

Approach Paper on Public Health Act

Task Force on Public Health Act

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BACKGROUND

Public Health is "the science and art of preventing disease, prolonging life and promoting health through the organized efforts and informed choices of society, organizations, public and private, communities and individuals"¹. And **Public Health Law** is the study of the legal powers and duties of the state, in collaboration with its partners, to ensure the conditions for the people to be healthy, and of the limitations on the power of the state to constrain for the common good the autonomy, privacy, liberty, proprietary, and other legally protected interests of individuals². **Public Health Law** essentially regulates the Core public health functions.

ESSENTIAL / CORE PUBLIC HEALTH FUNCTIONS / SERVICES

The Essential Public Health Functions / Services provide a working definition of public health and a guiding framework for the responsibilities of local public health systems. Many attempts to arrive at the essential functions are available; by APHA (American Public Health Association)³, CDC (Centre for Disease Control)⁴, PAHO (Pan American Health Organisation)⁵ and by WHO (World Health Organisation)⁶ being the major ones.

These services, unlike medical services, are largely invisible to the public. These services produce public goods which are of high priority for assuring good health outcomes. When public health systems falter people pay a high price in illness, debility and death. Public health outcomes, however, are influenced by a wide range of factors, many of them outside the direct ambit of public health sector agencies. Thus, to assure good health outcomes, health agencies have to engage continuously with a wide range of actors through advocacy, coordination, monitoring, oversight and regulation.

Law serves public health in at least two ways: First, law is itself a component of the public health infrastructure. 'Infrastructure' public health laws include legislatures' enactments that authorize the creation of government public health agencies and other statutes that endow them with broad legal authorities, for example, the authority to gather data, inspect, license, educate, and design interventions. "Interventional" or categorical public health laws are narrower in scope and seek to prevent or limit the danger posed by specific threats to health,

¹ Winslow, Charles-Edward Amory (1920 Jan 9). "The Untilled Fields of Public Health". Science 51 (1306): 23-33

² Lawrence O Gostin. Public Health Law: Power, Duty, Constraint. University of California Press. 2nd edition. 2008. Pg. 4

³ <http://www.apha.org/programs/standards/performancestandardsprogram/resexentialservices.htm>

⁴ <http://www.cdc.gov/nphpsp/essentialServices.html>

⁵ http://www.paho.org/english/DPM/SHD/HR/EPHF_2000-2007.pdf

⁶ <http://whqlibdoc.who.int/wpro/2003/9290610824.pdf>

examples include the authority to restrict minor' access to cigarettes, chlorinate public drinking water, mandate child safety seats in cars, quarantine people exposed to communicable diseases. What is dealt within this paper has overlapping components of both of these dimensions.

The fundamental problem with our response to public health emergencies is inadequate legal authority and many health department positions being staffed by individuals who are not properly trained and do not have adequate experience in public health regulation. The general inability to respond to public health threats generally, range from food borne illness to emerging infectious diseases and the growing threat that microbial resistance or newer diseases or morbidities will reverse much of the progress already attained. Although some States have the adequate legal authority to collect information about communicable diseases and to impose personal restrictions, they have failed to use the existing laws appropriately on account of non availability of skilled persons or ignorance about the public health importance of such laws.

WHAT IS THE CONSTITUTIONAL DESIGN OF PUBLIC HEALTH LAW?

The Constitution of India enumerates the separate and shared legislative powers of Parliament and State Legislatures in three separate lists under Schedule VII: the Union List, the State List and the Concurrent List.

The Parliament and State legislatures share authority over matters on the Concurrent List, which include: health related economic and social planning; population stabilization and family planning; mental health; drugs; food safety; labour safety and welfare, including maternity benefits; prevention and control of communicable diseases or vectors affecting humans; registration of births and deaths and other vital statistics for health; social security and social insurance; employment; education; legal and medical professions. Laws passed by Parliament with respect to matters on the Concurrent List supersede laws passed by state legislatures.

On the matters under Union List, the Parliament of course has total and absolute supremacy, which include matters like entering into and implementing international treaties and agreements, apart from some specifically health related matters like port quarantine, including hospitals connected therewith; seamen's and marine hospitals; regulation of labour and safety in mines and oilfields.

The Parliament generally has no power to legislate on items from the State List, which include matters like public health, hospitals & dispensaries, water and sanitation. However, two-thirds of the Rajya Sabha may vote to allow parliament to pass binding legislation on any state issue if "necessary or expedient in the national interest". In addition, two or more States may ask

Parliament to legislate on an issue that is otherwise reserved for the States. Other states may then choose to adopt / adapt the resulting legislation.

Constitution of India places obligations on the State to ensure protection and fulfilment of right to health to all, without any discrimination, as a fundamental right, by interpretation, under Articles 14, 15 and 21 (fundamental right to life, equality and non-discrimination); Article 23 (prohibition of traffic in human beings and forced labour); and Article 24 (prohibition of employment of children in factories, etc.); and also urges the State, under the Directive Principles of State Policy, to strive to provide to everyone certain vital public health conditions such as right to work, to education and to public assistance in certain cases (Article 41); just and humane conditions of work and maternity relief (Article 42); raised level of nutrition and the standard of living and to improve public health (Article 47); and protect and improve environment and safeguard forests and wild life (Article 48); and identifies certain concomitant fundamental duties like obligating every citizen to protect and improve the natural environment (Article 51). Independent India has legislated in various areas which has a direct implication on health; which is listed in annexure 2.

EXISTING PUBLIC HEALTH LEGISLATIONS IN INDIA AND NEED FOR A NEW BILL

Over a period of time, parliaments (Centre /State) have enacted legislations in public health. Since 'Public Health' was a state subject, the enactment was basically by the states. As of now there are 8 states with a public health law/draft in place. Many of these laws have been ineffective due to various reasons. Some of the States have then revised the legislations in order to address the issue of implementation. Tamil Nadu, for instance, revised their act, with 13 amendments after its first promulgation in 1939.

The reasons for the amendments made to the State acts are varied; some common and some State specific. The Central government, understanding the importance of uniform public health legislation across its States, meanwhile entrusted various agencies to draft model Public Health Acts. As of now, we have 3 such drafts in place; the Model Public Health Bill by Central Bureau of Health Intelligence (1987); the National Public Health Bill by National Institute of Communicable Diseases (2002); and the National Health Bill by the MoHFW Task Force (2009).

In the meantime, some States also came up with newer drafts on public health legislation. All the Acts have covered areas conventionally thought to be regulated by public health laws; water supply, drainage, buildings & lodging houses, sanitary conditions in fairs and festivals, parks, notifiable diseases, communicable diseases, markets, slaughter houses, burial grounds etc. The older drafts have largely used a 'Coercive based approach' and the newer ones have

used a 'Rights based approach' to legislation. The scope of each enactment is given in the annexure 1.

The Public Health legislations (State and Central - models) existing as of now are archaic and requires a re-thinking in its approach to dealing with public health problems in India. The ambit of the Act also needs to forecast the developments in the next few decades as well. The isolated ventures now need to be united by a common purpose, principles and direction. A fresh dedicated legislative intervention covering the entire gamut of public health, as we understand today, and how probably it function tomorrow, is required. The Task Force, instead of correcting the existing drafts, is hence proposing the development of a new draft, which should be promulgated within a stipulated timeframe.

WHAT ARE THE APPROACHES TO LEGISLATIVE DRAFTING?

Broadly two approaches to legislative drafting is possible; one is a coercive based approach and the other is a rights based approach. Brief descriptions of the approaches are given below.

Coercive approach

The approach tries to argue: 'Why governments have an enduring obligation to protect and promote the public's health?'. It uses theories of democracy to explain the government's role in matters of population health. People form governments for their common defense, security, and welfare; goods than can be achieved only through collective action. A political community stresses a shared bond among members; organized society safeguards the common goods of health, welfare, and security, while members subordinate themselves to the welfare of the community as a whole. The community hence has a stake in environmental protection, hygiene and sanitation, clean air and surface water, uncontaminated food and drinking water, safe roads and products, and control of infectious diseases. But people still incline to acts which are not for the neighbor's good. In our intricate civilization, many restrictions must be placed on individual conduct in order that we may live happily and healthfully one with another.

The word public in public health has two overlapping meanings - one refers to the entity that takes primary responsibility for the public's health and another that indicates who has a legitimate expectation of receiving the benefits. The government has primary responsibility for the public's health. The government is the public entity that acts on behalf of the people and gains its legitimacy through a political process. A characteristic form of public or state action occurs when a democratically elected government exercises powers or duties to protect or promote the population's health. The population as a whole has a legitimate expectation of

benefitting from public health services. The population elects the government and holds the state accountable for a meaningful level of health protection.

The field of public health would profit from a vibrant conception of the common that sees the public interest as more than the aggregation of individual interests. A non-aggregative understanding of public goods recognizes that everyone benefits from living in a society that regulates the risks shared by all. Laws designed to promote the common good may sometimes constrain individual actions.

In medicine, the meaning of the word 'good' is defined purely in terms of individuals wants and needs. It is the patient, not the physician or family, who decides the appropriate course of action. In public health, the meaning of 'good' is far less clear. Who decides which value is more important - freedom or health? One strategy for public health decision making would be to allow people to decide for themselves, but this would thwart many public health initiatives. Individuals have to make decisions despite cognitive limitations. Most people cannot process complex scientific information to arrive at an informed choice. They also face informational deficits - decision making without full and accurate information about the risks. In addition to cognitive and informational constraints, individuals have limited will power, as well.

Government can do many things to safeguard the public's health and safety that do not require the exercise of compulsory powers, and the state's first recourse should be voluntary measures. Yet government alone is authorized to require conformance with publicly established standards of conduct. Governments are formed not only to attend to the general needs of their constituents, but to insist, through force of law, if necessary, that individuals and businesses act in ways that do not place others at unreasonable risk of harm.

Protecting and preserving community health is not possible without constraining a wide range of private activities that pose unacceptable risks. Private actors can profit by engaging in practices that damage the rest of the society. Although regulation in the name of public health is theoretically intended to safeguard the health and safety of whole populations, it often benefits those most at risk of injury and disease. Everyone gains value from public health regulations, such as food and water standards, but some regulations protect the most vulnerable (e.g. closing an unhygienic restaurant). Frequently, those at increased risk are particularly vulnerable due to their race, gender, or socio-economic status.

Perhaps because engaging in risk behaviour may promote personal or economic interests, individuals and businesses frequently oppose government regulation. Resistance is sometimes based on philosophical grounds of autonomy, choice, or freedom from government interference. Citizens, and groups that represent them, claim that regulating self-regarding behaviours, such as use of seat belts or motorcycle helmets, is not the business of government.

Entrepreneurs tend to accept as a matter of faith that governmental health and safety standards retard economic development and should be avoided. Public health has historically constrained the rights of individuals and businesses so as to protect community interests in health - whether through the use of reporting requirements affecting privacy, mandatory testing or screening affecting autonomy, environmental standards affecting property, industrial regulation affecting economic freedom, or isolation and quarantine affecting liberty.

Public health powers can legitimately be used to restrict human freedoms and rights to achieve a collective good, but they must be exercised consistently with constitutional and statutory constraints on state action. The inherent prerogative of the state to protect public's health, safety and welfare is limited by individual rights to autonomy, privacy, liberty, property, and other legally protected interests. Achieving a just balance between constitutionally protected rights, and the powers and duties of the state to defend and advance the public's health poses an enduring problem for public health law.

Public health decision making, hence involves complex trade-offs between public goods & private interests. Distinct tensions exist in public health law between voluntarism and coercion, civil liberties and public health, and discrete health threats and aggregate health outcomes. These competing interests, and the substantive standards and procedural safeguards that circumscribe the lawful exercise of state powers, form the corpus of public health law.

Any theory of public health law would present this paradox. Government, on the one hand is compelled by its role as the elected representative of the community to act affirmatively to protect the health of the people. On the one hand, government cannot unduly assault individual rights in the name of communal good. Health regulation that over-reaches, in that it achieves a minimal health benefit with disproportionate human burdens, conflicts with ethical considerations and is not tolerated in a society based on rule of law. Consequently scholars and practitioners often perceive a tension between community's claims to reduce obvious health risks and individuals claim to be free from government interference.

Rights based approach

There is little doubt that most Indians continue to live in abysmally poor health conditions, deprived of basic health services and facilities, and where available subjected to inhuman and degrading treatment. The disease burden of Indians is so severe that it is not merely a health or a medical issue; it affects the very life fabric of Indians in every possible way. It persists in a vicious circle where it undermines the general socio-economic status and in turn right to health and well-being of population stays a distant goal due to the poor development of the underlying determinants of health that further impede its full realization. The long way the

country have to traverse in these areas, will essentially require the power of law so that the change gain a certain optimum momentum.

UN Committee on Social, Economic & Cultural Rights, affirmed that; “The realization of the right to health may be pursued through numerous, complementary approaches, such as the formulation of health policies, or the implementation of health programmes developed by the World Health Organization (WHO), or the adoption of specific legal instruments.”⁷

Union of India has signed various treaties, agreements and declarations specifically undertaking to provide right to health like: Universal Declaration of Human Rights (UDHR): Article 25 (1) (*“Everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services”*); International Covenant on Economic, Social and Cultural Rights (ICESCR): Article 12 (*“the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”*); Convention on the Rights of the Child (CRC): Article 24; Convention on the Elimination of All Forms of Discrimination against Women (CEDAW): Article 12; UN Convention on Rights of persons with disabilities (UNCRPD): Article 25, among others.

The right to health has also been proclaimed by the Commission on Human Rights, (in its resolution 1989/11) as well as in the Vienna Declaration and Programme of Action of 1993 and several other international instruments like: Declaration of Alma Ata (1978); Principles for the Protection of Persons with Mental Illness and the Improvement of Mental Health Care (1991); Declaration on the Elimination of Violence against Women (1993), Programme for Action of the International Conference on Population and Development, Cairo (1994); Platform of Action for the Fourth World Women’s Conference, Beijing (1995) and the Millennium Development Goals (2000); Declaration of Commitment on HIV/AIDS, ‘Global Crisis-Global Action’ (2001), International Health Regulations, and resolutions of the 58th World health Assembly (2005).

Several regional human rights instruments also recognize the right to health, such as the European Social Charter of 1961 as revised (Art. 11), the African Charter on Human and Peoples' Rights of 1981 (Art. 16) and the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights of 1988 (Art. 10).

⁷ UN Committee on Social, Economic & Cultural Rights, Twenty-second session, Geneva, 25 April-12 May 2000, General Comment No. 14, Para 1

It is noteworthy, here, that the central government is obligated (Under Article 253 of the Constitution of India) to give effect / legislate towards honoring its international obligations in any area, including in the area of health.

WHAT SHOULD BE THE APPROACH TO LEGISLATION: RIGHTS BASED OR COERCIVE?

When we look at the recent bills on public health, they have shown a tendency to move from coercive based to rights based approach. Why this change and are there any learnings from this experience? Well, there are certain advantages rights based approach has over the coercive based approach that one could consider;

- The rights language, with its inherent ***strong universal appeal*** that even an ordinary person can most easily relate to, helps link somewhat complex issues of health, and provide a common rallying point that can be easily taken up by people anywhere.
- Rights create a convenient avenue for demands to be raised and thus ***empower individuals, communities and organizations***, enabling them to negotiate for and demand in a specific, concrete way, particular services and facilities.
- The rights approach ***focuses on functional outcomes***, and measures all policy changes or declarations in terms of ***what people actually receive*** in terms of real entitlements towards their health needs. The rights approach thus ***provides a balancing corrective*** to the usual 'input based perspective' of officials by providing an output-based viewpoint.
- When the idiom of health rights becomes part of the overall discourse, automatically the related ***services become understood as public resources, to be universally accessible***.
- By their essential character, ***rights lend themselves to expansion and universalisation***. Once certain rights become established generally, they become a precedent for specific groups or marginalized sections to demand rights to address their special needs and vulnerabilities. Thus the rights approach naturally ***strengthens the claims of the disadvantaged*** and vulnerable sections of society, and helps challenge discrimination.
- ***Rights once granted cannot be easily reversed***, thus there is a pre-determinability, transparency and ascertainability to their contents inspiring greater confidence.
- Rights framework is indicative of political will transcending change in governments and party politics.

- As against the vertical, top down, welfare approach, rights are the reflection and growth of inherently ***inclusive and participatory processes, with strong community involvement and horizontal inter-linkages between the range of stake-holders***, and a stronger ownership by and among them, thus having much greater chances of their acceptability, use, implementability and accountability.

Despite the advantages stated above, this (rights based) approach, if solely used, can lead to situations where people are accessing judicial remedy where judicially discoverable & manageable standards for resolving it are unavailable. In the ordinary run of litigation, decision making occurs naturally within the context of a traditional case. Both the propriety of invoking the power of the court and the presentation of essential facts are defined under the legal provision (act) under question. If Justiciability is to be ensured, one must provide for a 'locus standi' within the framework of Public Health Law. Applying this principle to the context would mean a commitment by the respective governments (e.g. State) with a clear assurance of a 'package of services' offered through public or publically financed private facilities, without mandatory payments at the time of need, so that individuals ability to pay would not limit access to good quality services that are part of the package. This commitment, on the 'health care service entitlements' in the convergent areas and the authorities responsible to ensure the provision of these services will evolve over a period of time. The current legislation (PH Act) can only incorporate the existing 'commitments' and make provision for 'coordinated action' with the ones coming up in future. Hence, to address the limits upon the legal issues over which a court can exercise its judicial authority, (including locus standi), one must use a mixed approach. This will ensure Justiciability of the provisions of the act.

SHOULD THE ACT COVER ONLY 'PUBLIC HEALTH' OR ALL SOCIAL DETERMINANTS OF HEALTH AS WELL?

The understanding on 'health' has grown beyond its medical determinants, especially in the last decade. There is now sufficient understanding the world over that health is not absence of disease or infirmity. Committee on Economic, Social and Cultural Rights set up under the International Covenant on Economic, Social and Cultural Rights (ICESCR) has authoritatively interpreted health in a much larger, non-medicalised, social framework, tightly linking it up with the underlying socio-economic determinants. The Committee has elaborated upon the "right to the highest attainable standard of health" mandated under Article 12 of ICESCR to mean⁸: "as an inclusive right extending not only to timely and appropriate health care but also to the

⁸ Twenty-second session, Geneva, 25 April-12 May 2000, General Comment No. 14

underlying determinants of health, such as access to safe and potable water and adequate sanitation, an adequate supply of safe food, nutrition and housing, healthy occupational and environmental conditions, and access to health-related education and information, including on sexual and reproductive health.”⁹

The Committee has further stated: “The right to health is closely related to and dependent upon the realization of other human rights, as contained in the International Bill of Rights, including the rights to food, housing, work, education, human dignity, life, non-discrimination, equality, the prohibition against torture, privacy, access to information, and the freedoms of association, assembly and movement. These and other rights and freedoms address integral components of the right to health.”¹⁰

The law could therefore cover not just medical aspects of health but also the social, environmental, even cultural, economic and political aspects of health. Public health and health care are clearly interrelated and interdependent - they share the common vision of ensuring good health for all and often pursue overlapping strategies to achieve this vision. Again, dimensions of public health have been constantly evolving, and have changed the practice of medicine as well, to include areas such as human behaviour and mental health.

However, having a textually demonstrable legal commitment on the social determinants of health in public health is not maintainable. The people faced with denial of a social determinant is expected to litigate under those other laws dealing with them, but the linkage (as a function of the public health authorities) will be as framed by the Health Impact Assessment made under this law.

CENTRAL ACT OR MODEL ACT FOR THE STATES

First option would be to go by the Constitutional design of Public Health Law. This would mean that the State mandate on legislating in the area of public health is respected and the draft prepared at the Central level will only be a model Public Health Act.

The second option would be to get 2 or more states to request the parliament to legislate under article 252 of the Constitution, like the approach taken for the Clinical Establishments Act. In that case, State consultations would focus on making them (States) consider adopting or adapting (if the state already has an act in place) the Central act.

⁹ Para 11, General Comment No. 14 (2000)

¹⁰ Para 3, General Comment No. 14 (2000)

The third approach would be to rationalize on the mandate of the public international law (treaties / agreements) to which India is a signatory. This proposal (within the rights framework) does impinge upon matters from all the three lists (Union, State, Concurrent), especially relating to larger mandates of economic and social planning, and honoring international obligations, and the Union Government can proceed to draft a public health act (at the national level - not as a model). The Central government would however have to be clear that it is not seen usurping on an area under the purview of the States, for the law to be acceptable and practicable in the States. Therefore while drafting the Public Health Act, a fine balance will have to be struck between the Central government's international obligations and its obligation to honor the domain of the States.

RECOMMENDATIONS: WHAT THE ACT MUST DO?

1. The Task Force, instead of recommending corrections to the existing drafts, is proposing the development of a new draft, which should be promulgated within a stipulated timeframe.
2. The new draft would ideally be a Model Act for the States developed at the Central level
3. Along with development of this model act, 2 or 4 States may also be handholded to develop State specific Public Health Acts in place
4. Among the options available on legislative approach, the Task Force recommends a mixed approach; which uses coercive as well as rights based approaches
5. Involvement of the State from the conceptual stage onwards would help a lot in ensuring implementation of the Act
6. The Task force envisages that the proposed Public Health Act must be able to;
 - i. Modernize and amend antiquated laws to keep pace with scientific developments, developing standards & ethics; compliance with modern legal and ethical norms
 - ii. Clarify public health agencies' legal powers and duties
 - iii. Impact Public Health programs and policies
 - iv. Improve communication and smoothen relationships within the public health system
 - v. Suggest reforms in public health practice with specific clauses on 'Human Resources in Health' and establishment of 'Public Health Cadre' at Central and State level.

- vi. Demarcate areas to be covered (and complimenting the existing legislations having direct / indirect implications for public health) with the appropriate authorities and their capacities required to perform the specified functions.

CONCLUSION

A society is typically prone *not* to change by itself and requires certain tools, including but not limited to law, to catalyze a social change. The law is a critical tool to cause social transformation, as also a tool to strengthen the other tools, like education, health, and governance and so on. Especially where a social trend or phenomenon is continuing to cause large-scale damage to the basic rights of a population, there is a sound case for bringing in a new law without waiting for the society to change first. A certain level of social change has to precede a law to create the preparedness of the society for a law to prevail in that area. Else even the best of the laws would remain dead letter as the soil nourishing the entitlements they would entail is missing. However, in most such cases, in view of certain criticality of the situation, social change and legal reform cannot be an 'either-or' choice; they must be simultaneous imperatives of governance and must feed each-other, together making a sustained impact and transformation. In fact, more intractable a social phenomenon, more the inter-dependence of social change and the law (and other tools) around it.

The mission of the public health is defined as "the fulfillment of society's interest in assuring the condition in which people can be healthy. Legal preparedness of the public health is the result of the contribution legal tools make to assuring to those conditions. Therefore, the laws are to be integral part to robust public health system. Deficiencies in public health system legal preparedness (found generally in relation to planning, coordination and communication, surveillance, management of property and protection of persons during a public health emergency/crisis) in the states needs to be addressed by the proposed new public health act; the major issues being the selection of the appropriate authority, capacity of the authority, authority structure - coordination, and access to other support systems.

PLAN OF ACTION

Based on the recommendations, the Task Force is suggesting a Plan of Action for the next 14 months;

Activities	Rationale	Timelines
Approach paper to the Public Health Act	To receive guidance on the legislative approach to Public Health Law	July, 2012
Constitution of the sub-committee under the task force	To undertake specific tasks given by task force and to give feedbacks to the draft bill	August, 2012
State consultation meeting	<ul style="list-style-type: none"> a) For sensitize on the development of new Public Health Act b) State visits - in selected 2/4 states who are willing to enact Public Health Act 	September - October, 2012 State visits to continue depending on handholding / consultative support required
Study of the existing legislations related to public health in India with implications for the proposed draft	The new public health law to; <ul style="list-style-type: none"> (a) complement the existing legislations (uniformity, overriding, severability, compatibility, repeals & savings) (b) facilitate implementation (c) provide framework for public health legislations 	October to November, 2012
Study of the international agreements / treaties to which India is a signatory		December, 2012
Study of the legislations - good models from other countries		January, 2013
1 st sub- committee meeting with task force members	To provide inputs into the draft bill	February, 2013
Drafting of the Public Health	Model Act as well as State specific for the 2/4	March, 2013-

Act	selected States	May, 2013
Discussion of the 1 st draft with sub-committee	To provide feedbacks on the draft bill	May, 2013
2 nd draft	Model Act as well as State specific for the 2/4 selected States	June, 2013
Stakeholder consultation	a) Drafting to follow a consultative process b) Specific inputs on State specific Acts	July, 2013
Draft for submission to MoHFW	Modal Act as well as 2/4 State specific drafts	August, 2013
State consultations	For engaging positively on the new Public Health Act - adapt / adopt in the 2/4 selected States	August, 2013 - onwards (expected duration - 3 months)
Work on Public Health Rules	Drafting of powers of the appropriate authorities	Subjected to finalization of the Bill

**State visits can start early depending upon the State response*

The expected outputs & outcomes of the above mentioned plan of Action are;

- a) The expected outputs would be the development of a Model Act (for the States developed Centrally) by August, 2013 and 2/4 State specific Acts by September, 2013**
- b) The expected outcome would be to have the selected 2/4 States promulgate Public Health Act by October, 2013**

The team drafting the Public Health Act will require the following support;

- a) Two Consultants; one with legal research experience (for 1 year) and another with legal drafting and legal research experience (for 1 year). The consultants will report to Consultant (PHA & Legal), NHSRC.
- b) Formation of a Sub-Committee with specific tasks - this Sub-Committee is to be drawn from experts from all over India, and will be supporting the Task Force on specific areas.

This Sub-Committee will offer inputs / feedbacks to the draft at various stages, before the bill is open for stakeholder consultation or comments from general public.

Budget for the Public Health Act - Drafting Secretariat

Requirements	Unit cost (INR) / Remarks	Cost (INR)
A. Secretariat cost		
1. Consultant (PHA & Legal), NHSRC	Task force member	NHSRC
2. Consultant (legal drafting & legal research)	1 year duration (40,000 x 12)	4,80,000
3. Consultant (legal research)	1 year duration (40,000 x 12)	4,80,000
4. Establishment cost	Laptop (40,000 x 3)	1,20,000
	Data card/ internet/phone	1,00,000
	Other office cost	1,00,000
5. Travel cost	Outstation travel	6,00,000
	Local travel	1,00,000
	Accommodation at outstation	2,00,000
B. Sub-committee / other experts		
	10 members (travels twice)	3,00,000
	Special invitees (5 experts, once)	75,000
	Accommodation cost	2,50,000
	Honorarium for experts (4,000 per visit)	1,00,000
C. Consultation workshops (State / Stakeholder / subject)	2 state consultations 2 stakeholder consultations	12,00,000

	1 workshop / meeting	
D. Resource materials for draft	(books, Journals, other conference materials, subscription fees etc.)	2,00,000
Total		4305000
Miscellaneous	10%	4,30,500
Grand total		47,35,500/-

PUBLIC HEALTH LAWS (INCLUDING CENTRAL / STATE DRAFTS)

There are 5 State Acts, 4 State Bills and 3 Modal Acts made by various agencies / task force at Central level, which are available now. There is also a public health ordinance released prior to independence. These documents are listed in chronological order of their development / enactment.

1. Public Health (Emergency provisions) Ordinance, 1944

This is an ordinance released by way of the powers conferred by section 72 of the Government of India Act, 1935 to make special provisions in regard to public health in India. The purpose of this ordinance was to ensure the provision of adequate medical services, of preventing the spread of human disease, of safeguarding the public health and for providing or maintaining services essential to the health of the community. This ordinance gives the government to supersede the local authority if the latter fails to comply with any rule or order made in this direction.

2. Tamil Nadu Public Health Act, 1939

One of the earliest legislations in the area of Public Health in the pre-independent India comes from Tamil Nadu. The authorities faced difficulties in implementing the act which led to the constitution of 'The Tamil Nadu Public Health Act Amendment Committee' to make recommendations with regard to the amendments that need to be made to the Act. The report of the working group members has proposed the amendments following the below mentioned criteria in its report to the Director Public health & preventive medicine. Out of that, four amendments were related to adaptation of laws, one related to extension of the act to transferred territory and eight were related to principal act. The last of the amendments were made in 1990.

- To protect the public against the new highly infectious and pathogenic diseases (e.g. emergence of HIV/AIDS)
- Local boards have been reclassified or upgraded, downgraded or reconstituted and respective acts were promulgated and amended. Some of the acts incorporated with Tamil Nadu public health act were repealed and substituted with new acts. But they

were not incorporated and there is a need to incorporate them. (e.g. the district board was abolished and instead the panchayat unions are constituted - the Tamil Nadu district boards act, 1920 repealed by Tamil Nadu panchayats act, 1994)

- Certain new provisions have to be included to control vector borne diseases, industrial control, and implementation of total sanitation programme and definition of certain words. (bio-medical waste)
- The fines fixed under the act in 1939 have not been enhanced so far. Existing fine is very meager and requires enhancement. (letting out sullage or sewage into a street etc. - from Rs.50/- to Rs.5000/-)
- Defining new terms (unwholesome food - s.37A), including new categories (plastic materials - s.3(11), re-designations (“*surgeon general with state government*” to “*secretary to government health and family welfare department*”)

The final draft was accepted by the assembly in April, 2012 and within an year, as per modifications suggested by the assembly, the bill will come into force, as the Tamil Nadu Public Health Act, 2012.

3. Pondicherry Public Health Act, 1973 & rules 1981

This is a coercive based legislation. The act deals, among other areas, also with regulation of private clinical establishments. Since the Clinical Establishments (registration & regulation) Act, 2010 is in place, this portion of the Pondicherry act stands repealed. The Pondicherry Public Health rules, under the Act came into force in 1981.

4. The Goa, Daman and Diu Public Health Act, 1985 & rules 1987

This is a coercive based legislation. After its promulgation, the act was amended 10 times (latest 2009). The rules were also amended once (in 2010). Other than the conventional areas of public health, the act also covers areas like ‘operation of ambulance’, ‘screening of migrant labourers for construction work, ‘regulation of massage parlours’ etc.

5. Kerala Public Health Bill, 2009

This draft is a revision to the existing **Travancore Cochin Public Health Act, 1939** which covered the southern part of Kerala (and the Northern part was covered by the Madras Public Health Act of 1939). This also has followed a coercive approach but also has recognized need for

providing 'essential public health services and functions'. This act also takes about creation of 'Public Health Boards' at state level.

6. Model Public Health Act, Central Bureau of Health Intelligence - draft 1987

This draft is expected to 'make provision for health services in the state' and has followed a coercive based approach to achieve the objective. The draft Bill mentions about creation of structures (boards / committees) of health at various levels. The Bill also regulates 'private clinical establishments', and 'food adulteration', for which specialized legislations are now available (Clinical Establishments (registration & regulation) Act, 2010 and the Food Safety and Standards Act, 2007).

7. Gujarat Public Health Bill, 2009

This act follows a rights based approach. This act also regulates 'healthcare establishments'. Besides the conventional areas, this act also comes forward with 'public health planning', 'public health impact assessment' and clearance of projects, 'disaster management', 'obligations of the state government', provision for 'free and universal access to healthcare services', 'public health rights', 'reasoned order' by 'designated district courts', 'public dialogues' and 'public hearings', and 'least restrictive alternative', when rights of citizens have to be infringed for public purposes. This Act was a paradigm shift in the thinking of public health legislation, in an Indian State.

8. National Public Health Act, National Institute of Communicable Diseases - draft 2002

In addition to the conventional areas, the act mentions about creation of a 'National Board of Public Health', with technical, administrative, planning, coordinating, monitoring, review and supervisory roles. There is also a proposal for creation of a 'State Board of Public Health', with similar roles but functions at the state level.

9. Karnataka Public Health Bill, 2010

This was enacted with 4 major objectives, first one is to lay down responsibilities of individuals, corporations and the government towards promotion and protection of public health safety, two; for realizing active cooperation between the state, local governments, public and private sectors, three; monitoring of health indicators, and four; for preventing spread of disease and promoting and protecting health of people. This act also mentions about 'control of HIV and AIDS' and creation of a 'Public Health Board'.

The act also is very peculiar in terms of some of the coercive powers it gives to the appropriate authorities. The act mentions about the power of the health officer to 'isolate' persons who has

or is suspected to be a case, carrier or contact of an infectious disease. Another coercive power is the one given to the Director of Public Health to 'vaccinate by force' (mandatorily under Sec. 104) in case of an outbreak of an infectious disease.

Another peculiar feature of the act is the section dealing with 'cognizance of offence'. According to this section, no person can be tried for any offence, unless a complaint is made within 3 months of the commission of the offence by a competent 'executive authority'.

10. Karnataka Promotion of Public Health and Prevention of Diseases Bill, 2010

This Act is intending to preserve and protect the health of the public through the Public Health System while respecting individual rights to bodily integrity, health information privacy, nondiscrimination, and other legally-protected health interests by assuring the conditions in which people can be healthy; providing essential Public Health Services and Functions and seeking adequate funding to provide them, encouraging collaboration among public and private sector partners in the Public Health System; and accomplish Public Health goals through public or private sources. This bill has lot of overlapping areas with the Public Health Bill, 2006. Both the bills continue to be in the draft stage, receiving comments.

11. National Health Bill, MoHFW, Task Force on PH Act - 2009

This draft argued for a National Health Act rather than a 'Public Health Act'. This followed a rights based perspective. The National Health Act was a 'framework law on health' which wanted to provide for developing and facilitating a coherent and uniform legal response to cross-sectoral convergent issues. It argued for establishment of general framework of scope, core principles, rights, obligations, and a broad structure for implementation & justice mechanism to ensure health as a right. It stopped there and did not get in to the nitty-gritty of regulating each of the areas it covers. It left room, mandate and sanction for the implementing legislations and competent governments to determine specific measures to be taken to achieve them.

It makes reference to the Alma Ata declaration, which attempted to close the gap between the imperatives of health and development, in the last decade with understanding on 'health' grown beyond bio-medical determinants. It refers to the Committee on Economic, Social and Cultural Rights set up under the International Covenant on Economic, Social and Cultural Rights (ICESCR) which authoritatively interpreted health as much larger, non-medicalised, social framework, tightly linking it up with the underlying socio-economic determinants.

And arguing for a change in nomenclature; from Public Health Act to Health Act, the bill said; “health is today legally understood to include, but is not limited to, public health, the first option could be a more internationally consistent title, called Health Act”.

12. The Assam Public Health Act, 2010

This is a rights based legislation. This has been promulgated ‘for the protection and fulfillment of rights in relation to health and well-being, health equity and justice, including those related to all the underlying departments of health as well as health care and for achieving the goal of health for all’.

ACTS AND RULES RELATING TO HEALTH IN INDIA

The acts and rules relating to health in India have been classified below in to broad areas of their operation. Eighteen categories have been identified¹¹.

- I. Health Facilities and Services
- II. Disease Control and Medical Care
- III. Human Resources
- IV. Ethics and Patients Rights
- V. Pharmaceuticals and Medical Devices
- VI. Radiation Protection
- VII. Hazardous Substances
- VIII. Occupational Health and Accident Prevention
- IX. Elderly, Disabled, Rehabilitation and Mental Health
- X. Family, Women and Children
- XI. Smoking, Alcoholism and Drug Abuse
- XII. Social Security and Health Insurance
- XIII. Environmental Protection
- XIV. Nutrition and Food Safety
- XV. Health Information and Statistics
- XVI. Intellectual Property Rights
- XVII. Custody, Civil and Human Rights

1. Health Facilities and Services

- Indian Red Cross Society Acts, 1920
- All India Institute of Medical Sciences Act, 1956
- Post-graduate Institute of Medical Education and Research, Chandigarh, Act, 1966
- Bureau of Indian Standards Act, 1986

¹¹ Compilation and categorization by WHO

- Bureau of Indian Standards Rules, 1987
- National Institute of Pharmaceutical Education and Research Act, 1998
- Clinical Establishment Acts
 - Bombay Nursing Homes Registration Act, 1949
 - Delhi Nursing Homes Registration Act, 1953
 - Madhya Pradesh Upcharyagriba Tatha Rujopchar Sambandi Sthapas (Registikaran Tatha Anugyapan) Adhinyam, 1973
 - Orissa Clinical establishment (Control and Regulation) Act, 1991
 - Orissa Clinical establishment (Control and Regulation) Rules, 1994
 - Manipur Nursing Home and Clinics Registration Act, 1992
 - Sikkim Clinical Establishments (Licensing and Registration) Act, 1995
 - Nagaland Health Care Establishments Act, 1997 No.3 of 1997
 - West Bengal Clinical Establishment Rules, 2003
 - _ Clinical Establishments (registration & regulation), Act, 2010

2. Disease Control and Medical Care

- Epidemic Diseases Act, 1897
- Indian Aircraft Act, 1934
- Indian Aircraft (Public Health) Rules, 1954
- Indian Port Health Rules, 1955
- Medical Termination of Pregnancy Act, 1971
- Medical Termination of Pregnancy Rules, 1975
- Medical Termination of Pregnancy Regulations, 1975
- Transplantation of Human Organs Act, 1994
- Transplantation of Human Organs Rules, 1995
- Transplantation of Human Organs (Amendment) Rules, 2002
- Pre-natal Diagnostic Techniques (Regulation & Prevention of Misuse) Act, 1994
- Pre-natal Diagnostic Techniques (Regulation & Prevention of Misuse) Rules, 1996
- Pre-natal Diagnostic Techniques (Regulation & Prevention of Misuse) Amendment Act, 2002
- Pre-natal Diagnostic Techniques (Regulation & Prevention of Misuse) Amendment Rules, 2003

3. Human Resources

- Allopathy

- Indian Medical Council Act, 1956
- Indian Medical Council Rules, 1957
- Indian Medical Council (Election of Licentiates) Rules, 1965
- Establishment of New Medical Colleges, Higher Course Regulations 1993
- Indian Medical Council Amendment Act, 1993
- Medical Council of India (Norms Guidelines for Fees, Admissions Regulations) 1994
- Medical Council of India (Amendment) 1998
- Indian Medical Council Amendment, 2001
- Eligibility Requirement for Taking Admission in an Undergraduate Medical Course in a Foreign

Medical Institution Regulations, 2002

- Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002
- Eligibility Certificate Regulations, 2002
- Screening Test Regulations, 2002
- Medical Council of India, Regulations, 2000

- Dentistry

- Dentist Act, 1948
- Dental Council (Election) Regulations, 1952
- Dental Council of India Regulations, 1955
- Dental Council of India Regulations, 1956
- Dental Hygienists Revised Course, 1972
- Dental Mechanics Course Regulation, 1972
- BDS Course Regulations, 1983
- MDS Course Regulation, 1983
- Dental Council of India Regulations (Pension/GPF/Gratuity), 1984
- Dentist Amendment Act, 1993
- Establishment of Dental Colleges, 1993
- Dental Council of India (Establishment of new Colleges) Regulations, 2006

- Indian Systems of Medicine & Homeopathy

- Indian Medicine Central Council Act, 1970
- Homeopathy Central Council Act, 1973

- Homeopathy Diploma Course DHMS 1983
- Homeopathy Minimum Standards of Education, 1983
- Homeopathy (Degree Course) BHMS Regulation, 1983
- Indian Medicine Central Council (Amendment) Act, 2002
- Central Council of Indian Medicine (General) Regulations, 1976
- Homeopathy Practitioners (Professional Conduct, Etiquette and Code of Ethics) Regulations, 1982
- Practitioners of India Medicine (Standards of Professional Conduct, Etiquette and Code of Ethics) Regulations, 1982
- Indian Medicine Central Council (Minimum Standards of Education in Indian Medicine) (Amendment) Regulations, 1989
- Indian Medicine Central Council (PG Ayurveda Education) Regulations, 2005
- Nursing
 - Indian Nursing Council Act, 1947
 - Indian Nursing Council Regulations
- Pharmacy
 - Pharmacy Act, 1948
 - Pharmacy Council of India - Regulation Act
- Rehabilitation
 - Rehabilitation Council of India Act, 1992
 - Rehabilitation Council of India Regulation, 1997
 - Rehabilitation Council of India (Condition of Service), 1998

4. Ethics and Patients Rights

- Consumer Protection Act, 1986
- Consumer Protection Rules, 1987
- Consumer Protection (Amendment) Act, 2002
- Ethical Guidelines for Biomedical Research on Human Subject 2000

5. Pharmaceuticals and Medical Devices

- Drugs and Cosmetics Act, 1940
- Drugs Control Act, 1950
- Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954

- Medicinal and Toilet Preparation (Excise Duties) Act, 1955
- Drugs (Prices Control) Order, 1979
- Drugs (Prices Control) Order, 1995
- International Federation of Pharmaceutical Manufacturers Associations Code, 1994
- Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) Orders, 2005
 - Drugs and Cosmetics (inclusion of Sterile Devices), 2005
 - Drugs and Cosmetics (inclusion of Sterile Devices), 2005
 - Guidelines for Exchange of Human Biological Material
 - Part I - Drugs and Cosmetic Rules, 1945

6. Radiation Protection

- Atomic Energy Act, 1962
- Radiation Protection Rules, 1971
- Radiation Surveillance Procedures for Medical Application of Radiation, 1980
- Atomic Energy (Working of the Mines, Minerals and Handling of Prescribed Substance) Rules, 1984
- Atomic Energy (Safe Disposal of Radioactive Wastes) Rules, 1987
- Radiation Surveillance Procedures for Medical Application of Radiation, 1989
- Safety Code for Medical Diagnostic X-Ray Equipment and Installations
- Statutory Requirements for Safe Operation of Medical X-Ray Machines by Hospitals, Clinics and Other Medical Institutions in India

7. Hazardous Substances

- Narcotic Drugs and Psychotropic Substances Act, 1985
- Narcotic Drugs and Psychotropic Substances Rules, 1985
- Prevention of Illicit Traffic in Narcotic Drugs and Psychotropic Substances Act, 1988
- Hazardous Wastes (Management and Handling) Rules, 1989
- Rules for the manufacture, Use, Import, Export and Storage of Hazardous Micro Organisms Genetically Engineered Organisms of Cells 1989
- Manufacture, Storage and Import of Hazardous Chemical Amendment) Rules, 2000
- Hazardous Wastes (Management and Handling) Rules, 2002

8. Occupational Health and Accident Prevention

- Fatal Accidents Act, 1855
- Workmen Compensation Act, 1923
- Factories Act 1948 (Amendment), 1987
- Plantations Labour Act, 1951
- Mines Act, 1952
- Mines and Minerals (Regulation and Development) Act, 1957
- Mines Creche Rules, 1966
- Motor Transport Workers Act, 1961
- Personal Injuries (Emergency Provisions) Act, 1962
- Personal Injuries (Compensation Insurance) Act, 1963
- Beedi and Cigar Workers (Conditions of Employment) Act, 1966
- Child Labour (Prohibition and Regulation) Act, 1986
- Contract Labour (Regulation and Abolition) Central Rules, 1971
- Dock Workers (Safety, Health and Welfare) Rules, 1990
- Public Liability Insurance Act, 1991
- Public Liability Insurance Rules, 1991
- National Commission for Safai Karamcharis Act, 1993
- Building and Other Construction Workers (Regulation of Employment and Conditions of Service) Act, 1996
- Building & Other Construction Workers (CESS) Act, 1996

9. Elderly, Disabled, Rehabilitation and Mental Health

- Mental Health Act, 1987
- Central Mental Health Auth Rules, 1990
- State Mental Health Rules, 1990
- Persons with Disabilities (Equal Opportunities, Protection of Rights and Full Participation) Act, 1995
- Persons with Disabilities (Equal Opportunities, Protection of Rights and Full Participation) Rules, 1996
- National Trust for Welfare of Persons With Autism, Cerebral Palsy, Mental Retardation and Multiple Disabilities Act 1999
- National Trust for Welfare of Persons With Autism, Cerebral Palsy, Mental Retardation and Multiple Disabilities Rules 2000

10. Family, Women and Children

- Suppression of Traffic in Women & Girl Act, 1956
- Children Act, 1960
- Orphanages and Other Charitable Home (Supervision and Control) Act, 1960
 - National Commission for Women Act, 1990
- Juvenile Justice (Care and Protection of Children) Act, 2000

11. Smoking, Alcoholism and Drug Abuse

- Cigarettes (Regulations of Production, Supply and Distribution), Act, 1975
- Cigarettes and Other Tobacco Products (Prohibition of Advertisement and regulation of Trade and Commerce, Production, supply and Distribution) Act, 2003
 - Cigarettes and other Tobacco Products (Prohibition of Advt. and Regulation of Trade and Commerce Production, Supply and Distribution) Rules, 2004
 - Cigarettes and other Tobacco Products (Prohibition of Sale on Cigarettes and other Tobacco Products Around Educational Institutions) Rules, 2004

12. Social Security and Health Insurance

- Payment of Wages Act, 1936
- Minimum Wages Act, 1948
- Employees State Insurance Act, 1948
- Employees State Insurance (Central) Rules, 1950
- Life Insurance Corporation Act, 1956
- Life Insurance (Emergency Provisions) Act, 1956
- Maternity Benefit Act, 1961
- Maternity Benefit (Mines and Circus) Rules, 1963
- Insurance Regulatory and Development Authority Act, 1999

13. Environmental Protection

- Insecticides Act, 1968
- Insecticides Rules, 1971
- Insecticides (Amendment) Rules, 1993
- Insecticides (Amendment) Act, 2000
- Water (Prevention and Control of Pollution) Act, 1974

- Water (Prevention and Control of Pollution) Rules, 1975
- Central Board for the Prevention and Control of Water Pollution (Procedure for Transaction of Business) Rules, 1975
- Water (Prevention and Control of Pollution) CESS Act, 1977
- Water (Prevention and Control of Pollution) CESS Rules, 1978
- Water (Prevention and Control of Pollution) CESS (Amendment) Act, 2003
- Air (Prevention and Control of Pollution) Act, 1981
- Air (Prevention and Control of Pollution) Rules, 1982
- Air (Prevention and Control of Pollution) (Union Territories) Rules, 1983
- Bhopal Gas Leak Disaster (Processing of Claims) Act, 1985
- Bhopal Gas leak Disaster (Processing of Claims) Amendment Act, 1992
- Environment (Protection) Act, 1986
- Environment (Protection) Rules, 1986
- National Environment Tribunal Act, 1995
- Environment (Protection) Third Amendment Rules, 2002
- Bio-Medical Waste (Management and Handling) Rules, 1998
- Recycled Plastics Manufacture and Usage Rules, 1999
- Municipal Solid Wastes (Management and Handling) Rules, 2000
- Noise Pollution (Regulation and Control) Rules, 2000
- Ozone Depleting Substances (Regulation and Control) Rules, 2000
- Biological Diversity Act, 2002
- Biological Diversity Rules, 2003
- Disaster Management Act, 2005
- Constitution of National Disaster Management Authority, 2005

14. Nutrition and Food Safety

- Prevention of Food Adulteration Act, 1954
- Prevention of Food Adulteration Rules, 1955
- Prevention of Food Adulteration (1st Amendment) Rules, 2002
- Prevention of Food Adulteration (2nd Amendment) (Infant Milk Food) Rules, 2002
- Prevention of Food Adulteration (5th Amendment), 2002
- Prevention of Food Adulteration (6th Amendment) (Mineral Water) Rules, 2000
- Prevention of Food Adulteration (7th Amendment) (Sample to be sent) Rules, 2002
- Prevention of Food Adulteration (9th Amendment) (Vegetarian Food) Rules, 2001
- Infant Milk Substitutes, Feeding Bottles and Infant Foods Act, 1992
- Infant Milk Substitutes, Feeding Bottles and Infants Food (Regulation of Production, Supply

and Distribution) Rules, 1993

- Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Amendment Act, 2003
- Atomic Energy (Control of Irradiation of Food) Rules, 1996
- Edible Oils Packaging (Regulation) Order, 1998
- Vegetable Oil Products (Regulation) Order, 1998
- Public Distribution System (Control) Order, 2001
- Food Safety and Standards Act, 2006

15. Health Information and Statistics

- Births, Deaths and Marriages Registration Act, 1886
- Registration of Births and Deaths Act, 1969
- Collection of Statistics Act, 1953
- Collection of Statistics (Central) Rules, 1959
- Census Act, 1948
- Census (Amendment) Act, 1993

16. Intellectual Property Rights

- Patents Act, 1970
- Patent Rules, 1972
- Patents (Amendment) Act, 2005
- Trade Marks Act, 1999

17. Custody, Civil and Human Rights

- Indian Penal Code, 1860
- Societies Registration Act, 1860
- Prisoners Act, 1900
- Unlawful Activities (Prevention) Act, 1967
- Code of Criminal Procedures, 1973
- Protection of Human Rights Act, 1993