it?
'And why not', said the man.
'Aren't you one who treats everyone alike?'
'That is so,' said Death. 'I have no favourites,
the poor, the rich, the young, the old, the sick, the well – all look alike to me.'
'That is the reason you may come in and share my food' said the man.
Death entered and the two had a grand feast."

- ***Aurora Lucero White Lea*** [1]

For death, all may be equal and may treat everyone alike, but the same cannot be said for the living. The disparity in socio-economic indicators between people of different ethnic, gender, region, religion, caste and income groups could be so marked that some groups may not even reach up to the lowest indicators of other groups. This disparity can be seen vividly in health indicators of people[2]. Some important indicators have been included in the section on Health, Healthcare and Drug Situation in India. Martin Luther King, Jr. once said, "of all the forms of inequality, injustice in healthcare is the most shocking and inhumane". [3]

METHODOLOGY

Statement of Purpose

Having completed my Master's degree in Medical and Psychiatric Social Work and working on health related issues brought me face-to-face with the interface between health issues, law and public policy. That prompted me to take up the course on Medical Law and Ethics. The purpose of joining the course was to learn about how people could be helped to access 'healthcare as a right'. This led me into the area of Ethics and Public Policy. The purpose of this paper is to examine law and ethics involved in formulating health related policy.

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[1] Quoted in M. L. Kothari and L. A. Mehta, *Living, Dying* (Goa: The Other Indian Press, 1992)
[2] The World Health Report 2002, WHO, Switzerland
[3] Quoted in Down to Earth, 15 March 2003

"The health policy of a state or a nation depends on its value system'. [4] What value system does a secular state adopt – cultural, traditional, religious, a mix of all these or that of the dominant groups? A survey of literature of Health Ethics revealed two broad categories of influences – one, that is religious in origin and two ' that is 'medical profession' related. While Public Health Ethics draws from both the spheres, a more comprehensive ethics framework would extend it to include social justice and equity in health. This is not to discount the fact that religious texts or medical ethics contain values of social justice; the lacunae can be seen as a limitation in exposition of existing literature on the topic. This paper attempts to fill this gap by drawing up a framework of Public Health Ethics, which helps one to understand the process of policy formulation better and analyse it in the given context. An example of a recent policy – The Pharmaceutical Policy 2002 has been used as case-study for analysis, using the framework of Public Health Ethics.

Focus of Research

The primary questions researched in this paper are:

1) To determine the basis of Public Health Law and Ethics.
2) Policy Environment: What is the healthcare and drug situation in the country – the basis on which health related policy is formed?
3) To ascertain the link between Pharmaceutical Policy 2002, Public Health Ethics and the existing policy environment.

Research Method

A literature survey was conducted to obtain information on the above research questions. The list of books and articles surveyed are included in the Bibliography. The source of data was 'secondary', and can be broadly classified into 4 types.

1) General ethics and ethics related to health, medicine, science and technology.
2) Health reports and health policy related.
3) Drug-issues (including Pharmaceutical Policy 2002) and drug industry related.
4) Laws related to Health and Healthcare.

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[4] C. M. Francis, *Medical Ethics* (New Delhi: Jaypee, 1993)

Due to the medicalisation of health, the analysis of health related issues is often limited to 'cause and effect' analysis. However health, being related to 'development' at one end of the spectrum and to the 'individual' at the other end, an ethical analysis needs to be more comprehensive. This paper uses a reflective and dialectical discourse approach, while trying to raise questions and be non –judgemental.

The use of such approaches to ethical analysis of public health is also a step towards taking health away from the closed confines of 'medical profession' into the hands of society and the community. As Henry Sigerist, the famous medical historian said, "War against disease and for health cannot be fought by physicians alone. It is a people's war in which the entire population must be mobilized permanently".[5] The use of this analysis and the conclusions therein will also contribute to strengthen the voice of the voiceless and that of movements like the People's Health Movement who strive to work for equity and justice in health.

[5] .Quoted in Health Action, September 2003.

PUBLIC HEALTH ETHICS, LAW AND POLICY

'If Swaraj was not meant to civilize us, and to purify and stabilize our civilization, it would be worth nothing. The very essence of our civilization is that we give a paramount place to morality in all our affaires, public or private'.

(Mahatma Gandhi, 23 January1930, Young India, p. 26) [6]

I would like to base this paper and the analysis contained in it, on an ethical framework presented by Mahatma Gandhi during his life and struggle for India's freedom. The framework is relevant as we examine public health ethics from a perspective of health, not just begin' absence of disease', but as a 'right of every individual to enjoy and attain the highest state of well being'. Thus, 'health' transcends the realm of just being a 'medical' issue, and moves on to being on an 'existential' plane. While it would not be wrong to call it 'Gandhian Health Ethics', I would avoid usage of the term, for fear of not fully integrating the essence of his message into the analytical framework on health.

Swaraj and Public Health

Gandhi, writing in young India (19 March 1931), explained the meaning of *swaraj* (a vedic word) as meaning 'self-rule' and 'self restraint', and not freedom from all restraint which 'independence' often means! In the context of public health, *swaraj* refers to 'self rule', where the person enjoys the freedom to attain his/her highest state of well being in the manner s/he chooses. But *swaraj* is not complete without 'self restraint', where the person's way of life does not impinge of the right of others or themselves to attain the highest state of well being. Very loosely put, it can be termed as 'rights with responsibility'. A right, which can be claimed with authority, arising out of the fact that one is themselves respecting the rights of others. This is what Gandhiji called *Ramaraj* – i.e. sovereignty of the people based on pure moral authority'.[7]

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[6] Young India, 23 January 1930, p. 26 quoted in M.K. Gandhi, *Village Swaraj* (H. M. Vyas ed., Ahmedabad: Navajivan Publishing House, 1962)

[7] *Harijan*, 2 January 1937, p. 374 quoted in M.K. Gandhi, *Village Swaraj* (H. M. Vyas ed., Ahmedabad: Navajivan Publishing House, 1962)

Swaraj – A Universal Concept

Swaraj in public health as in any other sphere, is an egalitarian term, and is certainly attainable, as it arises out of every human being need to be treated with respect. It does not discriminate between race or religious distinction, however it is for all, 'including the farmer, but emphatically including the maimed, the blind, the starving toiling millions'.[8] In public health it translates into, all people everywhere, irrespective of their caste, gender, vocation or location being able to attain the highest state of well being, and having an environment which promotes it.

Poorna Swaraj and *Swaraj* of the Poor

Gandhiji said that his dream of *swaraj* was a 'poor person's *swaraj*', where the ordinary amenities of life that a rich person enjoyed was available to all.[9] He further added that *swaraj* was not *poorna* (complete) *swaraj* until basic amenities was guaranteed to all. In public health, the provision of accessible, affordable, and availability of quality health services is of primary importance. If *swaraj* is to be attained these services need to be given as a 'right' to all people, everywhere.

Price of *Swaraj* – Truth and *Ahimsa*

Swaraj comes at a price. As Gandhiji put it, '*Swaraj* has got to be won, worked and maintained through truth and *Ahimsa* alone'.[10] Untruth, false promises and illusions in development have become the order of the day in development; in the medical profession it has reached menacing proportions. The practise of prescribing drugs of select companies in return for monetary and other considerations is increasing.[11] To achieve *swaraj* one needs to be true to oneself as to others. Gandhiji has given the correlation between *swaraj* based on *ahimsa* and health, while writing in *Harijan*, in the

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8 Young India, 1 May 1930 quoted in M.K. Gandhi, Village Swaraj (H. M. Vyas ed., Ahmedabad: Navajivan Publishing House, 1962)

9 Young India, 23 January 1930 quoted in M.K. Gandhi, *Village Swaraj* (H. M. Vyas ed., Ahmedabad: Navajivan Publishing House, 1962)

10 *Harijan*, 27 May 1939 quoted in M.K. Gandhi, *Village Swaraj* (H. M. Vyas ed., Ahmedabad: Navajivan Publishing House, 1962)

11 A detailed study on the nexus between doctors and pharmaceutical companies is available on www.issuesmedical.ethics.org

issue dated 25th March 1939, 'Under *swaraj* based on *ahimsa*, nobody is anybody's enemy; everyone contributes his or her due quota to the common goal; their knowledge keeps growing from day to day. Sickness and diseases are reduced to a minimum'. [12]

Ahimsa and Public Health

Ahimsa in healthcare is a proactive concept, where one does limit oneself to not harming others, but actively contributes to working on a common goal so that the society is benefited. *Ahimsa* values the worth of the 'other' as that of its own self, and strives to work towards its upliftment. Here, the values and worth of every individual is as important as that of the whole. Speaking of *swaraj*, Gandhiji said that, '*swaraj* of a people means the sum total of *swaraj* of individuals'.[13] *Swaraj* in healthcare will only be reality, when the self-rule is based on health rights which, arises from a due performance of one's large duties to the self, society, environment, etc. Gandhiji was speaking about such a *swaraj* when he translated an Indian song into English – the song speaks about his vision of such a land – a land where swaraj reigns.

We are the inhabitants of a country where there is no suffering and pain
Where there is no illusion or anguish, no delusion nor desire,
Where flows the Ganges of love and the whole creation is full of joy,
Where all minds flow in one direction, and where there is no occasion of sense of time,
All have their wants satisfied;
Here all barter is just, here all are cast in the same mould
No selfishness in any shape or form, no high no low, no master, no slave;
All is light, yet no burning heat,
That country is within you – It is Swaraj, Swadeshi,
The home within you –
Victory ! Victory ! Victory !
He realises it who longs for it.[14]

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[12] *Harijan*, 25 March 1939 quoted in M.K. Gandhi, *Village Swaraj* (H. M. Vyas ed., Ahmedabad: Navajivan Publishing House, 1962)
[13] *Harijan*, 25 March 1939 quoted in M.K. Gandhi, *Village Swaraj* (H. M. Vyas ed., Ahmedabad: Navajivan Publishing House, 1962)
[14] Mahatma Gandhi – The Last Phase, 1956, Vol I, pp. 190 - 91 quoted in M.K. Gandhi, *Village Swaraj* (H. M. Vyas ed., Ahmedabad: Navajivan Publishing House, 1962)

Right to Life – The Indian Law and Policy

As seen in the freedom derived from the concept of *swaraj*, the constitution too guarantees the Right to Life. The Supreme Court in its rulings have interpreted the Fundamental Right to Life, as stated in Article 21 of the Indian Constitution to include right to health, as it is essential for human existence and is, therefore an integral part of the right to life. This judgement was given in Consumer Education and Resource Centre vs. Union of India case,[15] where the court also held that humane working conditions, health services and medical care are an essential part of Article 21.[16] On the issue of providing public health rights to Indian citizens, the Supreme Court judgements are in addition to the Directive Principles of the State Policy outlined in Constitution. Article 42 states "**Provision for just and humane conditions of work and maternity relief** – The state shall make provisions for securing just and humane conditions of work and for maternity relief", Article 47 states "**Duty of the State to raise the level of nutrition and the standard of living and to improve public health** – The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties and, in particular, the State shall endeavour to bring about prohibition of consumption, except for medicinal purposes, of intoxicating drinks and of drugs which are injurious to health".[17] The existing legislations in country are another source for citizens to claim their right to life and health. As an indicator of this fact, the legislations of Karnataka, which give right to its people, have been compiled and included in the report (refer annexure).

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[15] AIR 1995 SC 636
[16] PHM, *Position paper on Right to Healthcare'* (Mumbai: PHM, 2003)
[17] Part IV, Constitution of India adopted on 26th Novemember 1949 quoted in PHM, *Position paper on Right to Healthcare'* (Mumbai: PHM, 2003)

HEALTH, HEALTHCARE AND DRUG SITUATION IN INDIA

India – Demographic and Health Statistics [18]

Total population (2001 census): 1,025,095,000

Annual population growth rate (1991-2001): 1.8%

Life Expectancy at birth (both sexes) 2001: 60.6 years(Male: 60.0 and Female: 61.7)

Probability of children under dying - per 1000 (2001): Male: 89 and Female: 98

Comparative Health Indicators (India):

	1961-1962	1998-1999
Life expectancy – Both sexes	41.2	62.9
Infant mortality	146/1000 live births	69/1000 live births
Death rate	22.8/ 1000	8.9/ 1000
Birth rate	41.7	26.4

	1995	1996	1997	1998	1999	2000
Total Expenditure of health as % of GDP	5	5.2	4.9	5.1	4.9	4.9
Private expenditure on health as % of total expenditure of total expenditure on health.	83.8	84.4	84.3	81.6	82.1	82.2
Government expenditure on health as % of total expenditure of total expenditure on health.	16.2	15.6	15.7	18.4	17.9	17.8

[18] *The World Health Report 2002* (C.Murray, et.al. eds., Geneva: WHO, 2002)

Access to Essential Medicines

The United Nations has categorized India as number 4, i.e. technologically developed enough to be totally self-reliant, with research capability for the discovery of new chemical entities. India's march to self-reliance in drugs was the result of well thought out policies to accord a leadership role to public sector, develop self-reliance in drug technology, create a suitable patent environment, achieve self-sufficiency in production of essential drugs, reduce imports, ensure reasonable price, maintain high standards of production and promote research and development.[19] The Indian Patent Act 1970, Hathi Committee Report of 1975, The National Drug Policy, 1978 and the subsequent National Drug policy in 1986 and the National Health Policy of 1983 aided the advances in the people's health and in the Indian drug scenario.

However, current policies, which are in line with international agreements and instruments, are taking India away from the self-reliance that was painstakingly built up over the years. The analysis of pharmaceutical policy 2002, in the next section will highlight the case better. The worst-hit due to these policies are the poor, who directly bear the burnt of any price hike. WHO has estimated that up to 90% of total health spending in poor countries, most of which are on medicines, are out-of-pocket payments. To highlight the need for Access to Essential Medicines, the WHO celebrated the 25th anniversary of the first WHO Model List of Essential medicines with the message that 'Access to Essential Medicines is part of the progressive fulfilment of the fundamental rights to health.' [20] WHO's Action Programme on Essential Drugs had given India a score of two on a scale of five on the issue of accessibility to essential drugs.[21]

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[19] *The World Drug Situation* (Geneva: WHO, 1988)
[20] *Essential Drugs Monitor* (Geneva: WHO, 2003)
[21] *Comparative Analysis of National Drug Policies* (Geneva: Action Programme on Essential Drugs (APED), WHO, 1996)

Indian Drug Industry Fact sheet [22]

	1973	1999
Investment in Indian Pharmaceutical Industry	Rs. 225 crores	Rs. 2500 crores

	1969-1970	1999-2000
Pharmaceuticals units	2,257	20,059

	1965-1966	1999- 2000
Production of bulk drugs	Rs. 18 crores	Rs. 3777 crores
Formulations	Rs. 150 crores	Rs. 16,000 crores
Exports	Rs. 3.05 crores	Rs. 6631 crores
Imports	Rs. 8.2 crores	Rs. 3441 crores
R & D	Rs. 3 crores	Rs. 320 crores

Average profitability of industry	**1969-70**	15.47% of sales
	1991-92	6.1% of sales
	1994-95	1% of sales
	1998-99	8% of sales

Annual per-capita consumption of drugs	**Japan**	$ 412
	Germany	$ 222
	USA	$ 191
	India	$ 3

[22] Source: Drugs and Pharmaceuticals Industry Highlights: Published by National Information Centre for Drugs and Pharmaceuticals, Central Drug Research Institute, Lucknow

	Type of drugs	%
Sale of Pharmaceuticals in Developing Country Markets	Anti-infectives	24
	Vitamins and nutrients.	15
	Alimentary tract diseases	11.5
	Analgesics	9
	Cough and cold	7.4
	Cardio-vascular	6.4
	Dermatogicals	5.7
	Central Nervous System drugs	4.1
	Anti-TB drugs	3.2
	Others	13.7

Research and Development

Global Research and Development Expenditure on Health	**1998**	**$73.5 billion**
	Developed countries public funding	$34.5 billion
	Pharmaceutical Industry majors.	$30.5 billion
	Private not–for–profit	$6 billion
	Developing countries.	2.5%

Global spending on pharmaceuticals research and development in the private sector is $ 34 billion of which companies in the US spend invest than 70%. The top ten Multi-national companies spent $ 16.3billion. The companies are: Astra-Zeneca, Glaxo, Wellcome, Roche, Merck, Novartis, Bristol Myers-Squibb, Johnson and Johnson, Smith Kline Beecham, American Home, Products and Rhone- Poulenc-Rorer. A report by the French NGO MSF titled *'Fatal imbalance: The crisis in Research and development for Drugs in Neglected Diseases'* said that, in its study of the world's top 11 pharmaceutical companies, investment and research in diseases primarily of developing countries occurrences was minimal. Unfortunately, even countries like India with fairly advanced R&D capabilities do not invest much in R&D. The Organisation of Pharmaceutical Producers of India (OPPI) Study revealed that India spent Rs. 320 crores on research and development in the pharmaceutical sector in 1999-2000, which is 0.001% of world pharmaceutical industry. [23]

[23] Source: Financial Express, Mumbai, 6 February 2001

TRIPS and Intellectual Property Rights

The new TRIPS compliant policies, which will come into effect from the year 2005 have caused serious concerns in the industry and social sector. Since the topic is vast and outside the scope of this paper, the concerns will not be elaborated here. However, it is important to find the right balance between protecting Intellectual Property Rights and the basic human and life rights of the people.

In fact the TRIPS agreements itself calls for such an arrangement. Article 7 of the TRIPS Agreement states 'the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology to the mutual advantage of producers and in a manner technological knowledge conductive to social and economic welfare, and to a balance of rights and obligations'. Furthermore, article 8.2 states 'appropriate measures provided they are consistent with the provisions of the Agreement may be needed to prevent the abuse of intellectual property rights by rights holders or the resort to practices which unreasonably transfer of technology. R. A. Mashlekar, the Director General of CSIR has said that the "Ideal intellectual property rights regime strikes a balance between private incentives for innovators and the public interest of maximising access to the fruits of innovation. The balance is reflected in article 27 of the 1948 Universal Declaration on Human Rights, which recognizes that 'Everyone has the right to protection of the moral and material interest resulting from any scientific, literary or artistic production of which s/he is the author' and that 'Everyone has the right to share in scientific advancement and its benefits'. [24]

In light of evidences coming up that that the TRIPS regime could affect Indian people and the industry, policies need to be formulated to address this concern. The Commission on Intellectual Property Rights set up by the British Government said that the global expansion of intellectual property rights unlikely to benefit developing nations. On the other hand, it was most likely to impose high cost- such as highly priced medicines and seeds making poverty reduction more difficult. The independent International Commission comprising of commissioners from developed and developing

[24] R. A. Mashlekar, Current science, 81 (8) , 25 October 2001, p. 955

countries mostly experts in science, law, ethics, and economics also said that in addition, it would also increase in cost of access to many products and technologies. [25]

The South African case of high pricing of anti-retro viral (ARV) drugs for people living with AIDS by the patent holders, is another case in point. Most of African countries and companies (including MNCs) have approached Indian companies for buying ARV at a fraction of the cost offered by the big pharmaceutical companies.

> *Anglo, American, a South African mining giant approached Cipla for anti-AIDS drugs cocktail, which Cipla offers at $359 patient/year – which is one-thirtieth the prices charged by MNCs.*
>
> ***(The Financial Express, 20 August 2002)***

The 1999 Human Development Report also states that the TRIPS agreement on IPR was drawn up with very little analysis of its likely economic impact and should be fully reviewed to create a system that does not exclude developing countries from knowledge or threaten indigenous knowledge or access to healthcare.

Price Control

The Ministry of Chemicals and Petrochemicals statistics point out that 75% of medicines (1919 out of 2557) having annual sales of more than Rs. 1 crore have seen increase in prices. In 38 medicines, the increase is over 100%. In 2000 – 01, the prices of 49% (1245 medicines) increased, while those of 42% (1080 medicines) remained stagnant and 9% medicines (232) prices decreased. In case of most generic, non-scheduled medicines, the retail trade margins range between 300% to as high as 1,000 with the average margins prevailing at about 500%. In spite of these price rises and huge profit margis, the number of drugs under price control has been steadily decreasing over the years owing to industry pressures. Only 33 drugs remain under price control as against the previous 75 drugs (with a total market share of 22% as against the previous 38%). [26]

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[25] *Integrating Intellectual property Rights and Development Policy* (London: Commission on Intellectual Property Rights, 2002)

[26] Economic Times Mumbai, 7 September 2002

PHARMACEUTICAL POLICY 2002 – A CASE STUDY

Orientation

"The drug and pharmaceutical industry in the country today faces new challenges on account of: 1) liberalization 2) globalisation 3) new obligations undertaken by India under the WTO Agreements". ***(Pharmaceutical Policy 2002 Document)***

The policy begins by acknowledging that these are issues, that need to be addressed. People are being affected and will be further affected by these macro-economic policies. So, how does the policy address these issues? By making the industry more viable. There is no mention anywhere about the needs of the common people who are being affected by these changes. The new pharmaceutical policy is basically a industry oriented document. This admission is made in the policy document itself, which states: "These challenges (referring to the above) require a change in emphasis in the current pharmaceutical policy and the need for new initiatives beyond those enumerated in the Drug Policy 1986, as modified in 1994, so that policy inputs are directed more towards 1) promoting accelerated growth of the pharmaceutical industry and 2) towards making it more internationally competitive". These lines set the tone for the entire policy.

Growth of Pharmaceutical Sector

The logic for the government to indulge in a massive decontrol exercise "to promote accelerated growth and improve competitiveness" defeats logic because pharmaceutical stocks, even during the slowdown in rest of industry (except for the automobile sector), were the healthiest in the last quarter of 2001 and 2002. With the announcement of the pharma policy, the pharmaceutical stocks, in particular those of multinational corporations (MNCs), have further shot up.

Pharmaceutical vs. Health

Since medicines are an integral part of the health services package, it is expected that the Pharmaceutical Policy would be linked to the health policy. But our Pharmaceutical Policy preceded the new health policy, which was only declared later. The

pharmaceutical policy comes under the Department of Chemicals and Petrochemicals. According to a press statement issued by the Federation of Medical and Sales Representatives' Association of India (FMRAI), the Ministry of Chemicals and Petrochemicals (MoCF) had earlier circulated secretly a document, Pharmaceutical Policy, 2001, which has now got the Cabinet's approval. Incidentally they have described the new policy as a "major assault on people's access to essential drugs".

Over-ruling Good Sense

The Drugs Price Control Review Committee (DPCRC) had recommended that in the absence of health cover for majority of the population in the country, price controls should be continued till the government expenditure on health rises to a substantial level and the availability of essential drugs is improved. Neither of these has been achieved, yet the Pharmaceutical Policy 2002 has recommended that price controls should be reduced. By reducing the span of price control, the Pharmaceutical Policy 2002 overrules the suggestion of the DPCRC of 1999.

Policy in Data Vacuum

Any Govt. policy is expected to be formulated based on information collected from independent, and the most objective sources. However, the Pharmaceutical Policy 2002 confesses that no reliable data exist to ascertain mass consumption and the absence of sufficient competition in respect of a particular bulk drug - the two criteria which are used for the selection of controlled drugs. The document says that, in the absence of any exhaustive and comprehensive information, the ORG-MARG data are the best available. Hence the policy has been formed in a data vacuum.

TRIPS and Pharmaceuticals

Two major apprehensions of adopting the TRIPS Agreement in the pharmaceutical sector were regarding the higher prices of the patented products and their accessibility. By providing a blanket exemption from price control, the government is making the access to drugs difficult.

Price Control

It is interesting to quote from the background note circulated by the government to the Drug Price Control Review Committee (DPCRC)[27] set up under the chairpersonship of the Secretary, Department of Chemicals and Petrochemicals prior to its deliberations. It said, "The Drug Price Control Order (DPCO) is used as one of the essential instruments to achieve the objective of essential medicines of good quality, at reasonable prices, for the required health care of the masses. It has been an evolutionary process, which has been taking cognisance of ever-emerging new factors".

The "ever-emerging new factors" mentioned were:

- Inadequate machinery to administer the price control orders,
- Industry's demands to do away with price control. The document states: "... The industry, keen to get rid of price controls altogether, has time and again questioned these working principles... However the industry has not been forthcoming in providing data to substantiate their claims."

So, there is no mechanism to administer price controls, and also there is no data to support industry's claims that price controls are detrimental to the consumer, to the economy and to the industry, and that decontrol would actually help R&D.

Consequences of Decontrol

An analysis carried out by the Delhi Science Forum (DSF) on the impact of the 1995 decontrol throws up some interesting facts about the "market behaviour". The price movement of 28 essential drugs - eight under price control and 20 outside it - showed that out of the eight controlled drugs there was a decrease in six of them. On the other hand, the prices of the 20 drugs showed an increase in excess of 10 per cent and in some cases in excess of 20 per cent. More interestingly, the DSF analysis showed that in all segments there were wide variations in the prices of different brands of a given formulation and the top-selling brand in any formulation is not the cheapest one, sometimes twice as expensive. This is proof enough that the market mechanism does not stabilise drug prices and the market share of a brand is not dependent on its price. In

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[27]Background Note on Pharmaceutical paper 2002: Government of India, 2001

fact, the very reason for putting in place a price control mechanism was this atypical market behavior in the case of pharmaceuticals. [28]

Need for Price Control

Analysis in the increase in prices of 50 top-selling drugs between February 1996 and October 1998.[29] It showed that the average increase in the case of brands under price control was 0.1 per cent whereas that in the case of brands outside price control was 15 per cent. It was also found that the price rise was not a one-time increase owing to an escalation in raw material costs but was indicative of a trend of continual increase in the prices of decontrolled drugs.

Market Mechanism & Price Stability

There are wide variations in the prices of different brands of a given formulation. The top-selling brand in any formulation is not the cheapest one, and is sometimes twice as expensive. This is proof enough that the market mechanism does not stabilise drug prices and the market share of a brand is not dependent on its price. In fact, the very reason for putting in place a price control mechanism was this atypical market behaviour in the case of pharmaceuticals.

Drug Price Control Order

When it was argued that the change in the Patents Act would result in an increase in prices, the government said that it would use the mechanism of Drug Price Control Order to keep the prices in check. Now that the Patents Act has been amended, the TRIPS argument is being used to dismantle the DPCO. So, ultimately the industry, supported by the Govt., wins at the cost of the poor.

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[28] A. S. Gupta, Analysis of Pharmaceutical Policy 2002 quoted in FMRAI, *Access to Essential Medicine* (Kolkata: FMRAI, 1986)

[29] *ibid*

Formulations at the Cost of Bulk Drugs

In addition to making higher profit margins for the manufacturer possible, the policy has done away with the **ceiling on profitability on formulations** that existed until now (through the Third Schedule of DPCO 1995). In case of bulk drugs, the manufacturer has been allowed a 4 per cent higher rate of return over the existing 14 per cent on net worth or 22 per cent on the capital employed.

- Considering that more and more manufacturers are moving away from bulk drug manufacture to formulations, this provides an additional windfall.
- With no restriction on imports, pharmaceutical imports (which is largely of bulk drugs) have been rising at the rate of 29.3 per cent while exports (which are mainly of formulations) have been increasing at the rate of 18 per cent, according to the data of the Centre for Monitoring of Indian Economy (CMIE).[30]

Policy Implementation

The Policy uses the Moving Annual Total (MAT) value and market share to determine whether a drug should come under price control. However the companies are known to break up production figures through various means.

Market Forces vs. People's Health Needs

The selection of drugs for price control should be based on health need - namely, the list of essential drugs - and not on market behaviour, which, in the case of drugs, does not follow the norms of other consumables. But this has been the problem with the Indian drug policy over the past four decades, in which the inputs of the health sector are never reflected in the policy articulated by the Department of Chemicals and Petrochemicals, which in turn is influenced by the industry lobby. The policy does not offer any justification as to the final set of criteria that has the effect of keeping three-fourths of the drugs in the market out of price control.

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[30] CMIE: Pharmaceutical Industry data 2001

Pharmaceutical Policy 2002 And *Swaraj*

Medical vs. Health

When examined from an ethical framework of '*swaraj*', as presented in this paper, the policy falters on the first premise itself when it views drugs as a pharmaceutical industry and medical issue and not as 'health and well being' concern. The very fact that the Ministry of chemical and Petrochemicals formulates the pharmaceuticals policy is a grim reminder to this fact.

Self Rule and Self Restraint

The second premise of self rule and self restraint in *swaraj* also contradicts with the Policy where 'accelerated growth' and 'competitiveness' are the key words. Through the two sets of values are not inherently contradictory, the purpose behind each of these concepts places them at loggerheads with each other. While the former is intended to control oneself and benefit others, the latter is intended to benefit oneself and control others.

Egalitarian Concept

The third premise of *swaraj* is an 'egalitarian society', with positive discrimination towards the marginalised. A policy, which does not address the issue of access of essential drugs and services for all, goes against the basic tenets of *swaraj*.

Provision of Basic Amenities

The fourth premise of *swaraj* is the provision of basic amenities, which in pharmaceutical and healthcare terms would translate into availability of accessible, affordable and quality health service. However the policy does not address any of these three key issues.

Truth and Ahimsa

The fifth premise of *swaraj*, which is also the means of achieving it, is that of truth and *ahimsa*. A policy, which bases its assumptions on reports, which are produced and funded by vested interests and players who have a stake in the policy, is far away from the truth. The concept of *ahimsa* calls for pro-active contribution to the well-being of

society and its upliftment. A policy which is explicitly for the well heeded and formed to comply with international norms and industry demands, while totally neglecting the needs of majority of the population is actively against *ahimsà*. The points in the policy which imposes TRIPS compliant conditions while reducing the medicines in the price control list is a case in point.

CONCLUSION

As seen above, the Pharmaceutical Policy 2002, which was created in a data vacuum, contradicts with the existing ground requirements, as seen in the section on health and drug situation, and fails to address the need of providing access to essential drugs for the entire population. As the policy document admits the policy inputs were directed towards: 1) promoting accelerated growth of pharmaceutical industry and 2) towards making it more internationally competitive.

As globalisation increases, and market forces overtake every system of life, it is essential that existing social safety nets be strengthened and new ones be put in place to hold those falling out of the mainstream due to the adverse impacts of globalisation. This is to be done, not as a favour to those who get pushed out of the race, but because they have been wronged and providing safety nets are only ways to prevent further harm. However, new policies like the Pharmaceutical Policy 2002, are taking away even the little self reliance and self sufficiency that was built up over the years. Fifty-five years after India attained political freedom, it is on its way to losing its '*swaraj*', by playing into the hands of few vested, powerful interests. As the value base erodes, so does our '*swaraj*'.

The need of the hour is not narrowly defined nationalism, but an all-inclusive value base, which will provide the basis for governance and citizenship. Health of the citizens would be at the centre of such a value base. All policies would be directed towards achieving 'Health for All'. This is the goal and means of achieving *swaraj*. The dream of achieving 'Health for All' through *swaraj* will become a reality only when every, citizen takes it on as his/her responsibility achieve it and says in the words of Lokamanya Balagangadhar Tilak, that '*Swaraj* is my birth right, and I shall have it'.

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Annexure 1

HEALTH AND RELATED LEGISLATION IN KARNATKA

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November 2003

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Introduction

If the number of laws a land possessed were an indicator of a law-abiding society, India would have been highly ranked among the nations of the world. However, the mere possession of laws and other legal instruments do not ensure a law-abiding society, instead it just adds to the notion of lawlessness (more the laws, more will be the incidents of violations). However, legislations and legal instruments provide an avenue, which could be harnessed by an aware and vigilant civil society to ensure order and social justice.

The need for a vigilant and pro-active civil society has become all the more necessary in view of legislations and decisions increasingly being taken at a global level, way beyond the reach of local communities and very often, even national governments. The World Trade Organisation (WTO) negotiations is a case in point, where nations and continents are subdued into agreeing to norms and agendas that are very often set by powerful Trans-National Corporations (TNCs). However, WTO is not the only mechanisms for remote access and control of national resources and economies. Aid and loan given by industrialized nations and multi-lateral organisations like the World Bank to less-industrialized nations, are often means of coercing them to budge to the machination of powerful vested interests. The governments of the less-industrialized nations have repeatedly failed to stand up to such devices. In such a scenario, it is important for the civil society to be pro-active and work towards strengthening the existing spaces available for people to have access and control over their resources.

Much has been written about the impact of globalization on health. Even the National Health Policy 2001 makes a note of the threats faced by people due to globalization. However sadly, the Government action has been to reduce it's spending on health, even while taking the LPG (liberalization, privatization and globalization) route. More than 80% of health spending is already in the private sector. The opening up of the health sector under the General Agreement of Trade in Services (GATS) could see further changes in the health care scenario in the country.

There is a dire need to explore different ways in which health of the people can be secured. Prioritization of health spending, increasing the health budget and

strengthening the policy and legal environment are a few of the ways, in which this can be achieved. Strengthening the policy and legal environment helps people to stake a claim to health and health care as a right, if it is accompanied with proper enforcing, monitoring, redressing and mass-awareness creating mechanisms. The role of civil society in supporting the process cannot be over-emphasized here.

The knowledge of existing legislation is the first step in enforcing or improving the policy and legal environment. This document attempts to put together the legislations in Karnataka which form a major part of the existing policy environment in the state. However this has to be seen in the context of other policies and practices including the functioning of the Taskforce on Health which was set up the state Government, role of judiciary, rules framed under various Acts and regulations of local bodies like corporations, municipalities, panchayats, etc. and Government Orders (G.O.).

This purpose of this document is to serve a handbook for NGOs, health activists, academicians, Government functionaries, media persons and anybody who wishes to know the existing Acts as provided by the Karnataka state. It has been updated up to December 2002. A few important Acts passed in 2003 have also been included. The website of the Department of Parliamentary Affairs and Legislation, Government of Karnataka (http://dpal.kar.nic.in/) came in handy for preparing the handbook.

This handbook is only a preliminary document and needs to be expanded further to include laws and policies applicable at different levels. A critique of the contents of these laws and policies are also needed for an informed debate and policy refinement. That would be the next step in this journey!

Naveen I. Thomas

September 2003

Note: The following section lists the various Acts of Karnataka state, which have a link with health. The Acts of Karnataka state have been divided into seven sections:

1) Health related Acts
2) Agriculture/ Veterinary/ Animal related Acts
3) Urban related Acts
4) Rural related Acts
5) Tobacco/ Alcohol related Acts (including industrial use)
6) General Acts

Health related Acts

Sl.	Act	Amendment(s) / Remarks
1.	Anatomy Act, 1957 (23 of 1957)	Amended by Act 15 of 1999
2.	Ayurvedic, Naturopathy, Siddha, Unani and Yoga (Registration and Medical Practitioners) Miscellaneous Provisions Act, 1961 (9 of 1962)	Amended by Act 9 of 1966, 32 of 1966, 3 of 1968, 8 of 1969, 13 of 1972, 7 of 1977, 46 of 1981, 38 of 1991 and 11 of 1992
3.	Health Cess Act, 1962 (28 of 1962)	Amended by Acts 19 of 1968, 33 of 1976
4.	Medical Registration Act, 1961 (34 of 1961)	
5.	Nurses, Midwives and Health Visitors Act, 1961 (4 of 1962)	Amended by Act 27 of 1981
6.	Private Nursing Homes (Regulation) Act, 1976 (75 of 1976)	Amended by Act 9 of 1977
7.	Rajeev Gandhi Health Sciences University Act, 1994 (44 of 1994)	Amended by Act 11 of 1998
8.	District Vaccination Act 1892 (Bombay Act I of 1892)	Act which is in force in Belgaum area
9.	Drugs (Control) Act, 1952, (Bombay Act XXIX of 1952)	Act which is in force in Belgaum area

10.	Female Infanticide Prevention (Amendment) Act, 1897 (Bombay Act III of 1897)	Act which is in force in Belgaum area
11.	Indian Lunacy (Bombay Amendment) Act, 1938 (Bombay Act XV of 1938)	Act which is in force in Belgaum area
12.	Nursing Homes Registration Act, 1949 (Bombay Act XV of 1949)	Act which is in force in Belgaum area
13.	Vaccination Act, 1877 (Bombay Act I of 1877)	Act which is in force in Belgaum area
14.	Indian Medical Degrees (Coorg Amendment) Act, 1949 (Coorg Act IV of 1949)	Act which is in force in Coorg area
15.	Public Health Act, 1943 (Coorg Act I of 1943)	Act which is in force in Coorg area
16.	Vaccination Act, 1950 (Coorg Act IV of 1950)	Act which is in force in Coorg area
17.	Infections Diseases Act, 1950 (Hyderabad Act XII of 1950)	Act which is in force in Gulbarga area
18.	Vaccination Act, 1951 (Hyderabad Act XXIV of 1951)	Act which is in force in Gulbarga area
19.	Dangerous Drugs (Madras Amendment) Act, 1950 (Madras Act XVI of 1950)	Act which is in force in Mangalore – Kollegal area
20.	Drugs (Control) Act, 1949 (Madras Act XXX of 1949)	Act which is in force in Mangalore – Kollegal area
21.	Medical Degrees (Madras Amendment) Act, 1940 (Madras Act XX of 1940)	Act which is in force in Mangalore – Kollegal area
22.	Opium and Dangerous Drugs (Madras Amendment) Act, 1947 (Madras Act XXXIV of 1947)	Act which is in force in Mangalore – Kollegal area
23.	Opium (Madras Amendment) Act, 1951 (Madras Act XXXII of 1951)	Act which is in force in Mangalore – Kollegal area
24.	Public Health Act, 1939 (Madras Act III of 1939)- Amended by Karnataka Act 13 of	Act which is in force in Mangalore – Kollegal area

	1965, 83 of 1976.	
25.	Tuberculosis Sanetoria (Regulation of Buildings) Act, 1947 (Madras Act XVI of 1947)	Act which is in force in Mangalore – Kollegal area
26.	Drugs Control Act 1950 (Mysore Act V of 1950)	Act which is in force in Mysore area
27.	Lepers Act, 1925 (Mysore Act IV of 1925)	- Act which is in force in Mysore area - Amended by Karnataka Act 13 of 1965
28.	Public Health Act, 1944 (Mysore Act 10 of 1944)	- Act which is in force in Mysore area - Amended by Karnataka Act 13 of 1965
29.	Vaccination Act, 1906, (Mysore Act I of 1906)	- Act which is in force in Mysore area

Agriculture/ Veterinary/ Animal related

Sl.	Act	Amendment(s) / Remarks
1.	Agricultural Pests and Diseases Act, 1968 (1 of 1969)	
2.	Animal Diseases (Control) Act, 1961 (18 of 1961)	
3.	Live-Stock Improvement Act, 1961 (30 of 1961)	
4.	Sheep and Sheep Products Development Act, 1973, (12 of 1974)	- Amended by Acts 22 of 1978 and 20 of 1980 - Proposed for Repeal
5.	Prevention of Cruelty to Animals (Bombay Amendment) Act, 1953 (Bombay Act XXII of 1953)	Act which is in force in Belgaum area
6.	Prevention of Cruelty to Animals, the Bombay District Police and the City of Bombay Police (Amendment) Act, 1946 (Bombay Act XXVIII of 1946)	Act which is in force in Belgaum area
7.	Improved Seeds and Seedling Act, 1951 (Hyderabad Act XXVIII of 1951)	Act which is in force in Gulbarga area
8.	Restriction of Cash Crops Cultivation Regulation (Repealing) Act, 1953 (Hyderabad Act XIV of 1953)	Act which is in force in Gulbarga area
9.	Slaughter of Animals Act, 1950 (Hyderabad Act VII of 1950)	Act which is in force in Gulbarga area

Urban

Sl.	Act	Amendment(s) / Remarks
1.	Bangalore Water Supply and Sewerage Act, 1964 (36 of 1964)	Amended by Acts 6 of 1966, 10 of 1966 and 18 of 1984
2.	Prohibition of Beggary Act, 1975 (27 of 1975)	Amended by Acts 7 of 1982 and 12 of 1988
3.	Karnataka Slum Areas (Improvement and Clearance) Act, 1973 and Karnataka Public Premises (Eviction of Unauthorized Occupants) Act, 1974 (33 of 1974)	Amended by Acts 19 of 1981, 34 of 1984, 26 of 1986, 7 of 1988 and 21 of 2002
4.	Urban Water Supply and Drainage Board Act, 1973 (25 of 1974)	Amended by Acts 7 of 1976, 20 of 1977, 45 of 1981 and 19 of 1993
5.	Urban Development Authorities Act, 1987 (34 of 1987)	Amended by Acts 17 of 1991, 14 of 1992 and 12 of 1996
6.	The Karnataka Slum Areas (Improvement and Clearance) and Certain Other Law (Amendment) Act, 2002 (21 of 2002)	

Rural

Sl.	Act	Amendment(s) / Remarks
1.	Panchayat Raj Act 1993 (14 of 1993)	Amended by 10 of 1995, 9 of 1996, 17 of 1996, 1 of 1997, 10 of 1997, 29 of 1997, 29 of 1998, 10 of 1999, 21 of 1999, 8 of 2000, 11 of 2000 and 30 of 2001
2.	Village Defence Parties Act, 1964 (34 of 1964)	Amended by Act 22 of 2000
3.	Village Offices Abolition Act, 1961 (14 of 1961)	Amended by Acts 8 of 1968, 13 of 1978, 27 of 1984, 47 of 1986 and 22 of 2000

Tobacco/ Alcohol Related

Sl.	Act	Amendment(s) / Remarks
1.	Excise Act, 1965 (21 of 1966)	Amended by Acts 1 of 1970, 1 of 1971, 61 of 1976, 32 of 1982 28 of 1987, 36 of 1987, 1 of 1994, 2 of 1995. 7 of 1997, 21 of 98, 12 of 1999, 21 of 2000 and 15 of 2001
2.	Prohibition Act, 1961 (1 of 1962)	Amended by Act 10 of 1967
3.	Prohibition of Smoking in Show Houses and Public Halls Act, 1963 (30 of 1963)	
4.	Toddy Worker's Welfare Fund Act, 1981 (31 of 1994)	
5.	The Karnataka Prohibition of Smoking and Protection of Health of Non-Smokers Act, 2001 (2 of 2003)	
6.	(District) Tobacco Act, 1933 (Bombay Act II of 1933)	Act which is in force in Belgaum area
7.	Opium Smoking Act, 1936 (Bombay Act XX of 1936)	Act which is in force in Belgaum area
8.	Smoke-nuisances Act, 1912 (Bombay Act VII of 1912)	Act which is in force in Belgaum area
9.	Tobacco Duty (Town of Bombay) Act, 1857 and the Bombay (District) Tobacco Act, 1933 (Suspension) Act, 1945 (Bombay Act XI of 1945)	Acts which are in force in Belgaum area
10.	Power Alcohol Act, 1350 F (Hyderabad Act XI of 1350 F)	Act which is in force in Belgaum area
11.	Cigarette- Tobacco Safeguarding Act, 1939 (Mysore Act VI of 1939)	Act which is in force in Mysore area
12.	Power Alcohol Act, 1939, (Mysore Act VIII of 1939)	Act which is in force in Mysore area

General

Sl.	Act	Amendment(s) / Remarks
1.	Civil Services (Prevention of Strikes), Act, 1966 (30 of 1966)	Amended by Act 6 of 1967
2.	Civil Services (Regulation of Promotion, Pay & Pension) Act, 1973 (11 of 1974)	Amended by Acts 40 of 1976 and 25 of 1982
3.	Co-operative Societies Act, 1959 (11 of 1959)-	Amended by Acts 40 of 1964, 27 of 1966, 16 of 1967, Presidents Act 1 of 1972, Karnataka Acts 14 of 1973, 2 of 1975, 39 of 1975, 19 of 1976, 70 of 1976, 71 of 1976, 14 of 1978, 16 of 1979, 3 of 1980, 4 of 1980, 5 of 1984, 34 of 1985, 34 of 1991, 25 of 1998, 2 of 2000, 13 of 2000, 6 of 2001 and 24 of 2001
4.	Debt Relief Act, 1976 (25 of 1976)	Amended by Act 63 of 1976
5.	Departmental Inquiries (Enforcement of attendance of Witnesses and Production of Documents) Act, 1981 (29 of 1981)	Amended by Acts 43 of 1981 and 28 of 1986
6.	Devadasis (Prohibition of Dedication) Act, 1982 (1 of 1984)	
7.	Evacuee Interest (separation) Supplementary Act, 1961 (3 of 1961)	
8.	Existing Laws (Construction of References to Values) Act, 1957 (12 of 1957)	
9.	Essential Services Maintenance Act, 1994 (21 of 1994) (for a period of 10 years from the date of commencement i.e., 16-4-1994)	

10.	Famine Relief Fund Act, 1963 (32 of 1963)	
11.	Lokayukta Act, 1984 (4 of 1985)	Amended by Act 15 of 1986, 31 of 1986, 1 of 1988 and 30 of 1991
12.	Prohibition of Admission of Students to the Un- recognised and Un-affiliated Educational Institutions Act, 1992 (7 of 1993)	
13.	Resettlement of Project Displaced Persons Act, 1987 (24 of 1994)	
14.	Repealing and Amending Act, 2000 (22 of 2000)	
15.	Right to information Act, 2000 (28 of 2000)	
16.	Societies Registration Act, 1960, (17 of 1960)	Amended by Acts 1965, 20 of 1975, 65 of 1976, 7 of 1978, 48 of 1986, 11 of 1990, 9 of 1999, 7 of 2000 and 6 of 2002
17.	State Aid to Industries Act, 1959 (9 of 1960)	Amended by Acts 3 of 1964 and 20 of 1978
18.	State Commission for Women Act, 1995 (17 of 1995)	
19.	State Universities Act, 2000 (29 of 2001)	
20.	Transparency in Public Procurement Act 1999 (29 of 2000) and 21 of 2001	
21.	The Karnataka Fiscal Responsibility Act, 2002 (16 of 2002)	
22.	Charitable Endowments Act, 1890. (Central Act 6 of 1890)	This is a Central Act which has been amended by the Karnataka Act 19 of 1973
23.	Famine Relief Fund Act, 1936 (Bombay Act XIX of 1936)	Act which is in force in Belgaum area

24.	Fodder and Grain Control Act, 1939 (Bombay Act XXVI of 1939)	Act which is in force in Belgaum area
25.	Growth of Foodcrops Act, 1944 (Bombay Act VIII of 1944)	Act which is in force in Belgaum area
26.	Hindu Women's Rights to Property (Extension to Agricultural Lands) Act, 1947 (Bombay Act XIX of 1947)	Act which is in force in Belgaum area
27.	Molasses (Control) Act, 1956 (Bombay Act XXXXVIII of 1956)	Act which is in force in Belgaum area
28.	Refugees Act, 1948 (Bombay Act XXII of 1948)	Act which is in force in Belgaum area
29.	State Guarantees Act, 1954 (Bombay Act XXII of 1954)	Act which is in force in Belgaum area
30.	Village Industries Act, 1953 (Bombay Act XLI of 1954)	Act which is in force in Belgaum area
31.	(Emergency Powers) Whipping Act, 1947 (Bombay Act XXVII of 1947)	Act which is in force in Belgaum area
32.	Abolition of Whipping Act, 1956 (Hyderabad Act XXXVI of 1956)	Act which is in force in Gulbarga area
33.	Children Protection Act, 1343 F (Hyderabad Act IX of 1343 F)	Act which is in force in Gulbarga area
34.	Famine (Stricken Pettadars Property Protection Act, 1931 F (Hyderabad Act III c.1381 F)	Act which is in force in Gulbarga area
35.	Labour Housing Act, 1952 (Hyderabad Act XXXVI of 1952)	Act which is in force in Gulbarga area
36.	Mining Settlements Act, 1956 (Hyderabad Act XLIV of 1956)	Act which is in force in Gulbarga area
37.	Poisons Act 1322 F (Hyderabad Act IV of 1322 F)	Act which is in force in Gulbarga area
38.	Protection of Flood Stricken Debtors Property Act, 1318F (Hyderabad Act I of 1318 F)	Act which is in force in Gulbarga area

39.	Protection of Houses from the Floods of Mossi River Act, 1318 F (Hyderabad Act II of 1318 F)	Act which is in force in Gulbarga area
40.	Sati Regulation, 1830 (Madras Regulation I of 1830)	Act which is in force in Mangalore – Kollegal area
41.	Essential Articles Control and Requisitioning (Temporary Powers) Act, 1949 (Madras Act XXIX of 1949)	Act which is in force in Mangalore - Kollegal area
42.	Essential Articles Control and Requisitioning (Temporary Powers Re-enacting) Act, 1956 (Madras Act VI of 1956)	Act which is in force in Mangalore - Kollegal area
43.	Famine Relief Fund Act, 1936 (Madras Act XVI of 1936)	Act which is in force in Mangalore - Kollegal area
44.	Prevention of Couching Act, 1945 (Madras Act XXI of 1945)	Act which is in force in Mangalore - Kollegal area
45.	Rivers Conservancy Act, 1884 (Madras Act VI of 1884)	Act which is in force in Mangalore - Kollegal area
46.	Abolition of Whipping Act, 1949 (Mysore Act XII of 1949)	Act which is in force in Mysore area
47.	Betting Tax Act, 1932 (Mysore Act IX of 1932)	- Act which is in force in Mysore area - Amended by Karnataka Acts 11 of 1958, 7 of 1974, 22 of 1980, 20 of 1981, 21 of 1989, 18 of 1994, 6 of 1995, of 1997, 3 of 1998, 5 of 2000
48.	Essential Service (Maintenance) Act, 1942 (Mysore Act XXIII of 1942)	Act which is in force in Mysore area
49.	Limitation (War Conditions) Act, 1947 (Mysore Act I of 1947)	Act which is in force in Mysore area

50.	Lotteries and Prize Competitions Control and Tax Act, 1951 (Mysore Act XXVII of 1951)	- Act which is in force in Mysore area - Amended by Karnataka Acts 26 of 1957, 13 of 1965)
51.	Pension Act, 1871 (Mysore Act XXII of 1871)	Act which is in force in Mysore area
52.	Poisons Act, 1910 (Mysore Act 10 of 1910)	Act which is in force in Mysore area