Restricted Circulation

Sector Research Study
Healthcare

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EXECUTIVE SUMMARY

Healthcare sector is a social sector, where 'access and equity' are as important as the need to have further investment. Not only right to healthcare has been recognised as a fundamental right in India, there are several international obligations for India to pursue 'access and equity' in this regard. At the same time healthcare sector, with huge private sector participation, has immense commercial angle. The analysis in this paper has tried to balance between the welfare and the commercial aspect of the sector, hence, at some instances certain competition principles, like 'competition neutrality', may have been found to be compromised to achieve larger welfare gains.

The study found a plethora of entry barriers in the sector, which are mainly non-regulatory in nature as the sector remains largely un-regulated. Few important regulatory entry barriers that the study has tried to analyse are in Chapter 2 and Chapter 3, include: (1) those related with medical education; (2) domestic manufacture of medical devices; (3) health insurance; and (4) public health procurement.

The study suggests easing the eligibility and qualifying criteria for the establishment of medical colleges and nursing schools, so that more and more players, including private investors, are able to establish more and more such institutes without compromising on the quality of education. The qualifying criteria need to more quality-oriented against the present quantity-oriented. Bestowing 'infrastructure' status to healthcare can bring good dividend in sector.

The study also suggests rectification of the present approach to regulate medical devices under Drugs and Cosmetics Act, 1940 with introduction of a new Bill as well as rectification of custom duty structure that favours trading (import) over dis-incentivising local manufacture of medical devices, particularly high-end ones.

Under health insurance, the study advocates bringing a new regulatory regime for health insurance, separate from IRDA that can work in close conjunction and synergy with the existing and emerging regulatory regime for health service providers. This is because both directly affect each other, positively and negatively. For the purpose of public health procurement, the study

suggests review of the general practice of putting certain criteria for suppliers based on 'market standing' and 'turnover'.

The secondary literature survey has enriched the study in listing some anti-competition practices and other competition issues prevalent in the healthcare sector, which have generally been written and advocated about since long. The prescription practice of physicians in brand name, in violation of the relevant MCI regulation is perhaps the oldest recognised, yet most important, anti-competitive activity prevalent in the sector. The study suggests intervention of Centre/States, if MCI fails to properly implement the relevant regulation and also to adopt certain measures to tackle supply side nuances of this practice (read disciplining pharma promotion). Presence of collusive practices, between physicians and path labs and between hospitals and medical goods suppliers, were also found. The study has suggested some actions to rectify such practices.

Although there is a separate sectoral study for pharmaceutical sector, this study has dealt with certain limited and contemporary competition issues related with patents and M&As and has made certain recommendations for their early correction. The study recognises that the generic competition is the most important form of competition in the pharmaceutical market with highest potential of monetary saving for consumers.

The study has also found certain statutory provisions and government schemes to be pro-competition. The registration process in the Clinical Establishment Act, 2010 and the whole model of government health insurance scheme Rashtriya Swasthya Bima Yojna (RSBY) are pro-competition. The study suggests state governments to adopt the Clinical Establishment Act, 2010. The RSBY has the potential to bring competition not only in health insurance sector, but also amongst the health service providers. The study suggests expanding RSBY beyond BPL families (with lesser subsidy) in a calibrated manner.

In Chapter 4 (last) the study presents a Competition Advocacy Agenda for the healthcare sector in form of recommendations, which includes several suggestions made in chapter 2 and 3 of the study in broader terms.

CHAPTER 1: INTRODUCTION AND OBJECTIVES OF THE REPORT

Healthcare sector is a social sector, where 'access and equity' are as important as the need to have further investment. Not only right to healthcare has been recognised as a fundamental right in India, there are several international obligations for India to pursue 'access and equity' in this regard. The following excerpts from the Draft National Health Bill, 2009 being promoted by the Ministry of Health and Family Welfare provides a near exclusive list of constitutional and international obligations for India with respect to healthcare.

"The Constitution of India places obligations on the Government to ensure protection and fulfillment of right to health for all, without any discrimination, as a Fundamental Right under Articles 14, 15 and 21 (rights to life, equality and non- discrimination), and also urges the State, under the Directive Principles of State Policy, to eliminate inequalities in status, facilities and opportunities (Article 38); to strive to provide to everyone certain vital public health conditions such as health of workers, men, women and children (Article 39); right to work, education and 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 improvement of public health (Article 47); and protect and improve environment (Article 48A). The Union of India has also signed various international treaties, agreements and declarations specifically undertaking to provide right to health including but not limited to: Universal Declaration of Human Rights (UDHR): Article 25 (1); International Covenant on Economic, Social and Cultural Rights (ICESCR): Article 12; 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; 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), WTO Doha Declaration on TRIPS Agreement & Public Health (2001), International Health Regulations, 58th World Health Assembly (2005); and several other declarations and conventions on health."

In addition, India is a signatory to the Millenium Development Goals. These goals, agreed to by a community of nations and international organisations in 1992 represent the most comprehensive and specific development goals ever agreed upon by the world. MDGs represent the will of the world's nations to achieve development objectives by the year 2015. The importance of healthcare in the MDGs is highlighted by the fact that 3 out of 8 goals, 6 out of 21 targets and 18 out of 60 indicators pertain to healthcare.

Therefore, it is clear that providing healthcare to all is the duty of the Central and State Governments, 'health' being a state-subject under Indian Constitution. Unfortunately, India is far from providing a universal healthcare coverage[1]. Not only the improvements in health indicators

[1] "Universal Health Coverage (UHC) ensures promotive, preventive, diagnostic, curative and rehabilitative health services without financial hardship" as defined by the High Level Expert Group (HLEG) Report on Universal Health Coverage for India, Planning Commission of India, 2011

has not only been slow, India lags far behind in world, including most developing countries and few least developed countries with respect to health indicators (See Table 1 and 2 below). In addition, within India there are large disparities amongst states in achieving health outcomes (see Table 3).

Table 1: Health Indicators in India, 1951-2009

Indicator	1951	1971	1981	1991	1999	2005	2009
Birth rate	40.8	36.9	33.9	29.5	26.1	23.8	22.5
Death rate	25.1	14.9	12.5	9.8	8.7	7.6	7.3
Infant mortality rate	148	129	110	80	70	58.0	50.0
Maternal mortality ratio*	1321	853	810	424	407	254	212
Total fertility rate	6	5.2	4.5	3.6	2.9	2.9	2.6

Source: HLEG Report on UHC for India

Table 2: Key Indicators: India compared with other developing countries

Indicator	India	China	Brazil	Sri Lanka	Thailand
IMR/1000 live-births	50	17	17	13	12
Under-5 mortality/1000 live-births	66	19	21	16	13
Fully immunised (%)	66	95	99	99	98
Birth by skilled attendants	47	96	98	97	99
Health expenditure as percentage of GDP	4.2	4.3	8.4	4.1	4.1
Government share of total health expenditure (%)	32.4	47.3	44	43.7	74.3
Government health spending share of total government spending (%)	4.4	10.3	6.0	7.9	14.2
Per capita spending in international dollars	122	265	875	187	328

Source: HLEG Report on UHC for India

The lack of an efficient and accountable public health sector has led to the burgeoning of a highly variable private sector, which accounts for around 68 percent of overall health spending. Rise of private sector has also driven up health expenditure, pushing millions of Indians into poverty. India's unregulated private sector and deficient public sector, which suffers from management shortfalls, human resource shortages, and poor accountability, has resulted in a health system that is unable, at present, to cater to the needs of the entire population[2]. This is despite the fact that India's economy has been growing at a reasonably faster rate that many other countries and is only behind China in this regard.

[2] High Level Expert Group (HLEG) Report on Universal Health Coverage for India, Planning Commission of India, 2011

Table 3: Selected Health Status Outcomes in India and Major Indian States

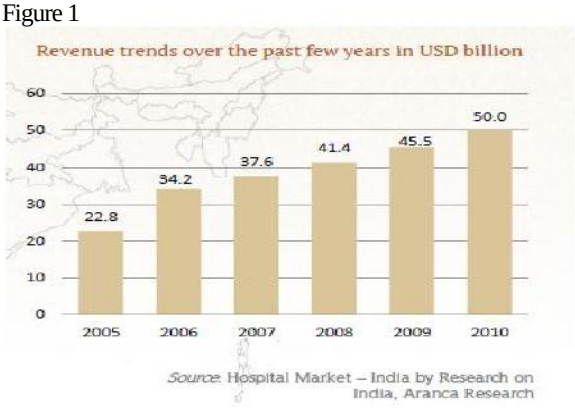
State	Life Expectancy at Birth, average for (SRS based Abridged life table 1998-02) (years)[1]	Neonatal Mortality 2005-06 (per 1000 live births)	Infant Mortality Rate (per 1000 live births) (Source: SRS 2009)[2]	Under Five Mortality Rate, (Source: NFHS 2005-06) (per 1000 live births)[3]	Total Fertility Rate, (Source: SRS 2008)[4]	Under weight children, (percent) (Source: NFHS 2005-06)[3]
India	62.5	39	50	74.3	2.6	48
Andhra Pradesh	63.5	40.3	49	63.2	1.8	42.7
Assam	57.9	45.5	61	85.0	2.6	46.5
Bihar	60.8	39.8	52	84.8	3.9	55.6
Gujarat	63.4	33.5	48	60.9	2.5	51.7
Haryana	65.2	23.6	51	52.3	2.5	45.7
Karnataka	64.5	28.9	41	54.7	2.0	43.7
Kerala	73.5	11.5	12	16.3	1.7	24.5
Madhya Pradesh	56.9	44.9	67	94.2	3.3	50.0
Maharashtra	66.2	31.8	31	46.7	2.0	46.3
Odisha	58.5	45.4	65	90.6	2.4	45
Punjab	68.5	28.0	38	52.0	1.9	36.7
Rajasthan	61.1	43.9	59	85.4	3.3	43.7
Tamil Nadu	65.2	19.1	28	35.5	1.7	30.9
Uttar Pradesh	59.1	47.6	63	96.4	3.8	56.8
West Bengal	63.9	37.6	33	59.6	1.9	44.6

Source: HLEG Report on UHC for India

Viewing the constraints of public sector, reliance on private sector for healthcare is imperative. The National Health Policy, 2002 also recognises this fact and tends to enhance the contribution of private sector by creating an enabling environment through policy, regulation, outsourcing, concessions and subsidies to the private sector.

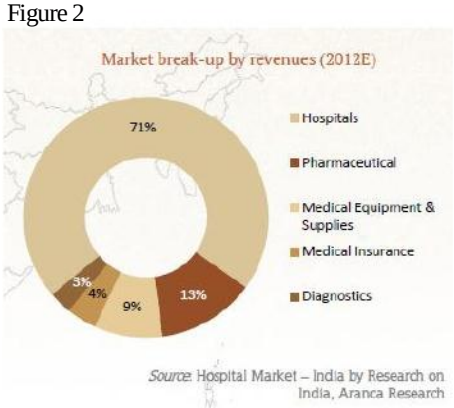
Healthcare sector sales have been rising at 17 percent CAGR over the period 2005-10. From USD 22.8bn in 2005, it has gone upto USD 50bn in 2010 (see Figure 1). Hospitals contribute to over 70 percent of total revenue from health sector followed by pharmaceuticals, which is 13 percent (see Figure 2). Total industry size in 2012 is estimated to be USD 79bn and is expected to reach USD 280bn by 2020[3]. The per capita expenditure of on health has shown rise of 8.5 percent CGAR over period 2007 to 2010 (see Figure 3).

Figure 1



Source: IBEF

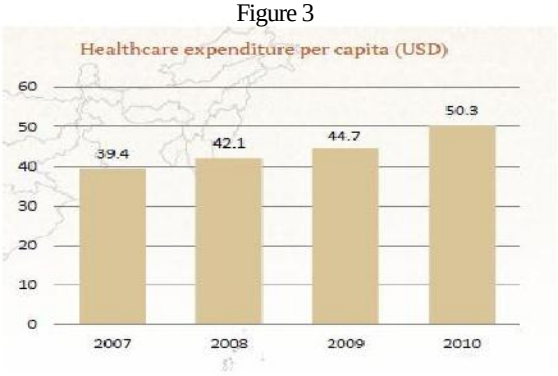
Figure 2



Source: IBEF

[3] Healthcare (ppt), India Brand Equity Foundation, November 2011

Figure 3



Source: IBEF

Box 1: Some important data with respect to public health sector
• In 2009, the per capita government spending on health in India (PPP$43) was significantly lower than in Sri Lanka (PPP$87), China (PPP$155) and Thailand (PPP$261); • In 2009, private expenditure in India accounted for 67% of the total expenditure on health - comparatively higher than in Thailand (24%), China (50%) and Sri Lanka (56%); • Two features of private out-of-pocket spending are important to note: (i) Outpatient treatment, and not hospital care, accounts for 74% of private out-of-pocket expenditures; and (ii) Medicines account for 72% of the total private out-of-pocket expenditure; • There are wide variations in public health expenditure across states. In 2008-09, for instance, public expenditure on health was Rs.498 in Kerala and Rs.411 in Tamil Nadu as against Rs.229 in Madhya Pradesh and Rs.163 in Bihar; • State governments, primarily responsible for the funding and delivery of health services, bear close to two-thirds (64%) of the total government health expenditure. The Centre accounts for the remaining third. Though the Centre's financial contribution is relatively small, its influence is substantial.

Source: HLEG on UHC for India

Although the problems in the healthcare system, both public and private, are galore and would require a multi-prong strategy, a competition policy approach could mitigate some of its inefficiencies, if not eradicate it. Particularly, if competition policy approach contributes towards "access and equity" in healthcare sector, it would be a welcome tool. There are studies pointing out prevalence of anti-competitive practices in the healthcare sector in India, which if tackled could yield consumer friendly dividends. Similarly, there are certain provisions in laws, rules and regulations governing the healthcare system, which either restricts competition or help anti-competitive practices to continue.

That said, after the enactment of Competition Act, 2002 and its enforcement in 2010, the Government of India is endeavouring to formulate a comprehensive National Competition Policy. In this regard, Ministry of Corporate Affairs, vide notification F.No.5/15/2005-IGC/CS dated 8th June 2011, has constituted the Committee on National Competition Policy and Related Matters (C-NCP) for:

a) Framing of a National Competition Policy (NCP)

b) Strategy for competition advocacy with government and private sector
c) Changes required in Competition Act for fine tuning it and
d) Any other matter relation to competition issues

The Committee has submitted its draft report on Competition Policy and will be submitting report on Competition Advocacy Strategy and will also propose changes in the Competition Act, 2002, if required. In order to develop a strategy for competition advocacy with the Government and private sector, the Committee seeks to have specific inputs and undertake evidence-based advocacy.

To carry out evidence-based advocacy, a review of distortive provisions in policies, laws, regulations, practices etc is required. Therefore sector-specific research is being conducted for 14 sectors, with the objective to identify and list provisions in different statutes, rules, policies and practices, which limit competition or have the potential to limit competition. In this regard, this study is for the healthcare sector.

The methodology adopted is predominantly secondary research with few consultations with two health ministry officials (Shri L. C. Goyal, AS & MD (CGHS) and Shri Sanjay Prasad, Director, MOHFW) and with one WHO India office staff (Ms. Anagha Khot). Shri Saket Sharma and Shri Navneet Sharma of CIRC also provided some useful guidance and study materials.

Several statutes, rules, regulation, notifications and policies were examined for the purpose of this study, however, most of them were found to be irrelevant and hence may not find place in the body of the study. The statutes, rules, regulations, guidelines, notifications and policies that were looked into include:

1. The Indian Medical Council Act, 1956
2. The Indian Nursing Council Act, 1947
3. The Rehabilitation Council Of India Act, 1992
4. The Epidemic Diseases Act, 1897
5. Drugs and cosmetics Act, 1940
6. The Drugs And Magic Remedies (Objectionable Advertisements) Act, 1954
7. Registration of Births and Deaths Act, 1969
8. Mental Health Act, 1987
9. The Transplantation of Human Organs Act, 1994
10. Medical Termination of Pregnancy (MTP) Act 1971
11. Pre-conception and Pre Natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994
12. The Persons with Disabilities (Equal Opportunities, Protection of Rights and Full Participation) Act, 1995
13. The Cigarettes And Other Tobacco Products (Prohibition Of advertisement And Regulation Of Trade And Commerce, Production, Supply and Distribution) Act, 2003
14. The Clinical Establishments (Registration and Regulation) Act, 2010
15. Patents Act, 1970
16. Insurance Development & Regulatory Act, 1999
17. The Establishment of Medical College Regulations, 1999
18. Minimum Standard Requirement for school for training ANMs
19. The Indian Medical Council (Professional Conduct & Ethics) Regulations, 2002

20. Draft Code of Conduct for Market Promotion by D/o Pharmaceuticals
21. Guidelines for manufacturing of medical devices in India
22. Guidelines for import of medical devices
23. National Health policy, 2002
24. National Drug Policy of India, 1986

For the purpose of this study, the healthcare sector is being divided into the following five components:

1. Health services
2. Pharmaceuticals Medical
3. devices
4. Public health procurement
5. Health Insurance

Also for the purpose of brevity the Chapter 3 (Identification and listing of anti-competitive provisions and practices) and Chapter 4 (Analysis of the identified issues) as suggested in the TOR have been merged and has been presented in Chapter 3 of this study titled "Identification, listing and analysis of anti-competitive provisions and practices" in a matrix form. This chapter is presented as Annexure I of the study. Some analysis has also been done in Chapter 2 titled "Market structure and reported competition issues".

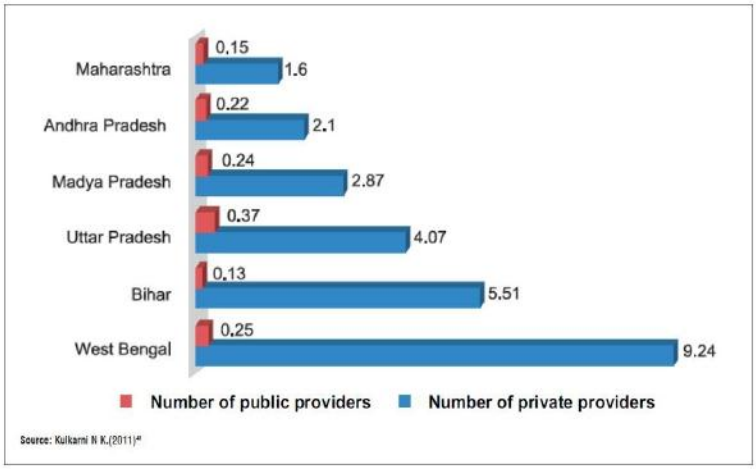
CHAPTER 2: MARKET STRUCTURE AND REPORTED COMPETITION ISSUES

Health Services

Health delivery system is generally divided into three levels primary healthcare, secondary healthcare (or community health centres) and tertiary healthcare. India has 23,673 Primary Health Centres (PHCs), 4,535 Community Health Centres (CHCs) and 12,760 Hospitals in the public health sector. The private health sector has grown exponentially in the country, from initially providing 8% of healthcare facilities in 1949, the private sector now accounts for 93% of the hospitals and 85% of doctors in India.

There is clear-cut rural-urban divide at all the levels of healthcare in India. It can easily be observed that except for public primary health centres, other levels of healthcare is virtually absent in rural areas, in most part of India. That means virtually **there is no competition in healthcare in rural areas**. Only 26 percent of doctors reside in rural areas, serving 72% of India's population. Furthermore, the urban density of doctors is nearly four times that in rural areas, and that of nurses is three times higher than that in rural areas. Almost 30 percent of public health expenditure (from both Centre and states) is allocated to urban allopathic services, while rural centres receive less than 12 percent[4]. Figure 4, below provides for availability of public and private healthcare providers within a village to average village population in few states.

Figure 4



Source: HLEG Report on UHC for India

It is an observable reality that there are **quacks** (we may call it so, but their usefulness cannot be negated) in villages, amongst whom **some competition** can be observed. These quacks generally have few years of experience working as compounders with some doctors in their respective district headquarters and most of them run their own pharmaceutical retail shops in their localities. In general, patients first approach to one of these quacks on the basis of their inter-personal relationship. If such a quack feels (there is a significant degree of honesty in this) that the treatment required for such patients are not within his/her 'expertise', s/he recommends to a doctor in district headquarter (here decisions can have expectation of some commission from the

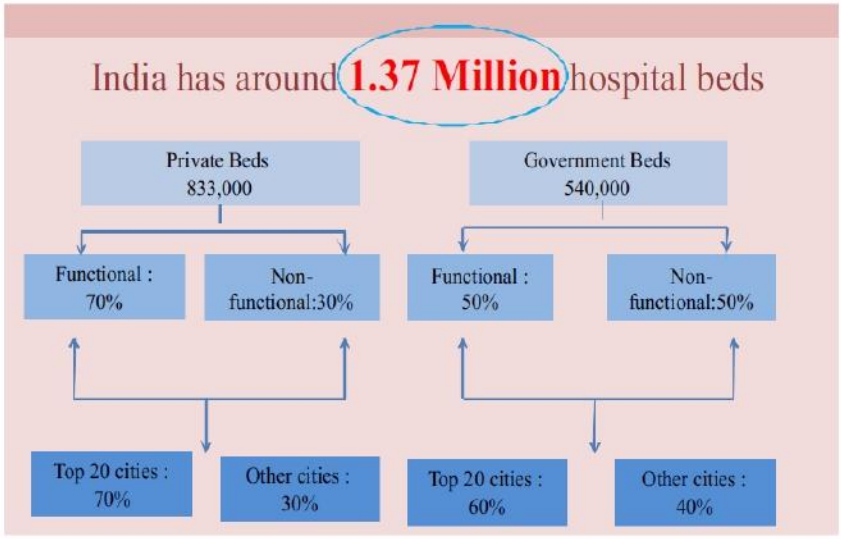
[4] *Supra 2*

doctor to whom patient is being recommended). Generally there is **collusion** between the quack, who refers a patient, and the doctor to whom the patient is referred. Due to lack of appropriate information and tendency to rely upon such quacks, the choice of patients of availing medical services is either nullity or greatly reduced.

It is also an observable fact that at the **district headquarters** (small to medium cities) there are quite **a number of doctors**, some of whom may also be runing their own nursing homes. There is, therefore, **significant degree of competition** amongst them to attract patients. There may, however, be monopoly in some therapeutic segments. These doctors and nursing homes can be said to cater primary level healthcare, and to a certain extent secondary level healthcare. In addition, in almost all the district headquarters there is presence of secondary healthcare in form of *sadar* hospitals.

As we move from small to big cities, the degree of catering to secondary level healthcare increases. That means bigger the cities more sophisticated the doctor's clinics and nursing homes become, including rise in their numbers. Again in medium cities there may be presence of private hospitals, generally run by a charitable trust, in addition to public hospitals. As per this observable fact, it can be said, in general terms, that **in cities there exists competition in primary level healthcare, while that for secondary level, it is either absent (monopoly of *sadar* hospitals) or meagrely present (duopoly or oligopoly).**

Figure 5: Distribution of Functional Hospital Beds



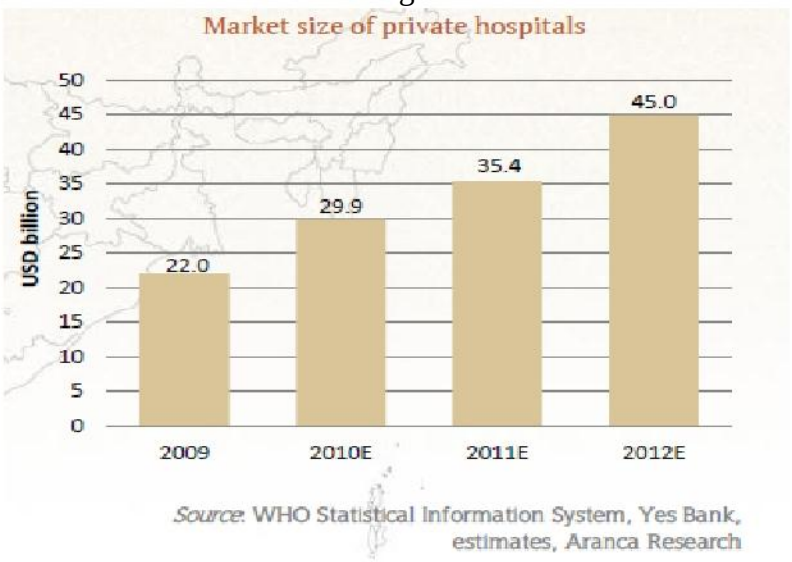
Source: HLEG Report on UHC for India

Tertiary healthcare units are mostly present in state capitals and/or cities that have medical colleges. There are private sector super-specialty hospitals in state capitals (and some big cities), but they clearly fall short of demand and are also inaccessible to poor section of society. However, their presence does provide some limited option to patients. In metros, however, the big corporate hospitals have come up, which compete with themselves, in attracting patients from affluent section of society. But healthcare, **being locality-specific in nature, dilutes such competition**.

The market size of private hospitals has been increasing at a considerable rate and at present being estimated to the tune of USD 45bn (IBEF, 2011), providing employment for over four million people[5], making it one of the largest service sectors in the economy today. The market size of private hospitals is being estimated to risen at a CAGR of 27 percent during 2010-12[6] (see also Figure 6). The private healthcare delivery is highly fragmented with over 90 percent of being serviced by the unorganised sector. Some 2 to 3 percent of hospitals are 200-bed plus,

some 6-7 percent are 100-200 bed size[7] hospitals, and the bulk 80 percent of private sector hospitals are very small, less than 30 beds .

Figure 6



Source: Healthcare, IBEF, November 2011

India's average of around 70 beds per 100,000 people compares poorly to the world average of 396 beds per 100,000 and the developing country average of 430 beds per 100,000. Increasing the number of beds to around 200 per 100,000 would mean creation of 1.3 million new beds, which would require fresh investments of USD 80bn[8]. The High Level Expert Group on Universal Health Coverage (HLEG) set up by the Planning Commission in its Report has also estimated the need of Human Resources for Health (doctors, nurses, para-medics etc.). According it by 2022 we would need 6.6 lakh Human Resources for Health at the level of tertiary care, 15.4 at Secondary care and 23.7 lakh at Primary healthcare level, if we are looking for universal coverage of health (See Table 4).

Even though the public health expenditure, which at present is mere 1.2 percent of GDP (as compared to 3 percent of GDP for developing countries and 5 percent for high income countries) is increased to 3% in next five years, it may still fall short of the requirement. Health is a state subject in India and cash-strapped state governments also are not likely to be able to provide budgetary support for such investment. Therefore, private players (domestic or foreign) would

[5] Rupa Chanda, Foreign Investment in Hospitals in India - Status and Implications, IIM Bangalore; 2008
[6] Healthcare, IBEF, November 2011
[7] *Supra 5*
[8] Healthcare needs infrastructure status; The Economic Times, 23rd December 2010

have to play a considerable role to meet the requirement of human resources for health (medical education) as well as hospitals (beds) (see Table 5).

Table 4: HRH Requirements at Health Facilities by 2022

	Category	SHCs (314547)	PHCs (50591)	CHCs (12648)	SDH (4561)	DH/ Hq. (642)	MCH (502)	Total HRH
1	ANMs	629094	101182	12648	-	-	-	742924
2	Health Worker-male	314547	101182	25296	-	-	-	441025
3	Nurses	-	252955	202358	597491	182328	253008	1488150
4	Pharmacists	-	151773	50592	22805	6420	7530	239120
5	Technicians etc.	-	202364	113832	91220	23112	42012	466672
6	Rural Healthcare Practitioners	314547	-	-	-	-	-	314547
7	Dentists	-	50591	12648	4561	1284	1506	70590
8	Doctor (AYUSH)	-	50591	12648	-	2568	-	65807
9	Doctors (Allopathy)	-	101182	75888	91220	15408	82830	366528
10	Specialists (Anaesthesia, Medicine, Obst., Ophth. Paediatrics & Surgery)	-	-	65770	104903	18618	20080	209371
11	Managerial Categories	-	101182	37944	18244	3210	2008	162588
	Grand Total	1258188	1113002	609634	930444	252948	404110	4567322

Source: HLEG Report on UHC for India

Table 5: HRH Education & Training Proposed Costs (XII and XIII Plans 2012 TO 2022)

	Institutions	Unit Cost (Crore)	Proposed					Costs (Rs. Crore)				Total Costs
			2012-2015	2015-2017	2017-2022	Total		2012-2015	2015-2017	2017-2020	2020-2022	
			A	B	C & D			A	B	C	D	
A	Educational Institutions											
1	ANM Schools - New*	5	201	31	-	232		1005	155	-	-	1160
2	ANM Schools- Strengthening	1	145	66	-	211		145	66	-	-	211
4	Nursing Schools - New *	8	98	93	191	382		784	744	784	744	3056
5	Nursing Schools- Strengthening	0.5	150	100	-	250		75	50	-	-	125
6	Nursing Colleges - New	10	15	14	29	58		150	140	150	140	580
7	Nursing Colleges - Strengthening	6	30	30	-	60		180	180	-	-	360
8	Medical Colleges - New	100	59	70	58	187		5900	7000	4000	1800	18700
9	Public Health Management colleges	10	10	10	10	30		100	100	100	-	300
10	Allied Health Professional Colleges	10	172	163	213	548		1720	1630	2130	-	5480
	Sub-Total		880	577	501			10059	10065	7164	2684	29972
B	Trainings & Quality Strengthening											
11	District Health Knowledge Institutes - Trainings, Bridge courses, LHV training, BRHC, Diploma courses - Technician	10	172	163	213	548		1720	1630	2130	-	5480
12	CHW Trainings at DHKIs	-	10 lakh CHWs	10 lakh CHWs	20 lakh CHWs	-		275	275	275	275	1100
13	LHV Schools - Strengthening	1	16	28	-	44		16	28	-	-	44
14	SIHFW & RIHFWs - Strengthening	1	25	19	-	44		25	19	-	-	44
15	Faculty Development Centres at SIHFWs	10	12	8	-	20		120	80	-	-	200
16	State Boards	1	35	-	-	35		35	-	-	-	35
17	State Health Sciences Universities	5	25	-	-	25		125	-	-	-	125
	Sub-Total		285	218	213	716		2316	2032	2680	275	7303
	Grand Total		1165	795	714	2674		12375	12097	9844	2959	37275

*District with > 5 lakh population

Source: HLEG Report on UHC for India

Despite near absence of regulation, the new private hospitals (foreign or domestic) are not coming up at a pace required to meet the excessive demand. No major regulatory hurdles seem to exist with regard to the setting up of hospitals. Although some form of regulation has been introduced with the enactment of Clinical Establishment Act, 2010 it is still to be implemented in most states. The Clinical Establishment Act, 2010, however, does not seem to create any unnecessary hurdle to competition. It would in fact help in propagating competition in the sector, if it gets adopted by more states. The registering process in this Act is pro-competition, where an applicant can apply for registration on-line in self-declaratory format i.e. (there will not be prior inspection). There are clear-cut timelines with deemed automatic approval in case applicants do not hear from the concerned authorities.

Also the Indian foreign investment policy is very liberal for hospitals. Since January 2000, FDI is permitted up to 100 percent under the automatic route in hospitals in India. Controlling stake is also permitted in hospitals for foreign investors. FIPB approval is only required for foreign investors with prior technical collaboration, but allowed upto 100 percent. Despite this only a few of the approved hospital projects have been completed.

Following are some of the identified **entry barriers**[9], not necessarily regulatory barriers, **in setting up of hospitals and medical colleges**.

- Long gestation period requiring a long-term commitment, which discourages investors. It takes around 4 to 5 years after establishment for a big hospital to break even.
- High initial establishment costs particularly related with cost of procuring land. Procuring land is particularly a problem in big cities and it is becoming more difficult. It has been estimated that of the total project cost around 40-50% are cost assigned to land and construction of building alone. In addition there are instances of are red tape and corruption in getting building clearances, getting water and electricity supplies etc. It can take up to 5 years for building a descend hospital.
- High cost of importing medical equipments & devices, because of limited domestic manufacturing capacity in this area up to 70% of such medical equipments and devices are imported. Medical equipments can constitute around 30% of all fixed assets because of this, and despite recent reductions in import duties. In addition, the rapid technological changes often render obsolete some high cost equipment, requiring fresh investments within a few years.
- Low health insurance penetration, which reduces the consumer base for sophisticated hospitals. It is estimated that less than five percent of Indians are covered with health insurance at present.
- Restriction/inadequate regulation on medical education and training providers, which creates bottleneck in supply of quality medical personnel at all levels. Human resources - doctors, nurses, paramedics etc. - are becoming a major challenge for all public or private hospitals, both in terms of quantity and quality. This bottleneck has bearing on medical education and relevant regulations, which is being dealt in some depth in the following paragraphs.

[9] Predominantly derived from: Rupa Chanda, Foreign Investment in Hospitals in India; IIM Bangalore; 2008

India has the largest number of medical colleges in the world, with an annual production of over 30,000 doctors and 18,000 specialists. However, India's average annual output is 100 graduates per medical college in comparison to 110 in North America, 125 in Central Europe, 149 in Western Europe, 220 in Eastern Europe. China, with 188 colleges, produces 1,75,000 doctors annually with an average of 930 graduates per college. China's increased number could be attributed to a higher rate of admissions per medical college.

The review by the HLEG of registration data from professional councils indicates the availability of one doctor per population of 1,953, with a nurse / ANM availability of 1.5 per doctor. This is far from the WHO norms of one doctor per 1,000 population, and 3 nurses / ANMs per doctor. It is imperative that the admission capacities of these critical cadres are also increased by establishing additional educational institutions in the states with weak HR capacity and high HRH requirements. In addition to HRH availability, it is important to emphasise appropriate education and training for skill up-gradation as recommended by the Commission on the Education of Health Professionals for the 21st Century[10].

According to the MCI guidelines (see relevant portions in the matrix, Annexure 1) only government or trust hospitals can set up such education facilities. It does not allow corporate hospitals to set up training facilities, even though it has permitted a number of substandard private medical colleges that have political patronage, which make money through huge capitation fees. Similarly, the Nursing Council does not allow private players to enter into nursing education unless they from trusts.

Furthermore, the guidelines seems inappropriate as far as the amount of land required, number of classrooms, and size with respect to setting up medical colleges and training schools. For instance, there is a restriction of 500-bed hospitals for getting permission to set up training colleges. Such educational facilities need to have minimum of 10-acre campus. Similarly, the Nursing Council of India requires 50 bed minimum and large size campus but trains only 50 nurses. Such infrastructure and volume based rather than value based approach seems unjustified, viewing similar institutions in developed countries.

In order to deal [11]with the above-discussed entry barriers and bottlenecks, following policy recommendations can be useful:

- Facilitating land acquisition with proper valuation of land and with some subsidization. Other forms of obtaining land could be explored by the investors, such as through leasing arrangements, joint development with real estate developers and arrangement with public sector hospitals owning land.
- Facilitating public private partnerships in hospitals, with private sector hospitals entering into limited period management contracts with public hospitals with suitable terms and conditions. The GOI is planning a policy shift, whereby governments would 'provider' of only primary and part of secondary healthcare while 'procurer' of a part of secondary and tertiary level healthcare from 'contracted-in' private sector.

[10] *Supra 2*
[11] *Supra 5*

- Removing the above-said regulatory barriers and freeing up medical education and encouraging private hospitals to enter into medical education and training in order to expand supply of medical personnel at all levels.
- Incentivising domestic manufacturing of medical devices and technologies. There is scope for further rationalisation of import duties. However, the structure of medical devices sector is such that it needs to be monitored on a continuous basis, particularly to check opportunistic pricing. (also see section on medical devices, below)
- Opening up of health insurance sector as well as introduction of a national or community based health insurance schemes. (also see section on health insurance, below)

In order to facilitate investment in the establishment of more hospitals and medical colleges, the GOI is thinking to bestow "infrastructure status" to healthcare sector. Having infrastructure status the investors in healthcare sector would get certain advantages, whereby further incentivising them. Following are the benefits of infrastructure status should that be provided to healthcare sector[12].

- This would enable healthcare sector to avail long-term funding from agencies such as India Infrastructure Finance Ltd at low rates of interest;
- This would exempt healthcare sector from payment of service tax to commercial or industrial construction companies, reducing input costs of healthcare projects;
- It will enhance external commercial borrowings (ECB) limit for hospitals from the present (capped) USD 100mn per year to USD 500mn, which would help healthcare companies to chanalise more capital to projects in India;
- It would enable healthcare projects to enjoy a 10-year tax holiday, which compensate them for long gestation period.

The granting of 'infrastructure status' to healthcare sector, however, could have certain conditions attached in order to reduce rural-urban divide and access to poor sections. Such conditions could include: (1) applicable in only tier 2 and tier 3 cities and rural areas; and (2) certain beds/OPD earmarked only for below poverty line (BPL) population and for the purpose of National Rural Health Mission (NRHM). These conditions go with the GOI's principle that "access and equity are as important as the need to have further investment in the healthcare sector".

Apart from above-discussed entry barrier, there are **other competition issue** that have been reported extensively and are being discussed below.

Tied selling or the **malpractice of cuts or commissions available to doctors (both public and private) for referring patients to a particular establishment for diagnostic, pathological, radiological and other tests** is rampant. According to the Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002, Consulting pathologists /radiologists or asking for any other diagnostic Lab investigation should be done judiciously and not in a routine manner (clause 3.1.2). However, the same has been observed to be done unjustifiably. According Clause 7.1 of the Regulations of 2002, if a doctor commits any violation of these Regulations, this would amount to 'misconduct' under Clause 7 and hence s/he will be liable for disciplinary

[12] Healthcare needs infrastructure status, The Economic Times, 23rd December 2010

action under Chapter 8 of the said Regulations. This seems to be the legal course of action according to the plain reading of the Regulations of 2002.

Furthermore, in order to rectify this, the government may like to adopt the Standard Treatment Guidelines, prepared by the WHO India Office in collaboration with Ministry of Health. The Guideline, not only provides for 'standard treatment protocol' but also price that could be charged for any test etc. Monitoring of prescription may also be needed in this regard.

Similarly, the **collusion between doctors and pharmaceutical companies** whereby former gets commission in cash or kind for prescribing latter's products, is another malpractice that has become a norm rather than exception. The effect of this makes pharmaceutical market an imperfect market, where generic competition becomes meaningless for consumers, who almost totally depend on doctor's prescription and advice.

In recent years, although MCI has shown some toughness in this regard, but this malpractice reportedly continues. An amendment was done in the Regulations of 2002 and a new clause 6.8 titled "Code of conduct for doctors and professional association of doctors in their relationship with pharmaceutical and allied health sector industry". This new clause came into force on 14.12.09 when it was notified in the Gazette of India. The amended Regulations, thus, clearly precluded medical practitioners from accepting any gift, travel facilities, hospitality, cash etc. from any pharmaceutical companies or allied healthcare industry. The violation of this Code would liable such medical practitioners for disciplinary actions under Clause 8 of the Regulations of 2002. This Code, therefore, needs to be implemented aggressively by MCI. If MCI fails to do so, government or CCI may like to intervene with requisite corrective actions.

The Ministry of Health & Family Welfare has also issued an order (Order SS-11025/45/10-MH-1, 26th May 2010), that government hospitals should prescribe generic medicines to the patients only. Subsequently, the state governments were also asked to ensure that doctors in public hospitals prescribed only generic drugs (as contained in the 45th Report of the *Parliamentary Standing Committee on Health and Family Welfare, August 2010*).[13] However, it is evident that such practices have not been adopted by the state governments in most states (expect a few like[14] Haryana, Bihar and Tamil Nadu), and that the consumer continue to pay high prices for drugs.

One of the suggestions made by the Parliamentary Standing Committee on Health & Family Welfare in its 45th Report is to make it mandatory for the doctors to prescribe in generic names, viewing failure of the MCI Code of Ethics in this regard. However, the Committee also warned about the flip side of mandatory 'generic only' prescription. That even if doctors starts prescribing in generic names, chemists will still be free to dispense any equivalent. The pharma companies then would start wooing chemists instead of doctors, which will be worse than the present situation. Since MCI do not have any jurisdiction over pharma companies, the Committee calls upon the Government to take action against such companies also who tries to woo doctors. In this regard, a Code of Marketing Practice for Indian Pharmaceutical Industry has

[13] http://164.100.47.5/newcommittee/reports/EnglishCommittees/Committee%20on%20Health%20and%20Family%20Welfare/45th%20report.pdf

[14] Unholy Alliances in Healthcare - Collusive Behaviour in Healthcare and Impact on Consumers: *Evidences from Assam & Chhattisgarh*, CUTS 2011

been formulated by the Department of Pharmaceuticals. Clause 6 and 7 of the Code precludes pharma companies to induce doctor's prescription by providing gifts and other benefits. The Code is intended to be voluntary and would be reviewed after five years, and if need be it could be turned into an enforceable statute. The Code is yet to be notified and hence is not in force at present.

It is **recommended** to enforce this Code as soon as possible. It is also recommended to reduce the review period from five years to one year, and if it is found after one year that the voluntary nature is not working it should be immediately be turned into an enforceable statute.

The said collusions between doctors & pharmaceutical companies and doctors & pathologists can also be checked with the adoption of a "standard treatment guidelines" for the whole of India. This would further mitigate the harm to consumers due to significant prevalence of information asymmetry in the healthcare sector, where most decisions are taken by doctors and consumers have no choice but to abide by them. A standard treatment guideline has already been devised by the WHO India Office in collaboration with MOHFW, India. It is recommended that the MOHFW should facilitate adoption of these guidelines as soon as possible and facilitate adoption of the same by state governments.

The above-said concern regarding doctor's prescription can also be mitigated to a significant level by adopting adequate awareness generation programmes. Mention of Dr. Samit Sharma (IAS) who served as District Magistrate in Chittorgarh and th agaur districts of Rajasthan would N not be out place. According to the above-mentioned 45 Report of the PSC, Dr. Sharma launched a campaign in these district by first convincing doctors to prescribe medicines by generic/ salt name as per the direction given by the State Government and removing the false notions about inferior quality of generic medicines. He also found huge gaps in procurement rate and MRP in several common medicines. He induced awareness about the huge difference in prices among all stakeholders, particularly pharmacists and patients. Advertisements to this effect were issued by the District Health Committee (Nagaur and Chittorgarh) under the National Rural Health Mission. As a result there was sharp fall in the treatment costs. For example, for the treatment of Pneumonia involving 7 days therapy, the cost was Rs. 1136 when branded medicines were used compared to just Rs. 139.51 with the use of generic medicines. A saving of Rs. 6.05 crore in the treatment of 4.03 lakh patients in 6 months was estimated. Private Chemist Associations also agreed to sell generic medicines at 50 percent discount on MRP.

Collusion between private hospitals and drug companies to exploit consumers has also been observed in India. According to a case brought in a consumer forum in Andhra Pradesh revealed that a private hospital had entered into a contract with a drug manufacturer to supply drugs to the hospital at prices, which were above the market price. In a survey, 27.2 percent of the hospitals surveyed c15 onfirmed that hospitals and manufacturers did enter into agreements to exploit consumers . There is hardly any regulation for hospitals to tackle such kind of practices. But the same can be dealt with in the Competition Act and may also amount to criminal offence under S.420 of IPC.

[15] Options for using competition law/policy tools to deal with anti-competitive practices in pharmaceutical industry and healthcare delivery system, CUTS 2006

Some anti-competitive practices, in form of "**market allocation**" have also been observed within certain corporate hospitals. There are anecdotal evidences to suspect that the hospital management while demarcating a doctor for a patient tends to nullify any option available with the latter. The practice of allocating work to a doctor (from the available pool in a therapeutic segment) who is responsible to bring extra income to hospital (say by prescribing unneeded diagnostic tests) against those who (from the given pool) a patient would have preferred, kills choice of consumers and are hence anti-competitive. Such matters may be looked into by the governments and Competition Commission of India.

Pharmaceuticals

**As a separate sector research study on pharmaceuticals is being conducted, this paper would reflect only on some select contemporary intellectual property related issues for competition advocacy, from public health point of view.*

According to the WHO, private expenditure in health care in India is around 74 percent, among the highest out-of-pocket expenditures on health anywhere. Of this 74 percent, 67 percent is spent only on pharmaceuticals. That means out of total expenditure on health care, around 50 percent is spent out-of-pocket on pharmaceuticals alone. In simple terms, if Rs.100 is the total healthcare expenditure, Rs. 74 is spent from consumers' pocket of which Rs.50 is spent on pharmaceuticals only. This makes the pharmaceutical sector very important from public health perspective.

As per obligations under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organisation (WTO), from 1st January 2005 onwards the product patent regime has been introduced in India vide Patent (Amendment) Act, 2005. Now product patent is enforced in all sectors, including the pharmaceutical and agro-chemical sectors, which so far had been out of such provisions.

As expected the likely impact of the product patent regime is being felt now (2010-11 onwards) when the first set of drugs with product patent has begun to enter into Indian market. Even though TRIPS Agreement read with Doha Declaration provide certain flexibilities to address concern with respect to access to medicines, and India incorporating almost all those flexibilities, some concerns remains.

The following paragraphs would illustrate upon those concerns and reasons behind them and would further endeavour to provide options to mitigate such concerns.

Patentability criteria

It has been observed in an study conducted jointly by WHO and ICTSD that "a greater number of grants of patent made on the basis of low standards of patentability may lead to unnecessary limitations on competition without any significant trade-off in terms of more innovation to address society's need". The TRIPS Article 27.1 prescribes patentability criteria in general terms, which permits Member countries to adopt different criteria to assess patentability. India has used this flexibility in its Patents Act vide Patents Amendment Act of 2005, in following a stricter standard of patentability criteria. This is perhaps the most pro-competition action taken by the Parliament, in this regard.

As far as patentability of pharmaceuticals is concerned, the Indian Patents Act excludes the following:

- New uses of known substances (section 3(d));
- New forms of known substances, without significant enhancement in efficacy (section 3(d));
- "Mere admixtures" (section 3(e));
- "Any process for the medicinal…therapeutic or other treatment of human beings" (section 3(i)).

These provisions aim to check the grant of frivolous patents in order to stop the 'evergreening' of patents and are meant not only to enhance access to medicines by promoting competition, but also to recognize the importance of competition as driver of innovation and technological development.

However, in a UNDP study[16] lacunae and inconsistency have been found in the way Indian Patents Offices are applying and interpreting the said provisions and hence undermining the intent of the Parliament (of following a rigorous patentability criteria). There are incidents where few pharmaceutical patents have been granted that could have been avoided had the Parliamentary intent been followed in spirit.

In the said study, the analysis of the claims contained in the 84 granted patents shows that patents relating to composition/formulation constituted by far the largest proportion (67 percent). A significant number (16 patents or 19 percent of the sample) of patents reviewed were formulated as composition claims but were in fact 'new use' or 'method of treatment' claims 'in disguise'. A number of patents relating to other secondary features, such as salt forms, esters, prodrugs, enantiomers, etc., were also granted (8 patents, or 10 percent of the sample).

Specifically the Patent Offices were found to err on the following:

- Interpretation of the meaning of 'efficacy' in Section 3(d). 'Advantageous properties' with respect to bioavailability, stability etc. of new forms of known substances has been treated as 'enhancement of known efficacy' within the meaning of Section 3(d). An advantageous property is not the same as efficacy.
- Lax examination of patent applications with respect to 'mere admixtures', compositions, dosage forms, formulations and combinations even without demonstrable synergistic effect between the components.
- Patent offices allowed insufficient and unclear data in the patent specification with respect to 'enhanced efficacy' requirement of section 3(d) and 'synergistic effect' requirement of section 3(e). These needed to be spelled out clearly in specification and not to be proffered for later date during the opposition hearing.
- Patent offices allowed reformulation of 'new use' claims as 'composition' claims, with respect to 'new use' exclusion of section 3(d).
- Patent offices overlooked the readily available prosecution history of patents rejected by USPTO and European Patent Office (EPO). Some patents have been granted in India, which were rejected by USPTO and EPO that have much more liberal patentability criteria than India.

These are serious drawback on the part of patent offices as far as implementing the public health safeguards available in the Indian Patents Act. These seriously hamper and/or delay generic competition in pharmaceutical sector at the cost of consumers. Therefore, things need to be rectified, sooner the better.

[16] Five years into product patent regime: India's response, UNDP, 2010

In this regard, the Government may like to consider the following recommendations:

- Provide a suitable illustration or explanation in the Patents Act as to what constitute "enhancement of known efficacy" within the meaning of section 3(d). It needs to be clearly mentioned that various common 'advantageous properties' (such as: improvements in bioavailability, potency, stability, higroscopicity, flow properties, ease of manufacture etc.) arising from converting a known substance into new form does not amount to "enhancement of known" within the meaning of section 3(d) and hence not patentable. To begin with such explanations can immediately be incorporated into the Patent Rules and patent examination guidelines.
- Provide clarifications in the Act with respect to interpretation of section 3(e) to clarify that admixture (composition, formulation and dosage form) claims require showing of synergy, independent of satisfying inventive step. As a general rule, formulation techniques and range of compounds that may be used to develop pharmaceutical products in different form need to be understood as known to a person skilled in the art.
- Ensure that patent examiners/controllers play, as a general rule, an adversarial role (instead of facilitative role) vis-à-vis patent claims in an application.
- Establish an institutionalized coordination mechanism between patent offices (DIPP) and DCG(I) (MOHFW) for scrutinizing pharmaceutical patent claims, in general, and those related to section 3(d), (e) and (i) in particular. The latter has the expertise to assess concepts like "enhancement of known efficacy", to determine "synergistic effect' etc.
- Expedite the process of making patent information online and fully searchable, including published applications, granted patents, complete specifications, examination reports, patent office decisions, details of opposition filed and correspondence between the applicant and the patent office.

The above-said measures would not only help enhance generic competition, but the government could also avoid spending its political capital necessary to grant and sustain compulsory licenses/government use. If patent applications were correctly scrutinized, there would be no need to have recourse to such measures. In contrast, there has been a consistent pressure to dilute or repeal Section 3(d) of the Patents Act, either by big global pharmaceutical companies (through lobbying and court cases) or developed countries in the wake of reaching bilateral trade and investment agreements. India needs to guard against such pressures.

Sufficiency of disclosure and Markush claims

The so called "Markush claims" are claims in a patent application that include general formulae with multiple options, which could protect several millions of molecules under a single patent. Further it is also possible to apply for a patent on a selection of originally covered molecules in such a way that protection may be extended for an additional patent term. Dr. Markush, who was founder president of Pharma Chemical Corporation of Bayonne, obtained an US patent on pyrazolone-based dyes that protected a generic chemical structure. Since then patenting of such structures are allowed in the US.

According to one study, in India, at least 630 out of the 1432 product patents granted during 2005-2008 contained Markush claims, Markush claims, if allowed by patent office for pharmaceuticals, could give rise to a very complex situation where a single patent can potentially limit or block R&D and commercialization of a very large number of products. In addition, this also raises

issues concerning (1) sufficiency of disclosure, because the patent applicant has in real terms obtained only a handful of the claimed compounds; (2) difficulty of prior art searches, virtually making it impossible; (3) transparency, making it difficult for third parties to identify patent applications that would merit pre or post-grant opposition.

More so, if patents are to encourage R&D, it is through public disclosure of information relating to inventions in the patent documents. If this is not done properly then the exclusivity allowed with the grant of patents are not justified. Even though there has been significant developments in the way Indian Patent Offices have been publishing grant of patents with complete specifications, many shortcomings have been found. Many researchers have complained that it is very difficult to obtain full and accurate information as there are gaps in the information contained in the patent office database. It has been alleged that key words are not reliable enough to determine the status of an individual product or process and the patent coverage. The claims granted or rejected are no easily obtainable. Titles of granted patents are often in very general terms, from which it very difficult to derive generic name of the active ingredient or international non-proprietary name (INN) of drugs to which patent refers to. It is very difficult to identify patents related to specific medicines. This information is particularly important for person desiring to file opposition to the grant of patent and for the agencies in making procurement decisions.

Furthermore, Resolution 61.21 of the 2008 World Health Assembly, urged the WHO to: "compile, maintain and update a user-friendly global database which contains public information on the administrative status of health-related patents, including supporting the existing efforts for determining the patent status of health products in order to strengthen national capacities for analysis of the information contained in those databases and improve the quality of patents."

Recommendation:

- The issues related with Markush claims need to be analysed in detail and adequate measures need to be adopted so that the granting of patents with such claims does not become a constraint for research on new compounds and/or create undue restriction to competition. Also claims for 'selection patents' to compounds covered by original patent should not be allowed.

- In order to improve the transparency of the patent system, the international non-proprietary name (INN) of drugs, when known at the time of filing of a patent application, should be mandatorily disclosed in its title and abstract.

Merger & Acquisitions

The world over, pharmaceutical industry is undergoing a paradigm shift in the way it conducts business to sustain its growth. With R&D pipelines running dry and many blockbusters going off-patent, big MNCs are trying to come up with new business model to continue its growth, including sale and manufacture of generic drugs. This has given rise to the takeover of Indian companies in the recent years. Given below is the list of Companies acquired by MNCs in the last five years:

Acquisition of Indian Companies by Foreign MNCs

Year	Indian Co taken over	Foreign Company which took over	Country of origin	Take over amount USD millions
Aug 2006	Matrix Lab	Mylan	USA	736
April 2008	Dabur Pharma	Fresenius Kabi	Singapore	219
June 2008	Ranbaxy Labs	Daiichi Sankyo	Japan	4600
July 2008	Shanta Biotech	Sanofi Aventis	France	783
Dec 2009	Orchid Chemicals	Hospira	USA	400
May 2010	Piramal Healthcare	Abbott	USA	3720

Acquisition of Indian pharmaceutical companies by multinationals is driven by following main factors:

- R&D of the global innovative companies for New Chemical Entities (NCE) are drying up
- Sixty one drugs worth USD 80 bn will go off patent in the US between 2011 and 2013. Indian pharmaceutical industry is all set to gain from the patent expiry of some blockbuster drugs by producing their generic equivalents.
- Increase in demand of generics, in high growth emerging and developing markets
- With increase in life expectancy, Governments in many developed countries are battling with increasing healthcare cost and promoting the usage of generic drugs. One key reason for the acquisition is the fact is that multinational companies want a cut out of the generic market in the developed countries and middle income countries which traditionally Indian companies have dominated. Moreover, Indian generic companies have a strong distribution network not only in India but other middle income countries - an area of major interest for MNCs.
- India has highest number of US-FDA approved plants, outside the US. Most of these plants have multiple approvals from regulatory authorities in Canada, Australia, Germany and other OECD countries
- Foreign Direct Investment (FDI) in drugs & pharmaceuticals upto 100 percent is permitted through automatic route in India
- Even though generics are a high volume low margin business, when one looks at the world as a market, the margins look encouraging.

The question is whether in the long run this trend of acquisition will benefit or harm Indian patients. There is a fear that with MNC management in place gradually the prices of medicines will begin to increase. Some of the possible consequences of the takeovers are listed below:

- To date, the impact of the introduction of product patents for pharmaceuticals in India in 2005 is only now starting to be felt. This is because there is a time lag between the grant of a patent and the moment the drug actually enters the market, mainly due to market

registration procedures. Changes in price due to the introduction of patent protection would first be experienced from 2011; this is because the first set of drugs under patent protection enters the market only now. Thereafter there is very likely to be a substantial increase in price levels. The Indian generic pharmaceutical industry will slowly lose its market share as the introduction of product patents makes itself felt. This is why a number of Indian promoters are selling off their stake in the generic companies to multinational companies.

- Rationalisation of product portfolio;
- Price increases to pay for the premium paid by the acquirers;
- Discontinuation of product for inadequate margins etc.
- The MNCs in India have already raised their share of the domestic market to 25 percent from 15 percent five years ago. The increasing dominance of the MNCs will lead to more prescriptions for the MNCs, driving away the domestic companies. It has received policy recognition that domestic pharmaceutical manufacturing units are *sine qua non* for meeting public health requirements. One of the objectives of National Drug Policy of India, 1986 is strengthening the indigenous capability for production of drugs.
- It is important to note that notwithstanding provision for compulsory licensing in the Patent Act, the domestic companies have not evinced interest in pursuing this option. There are two main reasons for their lack of interest: First, compulsory licensing procedure is very cumbersome, costly and the outcome is uncertain. There is also fear of reprisals. Secondly, many large domestic companies capable of making use of this provision have alliances with the MNCs involving commercial interests. They would not like to risk these alliances. **It is in this context that one should view more acquisitions**. They would leave the country without option for use of this important provision of compulsory license to meet the problems of public health.
- The reduced domestic availability of many essential medicines (anti-retroviral, anti-cancer, vaccines, etc.), earlier manufactured and sold by the acquired companies, may weaken competition leading to headroom for increase in domestic drug prices.

Thus, acquisitions could very likely impact affordability. Therefore, it is important that the generic industry is encouraged and at the same time there should be policy guideline which shields such companies from takeovers. This will not only be in the interest of the Indian consumers but, as shown above, for the world at large.

How to tackle this situation? There has been proposal from some quarters to cap the FDI in pharmaceutical industry by bringing it down from 100 percent to 49 percent in the wake of increasing acquisitions in the sector and subsequent fears on the availability of cost-effective generic drugs. However, this may not be desirable or even required. While 100 percent FDI could continue, an oversight mechanism may be needed for those brown field FDIs (M&A) that tends to change the ownership from domestic to foreign, with a view to assess its impact on public health, which have been described above.

The views prevailing in the Department of Health & Family Welfare is that the capping of FDI may not be an ideal solution. Instead it favours sectoral regulatory conditions in the pharma sector. That there is the need to exercise a certain degree of oversight over takeovers of the existing (brown field) firms/companies. Therefore the proposal of DOH is that the FDI in

Pharma sector should be 100 percent, however, in the brown field companies, any FDI beyond 51 percent be through the FIPB route. FDI in green field projects can remain at 100 percent. In other words, only those Brownfield FDI that exceeds 51% (change of ownership) need to come under FIPB route and the rest can be done through 'automatic route'.

There is certainly merit in DOH proposal. However, whether or not FDI through M&A gives rise to competition concerns either directly (e.g. giving dominant position with respect to any therapeutic segment) or indirectly (e.g. reducing options for issuing compulsory license) need to be examined on case-to-case basis. A close coordination between FIPB, MOHFW and Competition Commission of India would be required in this regard.

However, question from **competition neutrality** may arise when we target regulation with respect to 'ownership' of the merging entity. But it can be justified in light of the above-said discussions and future concerns that are likely to arise from public health perspective because of increasing M&As in pharmaceutical sector.

There has been media debate on this matter whether FIPB or CCI to look into the matters of pharmaceutical M&As, pointing as if only one of the two can be the gatekeeper. It is submitted that one is policy issue (FDI policy) and other is a legal mechanism and both can co-exist, similar to that in telecom, where FDI matter is policy issue separate from TRAI regulations and both are co-existing. It is also submitted that many public health concerns (including those which are futuristic in nature) are such that may not come under oversight of CCI within the present legal framework. For medicine and vaccine security a viable domestic (both public and private sector) pharma manufacturing unit is must.

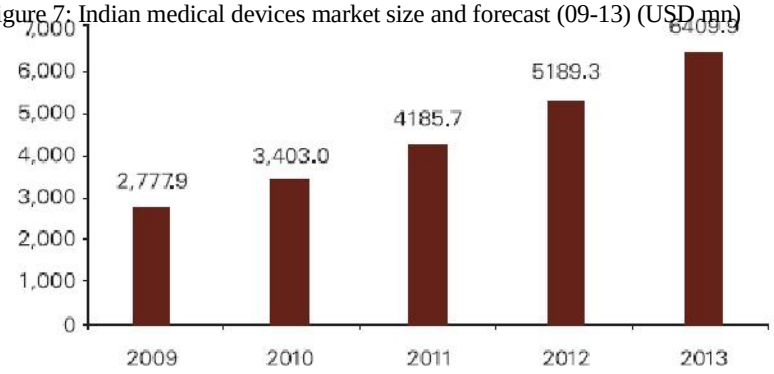
Most importantly, the 'motive' behind recent wave of M&As in pharmaceutical sector is clear and this motive is to reduce (or block) generic competition at some stage in future. Otherwise there was no justification of bidding such a high cost for a company. This 'motive' is outside the mandate of the Competition Law of India. If looked closely, there seems to be a concerted effort (read collusion) of a group of few global pharmaceutical companies (read cartel) 'to acquire' big Indian companies that can cause 'appreciable adverse effect' on generic market in India and abroad. *Prima facie,* **these kinds of arrangements fall under Section 3 of the Competition Act, 2002, and hence Competition Commission of India may initiate an investigation under Section 19 of the Act**.

Medical Devices

According to World Health Organization the term "medical devices" includes everything from highly sophisticated computerized medical equipment down to simple wooden tongue depressors. Therefore, medical device market is quite diverse which includes medical and diagnostic equipment; medical implants like heart valve and cardiac stents, pacemakers, cannulae, knee joints; and lower end plastic disposables, blood bags, IV sets, syringes etc.. Even within the same group of implants, there are diverse products which may have hardly anything in common: for examples, Intra-ocular lens and knee joints.

According to one source, in 2012, the Indian medical devices and diagnostics market has been estimated to have reached Rs. 139bn[17] that had potential to grow at a CAGR of 23.2 percent over the period 2009-13[18] (Figure 7). It has been estimated the market will g[19] by an average of 15.6 row
percent over the next few years, to around USD 4.8bn by 2015 . Increasing physicians' awareness and increasing patients' requirement to avail high quality care are amongst the driving force for such a growth rate. The Figure 8, below gives a vivid idea of such driving forces. However, the five largest global markets for medical devices (the U.S., Japan, Germany, France, and Italy) account for 13.1 percent of global population and 76 percent of global medical device use. The U.S. has a share of 50 percent in recent years of the world medical device market. Conversely, the five most populous countries (China, India, Indonesia, Brazil and Pakistan) account for nearly half of the global population but only 4.4 percent of global medical device use.

Figure 7: Indian medical devices market size and forecast (09-13) (USD mn)



Source: KPMG-CII

In India, there are around 700 medical device makers; however, major players remain the foreign companies. Few major players in medical devices industry include: B. Braun Medical(I)Pvt. Ltd; BL Life sciences Ltd; 8.3 Baxter India; Bayer Diagnostics India Ltd; Godrej Industries Ltd; Johnson & Johnson Medical India (JJMI) Ltd; Nicholas Piramal India Ltd; Opto Circuits (I) Limited; Philips Electronics India Ltd (Medical Systems Division); Roche Diagnostics India;

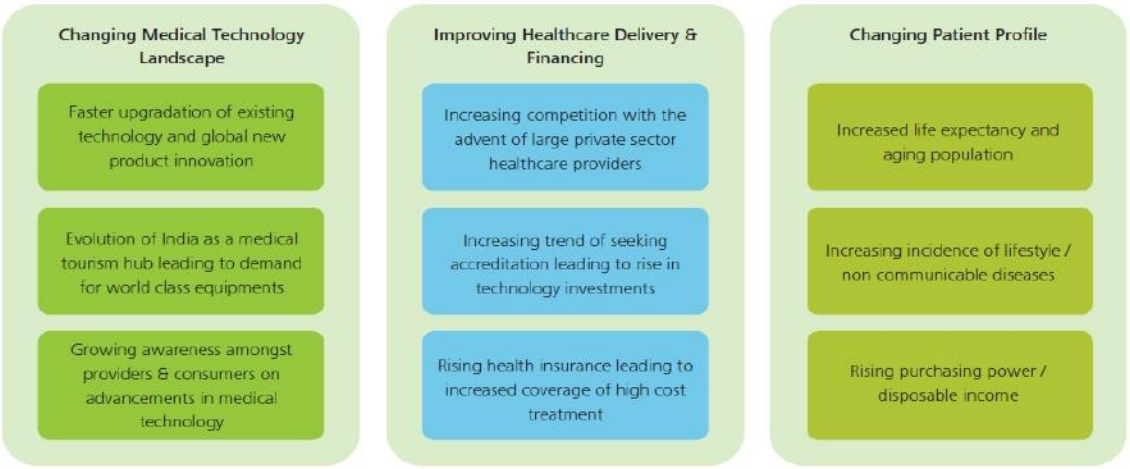
[17] Hidehiro Itokawa, Chairman, Arkay Piramal Medical Private limited; Express Healthcare; http://www.expresshealthcare.in/200809/market05.shtml

[18] Excellence in Diagnostic Care, KPMG-CII, 2009 http://www.kpmg.com/IN/en/IssuesAndInsights/ThoughtLeadership/Excellence_in_Diagnostic_Care.pdf

[19] *ibid*

Siemens India Ltd; Span Diagnostics Ltd; Trivitron Medical Systems; Wipro Biomed Ltd; Wipro GE Medical Systems.

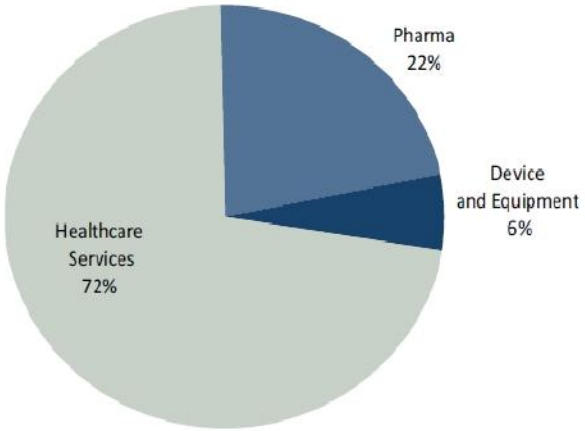
Figure 8: Key Growth Drivers for Medical Technology Industry in India



Source: Deloitte-CII

Although the Indian market for medical equipment and supplies ranks among the world's top 20, it is still plagued by low penetration and remains disproportionately small due to very low per capita spending. The per capita spend on medical technology in India is approximately US$2, as compared to US$5 for China and US$231 for Germany. One example to illustrate low penetration is sales of pacemakers, which at 18,000 units per year India's pacemaker penetration is just one percent of western levels. The medical device and equipment market in India constitutes of around six percent of the total healthcare market (See Figure 9), and is only 15% of pharma market size, compared to 28% worldwide, indicating underutilization of medical devices in Indian healthcare, pointing to untapped market.

Figure 9: Total Healthcare Market: India, Break-up by various segments (2006)

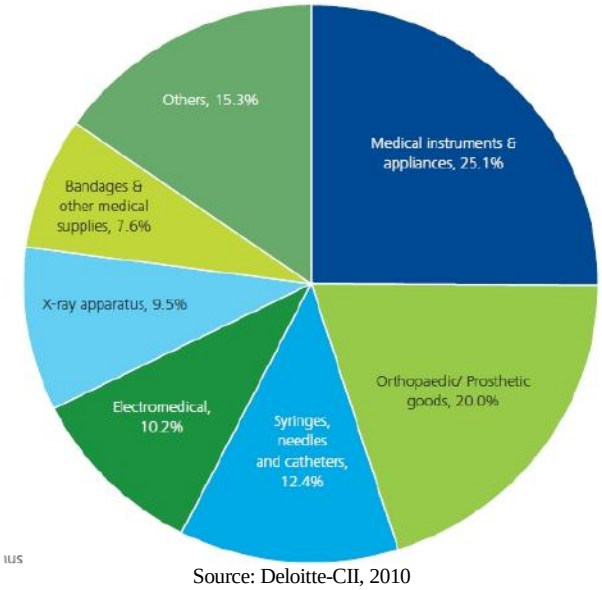


Source: NIPER, Ahmedabad

The presence of sufficient numbers of domestic and foreign players though makes the sector highly competitive, yet it is fragmented. While domestic firms primarily manufacture low technology products such as disposables/ medical supplies, MNCs primarily import high end

medical equipments. However, in recent years, some domestic firms have expanded local manufacturing operations to produce cost effective medium-end medical devices. Most MNCs are involved in distribution of medical technology products, though some of them have set up manufacturing operations in India. MNCs seeking to enter the industry typically form joint ventures with local manufacturers, establish subsidiaries or employ local agents to distribute their products. However, increasingly these companies are moving away from the practice of importing through local agents and setting up subsidiaries. According to industry sources, in 2007, over 25 foreign medical device companies received licenses to import medical devices in India through their subsidiaries[20]. On the other hand, many domestic manufactures[21]are turning into traders since it is more profitable for them to import devices from China to India .

Figure: 10 Indian Medical Technology Industry - Key Segments

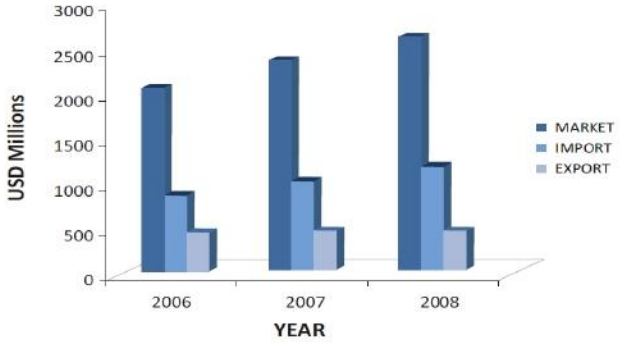


Source: Deloitte-CII, 2010

Indian imports constitute about 75 percent of total medical devices, at the same time nearly 60 percent of domestically manufactures medical devices is being exported. While imports constitute mainly high end devices, the exports constitute low-to-medium end devices. The exports of high quality, high tech Indian products are very[23] compared to other developing low countries[22] and which struggle with stigma for unreliability . Main import source for India in medical device is the US, which accounts for around 25 percent, followed by Japan at 11 percent (see figure 12).

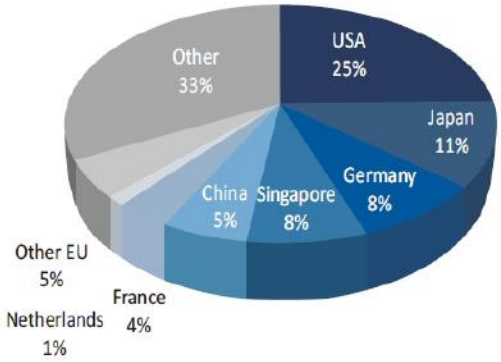
[20] Medical technology industry in India: Riding the growth; Deloitte-CII; July 2010; http://www.deloitte.com/assets/Dcom-India/Local%20Assets/Documents/Medical_technology_Industry_in_India.pdf
[21] *Supra 18*
[22] *ibid*
[23] *Supra 18*

Figure 11: Indian Market - Import and Export



Source: NIPER, Ahmedabad

Figure 12: Medical devices imports from different countries



Source: NIPER, Ahmedabad, 2009

The low domestic manufacturing base of high-end medical devices in India can be attributed to the following **entry barriers**, which are pre-dominantly non-regulatory in nature.

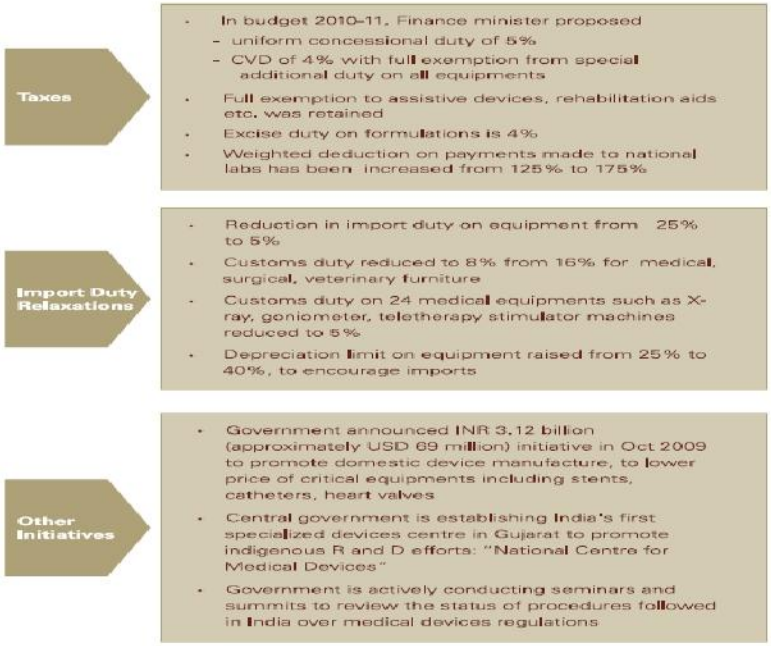
- Poor infrastructure for R&D and testing facility for efficacy and safety testing[24];
- Lack of trained personnel for serving in this industry with sufficient technical a[25] well as
- s
  pharmacy-based knowledge, which is integral for such a multidisciplinary sector ;
  Lack of incentive and non-proactiveness on part of the government to encourage local or foreign companies to set up a production base in India. The current duty structure and other fiscal benefits (see Figure 13) for medical devices and equipments favours imports, reducing the competitiveness and growth potential of the local medical technology industry. Unlike China, which encourages manufacturing of medical devices and equipments, Indian laws indirectly reward trading by charging higher duties on raw materials than on finished goods. For instance, titanium sheet/ rod imported for making implantable pacemakers attracts a total import duty of 23.89 percent, while import of the pacemaker itself attracts a duty of 9.36 percent. As a result, in many cases, cost of a
  finished[26]product manufactured within the country remains higher than an imported product.

[24] Medical Devices in India: Recommendations for NIPER; October 2009, NIPER, Ahmedabad; http://perdcentre.com/perdcenter/download/finalbook-events.pdf)
[25] *ibid*
[26] *Supra 20*

- Medical technology is capital intensive, and setting up a manufacturing plant requires significant investment. While the industry is on a high growth trajectory in India, the overall market remains small due to low penetration. As a result, volumes are low and do not provide economies of scale for most manufacturers. Pune based manufacturer of catheterisation labs (where stenting is done), Alpha X-Ray (acquired by Philips) is a case in point. Alpha X-Ray began making its own path labs from scratch less than seven years ago at less than half the price of an imported one and expanded access to many districts in Maharashtra. Yet Alpha's promoters sold out, since it was struggling for funds, according to P.V. Gopal, a co-founder.[27]

Local manufacturing will not only enable production of cost-effective devices and hence increase penetration; it will also curtail present dependency on imports which has been recognised as one of the entry barriers in setting up a hospital. The cost-effectiveness can be explained from the example of GE baby warmer, which was earlier imported at USD 30,000 now sells for less than USD 3,000 after being domestically manufactured. What has helped keep the production cost low is the company's policy of manufacturing not just the finished products in India, but also many of the components that go into it[28].

Figure 13: GOI's initiatives to incentivise medical device sector



Source: CII-KPMG

Apart from the above-said entry barriers, one reported competition issue in the sector relates with the procurement of medical devices by CGHS and ESIC which amounts to **disincentive for local manufacturers as well as competition distortion** in the relevant market. Recently CGHS and ESIC issued a notification in which they prescribed three different ceiling of prices for medical devices on the basis of country of registration - lowest for Indian approved devices and highest for US-approved and in between that for EU-approved. For instance, in the CGHS notification, a

[27] *ibid*
[28] *ibid*

drug eluting stent with the US approval had a ceiling price of Rs 65,000 a piece, the limit for Europe-approved stent was Rs 50,000 and Indian one was Rs 40,000. Similarly, a higher price was allowed in ESIC tenders for supply of devices such as electrosurgical generators and diathermy that had the USFDA approval, than products with Indian registration or any other European registration[29].

These government agencies need to desist from such discriminatory practices because this would not only adversely affect increasing domestic base of medical device manufacturer, but also tend to **reduce the incentive of suppliers to compete**. Firstly it undermines the domestic drug regulatory regime by implying that the DCGI approval is not optimal. Secondly, in the absence of a clear rationale and justification for favouring foreign regulatory approvals it seems *prima facie* discriminatory and a regulatory barrier against the domestic medical device manufacturers. Thirdly, if without basis and justification, it influences consumer minds that are victims of asymmetrical information in the relevant market to choose foreign medical devices over purely domestic medical devices on baseless grounds[30].

Table 6: SWOT Analysis of Medical Device Industry

Strengths	Weaknesses
• Potentially huge market with growing urban middle class population • Growing private hospital sector aiming to attract health tourists	• Low per capita expenditure • Lack of implementation of government policies and infrastructure • Untapped rural markets • Excessive dependency on imports • Academic know-how not well developed • Support system from R & D not available
Opportunities	**Threats**
• Overseas companies investing in India to set up research units and develop new products • Increasing joint ventures and agreements • Overseas aid assisted projects to improve healthcare infrastructure • Regulations to improve market for domestic manufacturers	• Regulation policies may slow down the development of the market • Unorganized market for medical disposables • Lack of regulations in Medical disposables and surgical items leading to spurious products

Source: NIPER, Ahmedabad

Regulation of Medical Devices

Medical device in India has no separate legal status and is currently regulated by the Drug Controller General of India (DCGI) of the Central Drugs Standard Control Organization (CDSCO) under Drugs and Cosmetics Act 1940. A medical device falls under regulation cover in India only when it is notified to be included within the definition of "drugs" under sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940. So far only 14 medical devices (e.g. cardiac stents, catheters, orthopaedic implants etc.) have been notified for regulation, where as more than 3000 medical devices are available in the market.

[29] Business Standard, 23rd December 2011
[30] Competition Distortion in India; No. 14, October-December 2011; CUTS International

Therefore, the present piecemeal regulatory approach for medical devices in India results in application of redundant rules. In certain cases, product registration and manufacturing standards intended for drugs are applied to the manufacture of devices - e.g. it is insisted that an expiry date be given on certain medical devices, whereas this is not required for such products. This also results in lack of clarity and transparency about regulation. There are also problems pertaining to multiple levels of government authority involved in enforcing the guidelines, as well as inconsistent interpretation and application of the regulatory guidelines by customs officials at the ports, state drug controllers, and officials within CDSCO. This results in a prolonged and cumbersome regulatory pathway, especially for new products.[31]

The Health Ministry recognises that the above-said inadequacies of the present regulatory regime of medical devices and is endeavouring to rectify the problems. The Ministry is in the process of drafting a new Bill especially for the regulation of medical devices, which would have separate definition for medical devices and there would be provisions for separate manpower for its regulation and separate standards for clinical trials of a medical device. Then there would not be any need to notify all the time for a device let it into regulatory control.

A draft Bill titled Medical Devices Regulation Bill, 2006 is available for comments at the Department of Science and Technology website, but it has not been well received by the Health Ministry and hence it is not likely to move further. In 2007 the MOHFW had drafted a Bill to amend D&C Act for the purpose of regulation of medical devices, which went to the Parliamentary Standing Committee. Many recommendations were suggested and with majority of them states were not comfortable. The Bill was based on the Mashelkar Committee report that had recommended that the licensing should be with the Central Government, functioning through a Central Drug Authority. Many states are not comfortable with this set up.

In 2004, the Mashelkar Committee called for the creation of a specific medical devices division within the Central Drugs Standard Control Organisation (CDSCO) to address the management, approval, certification and quality assurance of all medical devices in India. These regulations work within a similar framework as medical 'drugs' (or combination products) and aim to enhance the requirements for devices that were subject to few or no controls, reduce duplication of devices previously assessed by foreign regulatory bodies and place increased emphasis on manufacturer quality, risk management systems and post-market surveillance[32].

Box 2: Salient features of current guidelines for manufacturing of medical devices
• Application for the grant of licence for manufacture of the notified sterile Devices in the country shall be made in Form 27 to the State Licensing Authority, accompanied by the requisite fee in the Form and manner as prescribed in the said rules along with a copy to the office of DCGI. • A period of 60 days would be provided for making the application for manufacture from the date of publication of these guidelines. • In case of devices belonging to the categories, which have not been manufactured in the country before the date of notification, no manufacture would be permitted henceforth without the approval of the competent authority as per norms prescribed.

Source: NIPER, Ahmedabad

[31] *Supra 20*
[32] *Supra 24*

Box 3: Salient features of the Guidelines for import of medical devices
• For the purpose of import of Devices, the procedure for registration and import licence as prescribed under the Drugs and Cosmetics Rules shall be followed. • A period of 60 days would be provided for the importers to make application for import and registration from the date of publication of these guidelines. • In case of devices which have not been imported in the country before the date of notification no import would be permitted without the approval of the competent authority. • For the time being and for a period upto six months, until an application is approved or rejected, whichever is earlier, the devices which are currently in use will be permitted to be sold. In case of stents or drug eluting stents, the import will not be permitted if the applicant has sold less than one thousand stents of the particular specification prior to the date of issue of these guidelines. • Separate committees consisting of subject experts and representative of DCGI office would be setup for their expert advice for evaluation of specific categories of devices. The expert committees would formulate their own benchmarks and procedures for evaluations and the standards to which such devices should conform. Source: NIPER, Ahmedabad

Two features of the Guidelines for imports of medical devices, mentioned in Box 3 above, seems to be problematic from competition policy point of view. (1) The requirement for an applicant "to have sold at least one thousand stents of particular specification prior to the date of issue of the guidelines" *prima facie* seems to create an **'entry barrier'** in absence of any valid justification. (2) The fact that the "expert committees would formulate their own benchmarks and procedure for evaluations and the standards to which devices should conform" *prima facie* seems **'arbitrary'** in nature giving rise to regulatory uncertainty.

That said, for the purchase of medical equipment/devices the government authorises the public and private hospitals to issue global tenders. These tenders are permitted even if a product is manufactured domestically, which is pro-competitive. Most of the government tenders follow two parts: technical bid and commercial bid. Generally the government decides on the lowest bidder. The private hospitals evaluate the products on the basis of the technology, cost and price. It has been observed that while decision-making is faster in the private hospitals that of public hospitals are time consuming due to extensive bureaucratic structure.

Customs duty is levied on the imported medical devices. The duty levied depends on the product classification and the end user. The products that are classified by the Ministry of Health as "life saving medical equipment" have reduced duty applicable on them. Also, the government hospitals/institutions are permitted to import equipment/devices at a reduced duty. The government hospitals can import at a lower duty rate only if the product is imported directly from the manufacturer. **This is applicable only for the government institutions and not for the private institutions.** This discrimination in the application of lower duty rate could be taken as against principles of competition policy i.e. **competition neutrality.** However, as government hospitals provide free (or highly subsidised) service to people, this deviation from the principle of competition neutrality can be justified.

Public Health Procurement

All over the world, public procurement is viewed as an area where problems of mis-governance tend to arise. The scale of public procurement is simply enormous and estimates vary between 15 to 20 per cent of GDP or about Rs. 12 to 15 lakh crore per annum in case of India. The OECD has estimated that losses due to inappropriate procedures can be[33] 20 to 30 percent. Reform of public procurement is a major potential bulwark against corruption .

Currently the public health system in India spends about Rs. 6000 crores (0.1% of GDP) for procuring drugs. In the event of India providing Universal Health Coverage, an additional medicine purchase of amount Rs. 24,000 crores would be required by the public health system. That means India need to spend 0.5% of its GDP on procuring medicines alone in the event of universal health coverage (total spending on healthcare at present is 1.2% of GDP). This makes public health procurement a crucial exercise. It is now well accepted that competitive bids for procuring bulk drugs complemented by streamlining the rational use of drugs can result in enormous amount of saving of the public money.

Apart from drugs, public health procurements also include health devices and other materials required for public hospitals. Furthermore, present line of thinking in the government is to shift 'from supplier to procurer' of health services for part of secondary level and whole of tertiary level healthcare by 'contracting-in' private sector. This can happen either by procuring such services directly or indirectly by procuring requisite health insurance. It is believed that health insurance route would be more transparent, cost-effective and accountable, than that done through direct procurement of health services. However, the Report of the High Level Committee on Universal Health Coverage recommends (page 31-34) not using insurance companies or any other independent agents to purchase healthcare services on behalf of the government. It has cited many reasons for this in the Report inferring that in the long run it would be in public and national interest when states procure healthcare services directly.

The commonly followed purchase methods in Indian hospitals include:

- Direct purchase from the manufacturer.
- Purchase through bids. Tendering process is usually time-consuming and involving various complex formalities like agreement, security deposits and presentation of other related documents along with the rates.
- Competitive negotiation where the buyer approaches a limited number of suppliers for their price quotations and then bargain with them to fix the deal.
- Purchase through a contract. The contracts can be fixed quantity contract, running contract or rate contract.
- Local purchase. It is also known as emergency purchase and is made to meet an emergency situation. Sometimes it is needed due to the failure of the supplier to supply the ordered item.

[33] Montek Singh Ahluwalia, Preface to The Public Procurement Bill, 2011, September 2011 (Draft for Discussion, Version 1)

According to a study by NIPER[34], there are twelve guiding principles of good pharmaceutical procurement, which can be said to be important from competition policy point of view. These principles are grouped in four categories, and are given in the box below.

Twelve Guiding principles of good pharmaceutical procurement
A. Efficient and Transparent Management 1. Different procurement functions and responsibilities (selection, quantification, product specification, pre-selection of suppliers and adjudication of tenders) should be divided among different offices, committees and individuals, each with the appropriate expertise and resources for the specific function. 2. Procurement procedures should be transparent, following formal written procedures throughout the process and using explicit criteria to award contracts. 3. Procurement should be planned properly and procurement performance should be monitored regularly; monitoring should include an annual external audit. *B. Drug Selection and Quantification* 4. Public sector procurement should be limited to an essential drugs list of national/local formulary list. 5. Procurement and tender documents should list drugs by their International Nonproprietary Name (INN), or generic name. 6. Order quantities should be based on a reliable estimate of actual need. *C. Financing and Competition* 7. Mechanisms should be put in place to ensure reliable financing for procurement. Good financial management procedures should be followed to maximize the use of financial resources. 8. Procurement should be effected in the largest possible quantities in order to achieve economies of scale; this applies to both centralized and decentralized systems. 9. Procurement in the public health sector should be based on competitive procurement methods, except for very small or emergency orders. 10. Members of the purchasing groups should purchase all contracted items from the supplier(s) which hold(s) the contract. *D. Suppliers Selection and Quality Assurance* 11. Prospective suppliers should be pre-qualified, and selected suppliers should be monitored through a process, which considers product quality, service reliability delivery time and financial viability. 12. Procurement procedures/systems should include all assurance that the drugs purchased are of high quality, according to international standards. Source: NIPER

While General Financial Rules, 2005 seems to be the principal regulation with respect to government procurement, there are other departmental orders (Office Memorandums) with respect to purchase of drugs and other medical devices. In addition, different states (and also different programmes) seem to have their own procedures of public health procurement. This makes the analysis complex as to which rule(s) would apply on a particular procurement.

One Central Government order that merits mention is the Department of Chemicals & Petrochemicals OM No. 50013/1/2006-SO(PI-IV) dated 7th August, 2006, which grant purchase preference exclusively to Pharma CPSEs and their subsidiaries in respect of 102 specified medicines manufactured by them. The salient features of this Purchase Preference Policy (PPP) are as under:

[34] ~~Impact of TRIPS on Pharmaceutical~~ Prices, NIPER, Punjab, 2006

- PPP in respect of a maximum of 102 medicines would be applicable to purchases made by Ministries / Departments, PSUs, Autonomous Bodies, etc. of the Central Government It would be valid for a period of five years.
- This would also be applicable to purchase of 102 drugs made by State Governments under health programmes which are funded by Government of India. (e.g. purchases under National Rural Health Mission etc)
- PPP will extend only to Pharma CPSEs and their subsidiaries (i.e. where Pharma CPSEs own 51 % or above shareholding).
- It would be applicable to a maximum of 102 medicines, The list of 102 medicines would be reviewed and revised by Department of Chemicals & Petrochemicals as and when required taking care not to include any item reserved for SSI units.
- The Purchasing Departments / PSUs / autonomous bodies etc. of the Central Government may invite limited tenders from Pharma CPSEs and their subsidiaries or purchase directly from them at NPPA certified / notified price with a discount upto 35%.
- The purchasing departments would purchase from Pharma CPSEs and their subsidiaries subject to their meeting Good Manufacturing Practices
- (GMP) norms as per Schedule 'M' of the Drugs & Cosmetic Rules. If no Pharma CPSE is forthcoming to supply these 102 medicines, the purchasing departments would be at liberty to purchase from other manufacturers.
- If the Pharma CPSEs or their subsidiaries which have the benefit of PPP, fail to perform as per the purchase order, they would be subject to payment of liquidated damages or any other penalty included in the contract
- The medicines covered under Drug & Price Control Order (DPCO) would be supplied at the rates fixed by National Pharmaceuticals Pricing Authority (NPPA) rates minus discount up to 35 per cent.
- In case of medicines not covered under DPCO, prices would be got certified from NPPA, only for the limited purpose of supply to Central Government Departments and their Public Sector Undertakings, autonomous bodies etc. On the certified price, Pharma CPSEs and their subsidiaries would provide discount up to 35%.
- The Purchase Preference Policy (PPP) as contained in Department of Public Enterprises O.M. No. DPE.13(12)/2003-Fin.Vol.ll dated 18.7.2005 would not be applicable to Pharma CPSEs.

On the face of it, such preferential purchasing policy goes **against the principles of competition policy - competition neutrality.** However, this may be justified if it is needed to keep such central public sector enterprises alive, to which government can turn to in cases of public health emergency. This particularly resumes importance because of closure of public pharmaceutical manufacturing units, on the one hand, and acquisition of major domestic pharmaceutical companies, on the other hand. The way the two phenomena are happening side by side, the very tool of 'compulsory license' could become redundant, with adverse consequences for competition in pharmaceutical sector, and hence on consumers who pays for it out-of-pocket.

In order to consolidate and streamline fragmented procurements by its different divisions and agencies, Ministry of Health and Family Welfare, India, vide its OM dated 28 October 2005, established a central procurement organisation called Empowered Procurement Wing (EPW). This is however, for procurement for hospitals under central government.

As 'health' is a state subject under the Constitution of India, states enjoy freedom in the way they procure medical products. As far as best practices in public health procurements are concerned, two models i.e. Delhi Model and Tamil Nadu Model have been widely cited by several authors, they are being briefly described in boxes below.

Box3: Delhi Model

The Delhi Society for Promotion of Rational Use of Drugs (DSPRUD) is a non-profit organization which has introduced the centralized drug procurement system with the government hospitals of Delhi in 1996 with the technical support of the WHO. The objective of the Delhi model of procurement was to ensure availability of good quality medicines with these hospitals and to promote rational drug use.

Before the introduction of the system, it was nothing but a total chaos in the supply of medicines with the hospitals in Delhi as in any part of the country. This is despite that 30-35% of the health budget of the government was spent on medicines. Each hospital in Delhi used to procure the drugs independently. The system was ruined by mismanagement and corruption. Many of the drugs so procured by the hospitals were rarely needed while the required medicines were almost perennially in short supply.

The introduction of this system has transformed the situation dramatically; the new system procures drugs centrally for half a dozen main and many smaller hospitals run by the Delhi government. Under the initiative, it was found that only a limited number of basic drugs were actually needed for treatment in almost 90 per cent of the hospital cases. These were identified and procured centrally for supply to the hospitals.

Besides, in keeping with the WHO guidelines, the expensive combination drugs were kept out of the supply list. As a result of this, the actual cost of drugs to the hospitals was cut by as much as half. A sea change could be brought about the procurement modalities, so that 75 to 90% of the medicines prescribed in the hospitals are now being provided to patients free of cost.

The pooled procurement system is now in place for all state-run hospitals and 150 primary health centers in Delhi. The system has resulted in a fall in drug prices to the hospitals by 30-40 per cent, better quality assurance and less duplication of effort. About 80 per cent of the patients in the hospitals run by Delhi Government are now supplied with all prescription drugs.

A list of 250 essential drugs was prepared for larger hospitals and a list of 100 for smaller hospitals. The list is revised from time to time. The hospitals in Delhi now spend over 90 per cent of their drug purchase budget to buy these listed medicines and 10 per cent to buy drugs outside the list. Standard Treatment Guidelines covering 15 diseases affecting adults and five childhood diseases have been drawn up for the benefit of doctors working in primary health centers, who were also provided with an essential drug list and important patient information.

The pooled procurement system uses a two-stage tender system. This ensures that only those companies that are capable of supplying products of adequate quality receive orders. **The tender process is limited to companies that fulfill the technical criteria**. Through a two-envelope system (technical bid and price bid), the drug purchase committee of the society is able to ensure that the purchases are made from companies complying with the Good Manufacturing Practices. A company which does not fulfill the **technical criteria of a minimum annual turnover of Rs 12 crore** and adherence to prescribed Good Manufacturing Practices (GMP), is automatically disqualified for making a price bid. The companies are required to undergo GMP inspections and random testing of products. There are instances of companies being blacklisted for want of proper compliance with GMP and poor quality of products. Doctors are asked to prescribe only products on the procurement list, although hospitals are allowed to use up to 10% of their drug budget on unlisted products.

Source: NIPER 2006

Box 4: Tamil Nadu Model

TN Government set up a Government Company, Tamil Nadu Medical Service Corporation (TNMSC), with the primary objective of ensuring ready availability of all essential drugs and medicines in all the Government health facilities by adopting a streamlined procedure for their procurement, storage and distribution, which began functioning from January 1995.

The first step taken by TNMSC was to finalise the list of essential drugs to be procured. Keeping in view the WHO's Model List of essential drugs, the then existing list of nearly 900 drugs was pruned to a list of 240 drugs. Now, TNMSC has 271 items of drugs and medicines on its list, accounting for around 90% of the budget outlay for the purpose, leaving other drugs of small quantities to be purchased locally by the institutions from out of the remaining 10% budget. The TNMSC follows WHO's recommendation for the use of the international non-proprietary name (INN, commonly known as generics) for each drug. In order to ensure the procurement of only quality drugs at competitive prices, an **open tender system** is followed and **purchases are made only from manufacturers and not through agents or distributors**.

It has been further stated that such manufacturers **should have a GMP** certificate and also have a **market standing for at least three years**. **A minimum turnover is also fixed in order to eliminate the very small firms since such firms may fail to keep delivery commitments**. To eliminate sole dependence on one supplier, the next two lower suppliers willing to match the lowest price were also approved.

With the dual objectives of maintaining quality and preventing wastages and pilferages, all tablets and capsules are procured with only strip or blister packing, as against the earlier practice of bulk packing which required manual handling at the time of distribution. Both inner and outer packages of all items are required to bear the logo of TNMSC with a marking to show that the drugs are manufactured only for the state government supply and are Not for Sale. On account of this, the credibility and acceptability of the drugs by the public also improved immensely. Samples drawn from different batches are coded and sent to private approved laboratories to ensure effective quality control.

In order to ensure a regular supply and for preventing stock-outs, TNMSC has established a chain of godowns to stock all items of drugs. Each district has a drug warehouse as a point of distribution for all medical institutions in the district. The suppliers are required to supply the drugs to the district warehouses, which would keep a working stock of three months requirement at any point of time. Each institution is given a passbook indicating its annual entitlement (i.e. budgetary allocation) within which it can draw drugs from the district warehouse. There is no need for an advance indent because any drug in the approved list could be obtained within the entitled financial limit.

One of the outstanding features of TNMSC is the **total computerisation** in all aspects. Each district warehouse has a computer linked to the Head Office computer via the Internet. As the receipt and issue of drugs at all the district warehouses level is done using computers, the information on the inventory level for any drug at any warehouse at any point of time is readily available with the central computer at the Head Office, on the basis of which the stock position is effectively monitored and reorder is effected to prevent any stock out situation.

Further, on the basis of the inventory levels of all the warehouses, transfer of items from one warehouse to another are effected so as to optimise the utilization of drugs and to maintain minimum required stock levels. Other activities such as accounting, quality control, warehouse monitoring and administration are also conducted through computers for total error free strong logistic management. The solution starts from the identification of drugs to the Management Information System (MIS). Computerisation of the entire operation has improved inventory management, and cost control, and enhanced availability of drugs in government health facilities.

This innovation of the Government of Tamil Nadu in drug procurement and management has improved availability of drugs in nearly 2000 government medical institutions throughout the State. **The competitive procurement system has resulted in savings in the outlay on drugs to the extent of 36% of the allocation**. Apart from better budgetary control on drug consumption, medical institutions have become more cost conscious. It also resulted in a better perception in people in addition to enhanced availability of drugs at all facilities.

Source: NIPER 2006

The procurement model of the Tamil Nadu Medical Services Corporation (TNMSC) has stood the test of time over the last 15 years, and has been hailed as the most efficient, reliable, transparent and replicable model. Neighbouring Kerala has adopted that model recently, while other states such Bihar, M.P. and Orissa are in the process of replicating it .[35]

Box 5: Bihar Initiative

Based on the TN Model, Bihar has set up a corporation, called as Bihar Medical Services and Infrastructure Corporation (BMSIC), which will become functional in April 2012. The overall objective of the corporation, set up last year, is to procure and ensure provision of quality drugs at competitive prices and equipment and build proper infrastructure for health services. All procurements would be done by the Corporation and would be supplied at district level *godowns*. A list of 263 generic medicines has been prepared, which will form the basis for drug procurement.

It will work in a transparent and equitable manner as well as ensure that the services are provided in a timely manner. As in the TN Model, according the present mechanism each hospital will maintain a medicine pass-book with entry for each supply. Everything will be online and information about the stock will be easily available with a click of mouse.

The corporation would also facilitate the construction of quarters for doctors and nurses coupled with 30-bed hospitals at block and district levels. All additional PHCs in the state is being planned to be converted into a 30-bed hospital. State-level monitoring would be done to maintain transparency and accountability.

Source: Dainik Jagaran, 28-01-12; Times of India, 28-01-12

All though such pooled procurement efforts are laudable, a question from competition policy, however, does arise, with respect to technical criteria regarding annual turnover, as it does tend to create some sort of **entry barrier** to new enterprises. One can understand the criteria regarding GMP viewing the safety of consumers, but that related with turnover can be reviewed. (Even though the threshold of Rs.12 crore is low in case of Delhi, in present case, it is the concept of putting such criteria that can be problematic from competition policy angle.) Technically there can be a good manufacturer meeting the GMP criteria, but failing on account of 'market standing' and 'turnover'. Should such firms be out of consideration *per se*? In case of TN, it is said that this is done with the assumption that smaller firms may fail in supplying the requisite drugs in right amount. Is this assumption correct?

It would not be out of place to mention about launch of a pan India scheme/intervention of the Central Government in the context of drugs procurement, which is at near-finalisation stage, whereby there will be free supply of essential medicines to all those who seek healthcare in public health establishments anywhere in India. It would be wholly funded by GOI. Procurement for this scheme would be (a) only of generic-generic and unbranded generic medicines, (b) only from national essential list and state list of essential medicine, where applicable, and (c) procurement would be in bulk and directly from manufacturer. The Tamil Nadu model of drug procurement is being replicated by the Central Government.

In order to implement the proposed scheme, money would be given by Central Government to State Governments to procure drugs through a MOU requiring the latter to have certain

[35] *Supra 2*

necessary systems in place, as pre-condition. This is being done to avoid misuse. For instance, it would be mandatory for state governments to form a corporation for the purpose of procuring drugs and having proper staff to do inventory etc. Main concern for GOI is leakage due to corruption, particularly at the PHC level. Ideas to check this would be welcomed by MOHFW. At present the GOI is thinking towards having a community oversight/social audit mechanism to check such leakage.

It is pertinent to note that like TN and Delhi models, GOI for this scheme also proposes certain technical criteria with respect to minimum turnover (e.g. Rs.25 crore) and operational timeframe (e.g. 3 years) on part of the suppliers. This is being done in order to obtain quality generic drugs with certainty in their supply.

It is true that in India we have a plethora of domestic manufacturers of medicine hence we may not require to incentivise the new comers. But would we like to maintain this concept of turnover and minimum operation as criteria for high-end medical devices? Would we not like to incentivise new comers, viewing the scanty presence of high-end medical devices manufacturers in India? Therefore we need to review the concept of putting turnover and operation time as criteria for firms to qualify for bidding to supply goods and services to government, without compromising on quality and sustainability of such supplies.

Table 7: Trends in State-wise Government Drug Expenditure in India

State Name	State wise Government Drug Expenditure in India					
	2001-02			2010-11		
	Overall (Lakh)	Per Capita (Rs.)	Drug Exp. as % of HE	Overall (Lakh)	Per Capita (Rs.)	Drug Exp. as % of HE
Assam	1530	5.7	4.7	8635	28.5	5
Bihar	2203	2.6	3.1	13350	13.8	7
Gujarat	2693	5.3	3.7	15431	26.4	7.6
Haryana	3096	14.7	9.8	6090	24.2	5.5
Kerala	12420	38.9	17	24861	72.3	12.5
Maharashtra	20305	20.8	11.3	20882	18.7	5.2
Madhya Pradesh	7921	13.0	11.8	12213	17.1	9.3
Punjab	916	3.7	1.4	1545	5.6	1
Rajasthan	9045	15.9	9.3	3854	5.7	1.5
Uttar Pradesh	7104	4.2	5.2	31481	15.9	5.3
Jharkhand	NA	NA	NA	2716	8.7	3.4
West Bengal	5798	7.2	4.3	21403	24.1	6.8
Andhra Pradesh	12704	16.6	9.6	23458	27.9	10
Karnataka	7783	14.7	7.9	14831	25.1	6.3
Tamil Nadu	18097	28.9	15.3	43657	65.0	12.2
Himachal Pradesh	NA	NA	NA	1122	16.6	1.9
J & K	NA	NA	NA	4550	39.2	4.3
Central Government	72649	7	12.2	253368	21	15
All India	**188903**	**18**	**9.6**	**503447**	**43**	**13**

Source: HLEG on UHC for India

Health Insurance

The World Bank (2002) estimates that: one-quarter of all Indians fall into poverty as a direct result of medical expenses in the event of hospitalisation; more than 40 percent of people who are hospitalised in India, borrow money or sell assets within in a year to cover cost of healthcare; the hospitalised Indians spend more than half of their total annual expenditure on healthcare; and the poorer section of the Indian society is[36] 2.6 times more likely than the richer section to forgo medical treatment in the event of illness . Still "more than Rs. 100,000 crore is being spent annually as household expenditure on health, which is more than three times the public expenditure on health," according to the National Rural Health Mission Framework document.

It is pertinent to note that highest level thinking is going on within Central Government to provide universal health care to all Indians, and a significant move is likely to take place in this direction under the 12th Five Year Plan. How to finance the universal healthcare coverage would indeed be an issue.

At present the healthcare finance system in India has a dual mode: (1) private fee-for-service based sector where money is paid out-of-pocket by the individuals; and (2) a tax-based public sector where healthcare providers are salaried (e.g. public hospitals). Health insurance mode is utilised under both the systems, but is generally restricted and rationed by the affordability of individuals and availability of the budget.

As far as tax-based public finance of universal healthcare is concerned, this again can take two approaches: (1) by providing all the expenditure from general revenue; and (2) by adopting Social Health Insurance (SHI), which is based on income-determined contribution from entire population with the government subsidising the financial vulnerable sections. In countries like India, with large rural and informal sector accounting for 90% of the population and poor institutional capacity to organise them, will be constricting factors for the upscaling of the SHI in near or medium term.[37]

As far as private insurance coverage through out-of-pocket spending by individual household are concerned, only half the country's population can at best be reached induced by best possible efforts. The other half, which consists of low income population, is most likely to remain outside the ambit of private health insurance. For the low-income people neither government provided nor market mediated arrangement is appropriate. Community based health insurance (CBHI) because of its certain features such as, the voluntary participation of the people, not-for-profit objective in organising the scheme, scheme management by the community itself, and some degree of risk pooling, is more suited to insuring the poor[38]. Besides, CBHI can take various forms suited to the needs of the community.

Viewing the present thinking in the government - of providing universal primary health care and part of secondary healthcare and procuring from private players the other part of secondary healthcare and whole of tertiary healthcare - there could be a mix of direct financing and that

[36] Ahuja, R. Health Insurance for the Poor in India, ICRIER, 2004
[37] Rao, Sujatha; Report of the National Commission on Macroeconomics and Health, Government of India
[38] Supra 36

through social/community/public/private health insurance. Viewing the fiscal constraints, health insurance (be it government initiatives or community-based insurance schemes or private insurance providers) can be an important means for government to avail high-end healthcare services from private players. It is believed that the upper and middle class will rely on private health insurance; the poorer sections would be covered under subsidised (fully or partly) health insurance schemes of the government, which in turn could be a mix of social, community, public or private health insurances.

However, while there are advantages in relying on health insurance route, there are certain disadvantages as well. It is believed that pooling of risks through prepaid insurance schemes, being more equitable, is one of the significant drivers of improvement in healthcare provision by encouraging investment and innovation, including improvement in quality and efficiency by continually benchmarking it. The pitfalls of private insurance include leaving out the low-income individuals who cannot afford premiums; denying coverage to sick people, old and women; excluding some important diseases; limiting coverage for high-cost conditions or services; and the so called "moral hazards" due to asymmetry in information and lack of regulation of healthcare providers. These pitfalls need to be reduced through appropriate regulation.

Due to **asymmetry in information** both patients and insures are at a disadvantage position because of their inability to resist or challenge medical opinion given by the healthcare providers. Furthermore, due to absence of knowledge of prices, the providers also tend to overcharge the insured patients. Particularly, cashless insurance creates disincentives to control costs as it appears to be 'free' good for the patient and the provider, often resulting in excessive treatment by the provider and frivolous use by the patient taking treatment even for [39] condition a which he would have normally ignored or cured with a home remedy (moral hazards) .

Some problems also occur because normally those people tend to subscribe health insurance who knows that they are in need for health care. This entails the insurance companies to adopt stricter risk selection process before providing the coverage, whereby increasing the cost of premium. Generally, the insurance companies tend to focus on low risk groups, such as young and healthy and leaving out high risk groups, such as old, poor, young women in reproductive age group and the ill. This is also the reason for attracting group discounts, which is as high as 67 percent.

Another problem associated with health insurance is that they, generally, follow indemnity approach, whereby the insured first pay the medical expenses and then seek reimbursement. To add to this, all known serious diseases are in the exclusion list of the coverage. Therefore, those most in need do not enjoy the fruits of health insurance. In addition, as the health insurance policies come with a ceiling of the assured sum, the insured are in a disadvantageous position because neither provider not insure have any obligation to provide quality care and/or over provide/over charge services so long as amounts are within the assured amount. Also the fact that the health insurance system is voluntary makes it difficult to form sustainable risk pools for keeping premiums low.

[39] *Supra 37*

All the aforesaid problems not only make health insurance less lucrative, but also contribute for their poor penetration and creation of **entry barriers**[40] despite a huge estimated market (see below for market structure). These are summarised below, with necessary recommendations:

- Because insurance companies do not have the data, the expertise and the power to regulate the providers, they are less aggressive in selling their products. Unchecked collusion between patients and healthcare providers add to their problem. **Regulation and control on provider behaviour, quality and cost is urgently needed to mitigate adverse effect on health insurance penetration.** Healthcare providers need to mandatorily share data, particularly on cost.
- Due to excessive treatment and overcharge (moral hazards) and higher claim ratios (which is on rise), as well as presence of asymmetry of information, the insurance companies tend to fix and charge higher premiums. This in turn results in low penetration of health insurance. **The above-recommended regulation and control can also help mitigate this situation to a significant level**.
- In India, an insurance company cannot sell non-life as well as life insurance products. Had it been allowed, the companies could have innovated in cross subsidising more profitable ventures of fire/theft insurances for providing less lucrative health insurance. **Policy makers may like to examine the feasibility of allowing insurance business linking life and non-life insurance**.
- As per Indian regulation, there is an entry requirement of a minimum capital of Rs.100 crore, which for some can act as **entry barrier**, because it is estimated to take around 13-15 years to breakeven. This may also discourage non-government organisations to introduce CBHI schemes. **If feasible, this regulatory requirement may be eased for private players and be made flexible for CBHI schemes**.
- Similarly, as per the Indian FDI policy, only 26 percent foreign investment is allowed in insurance sector. Removal of this cap for health insurance may bring in new players in the market, hence more competition resulting in more benefits for consumers.
- The potential consumers of health insurance policies are reluctant to buy because of (1) non-transparent procedures making it difficult for them know their entitlements; (2) too many exclusions that go against their logic of covering health risks; (3) lack of options due to near standardised format of health policies, which may not suit the need of the insured; and (4) delays (or denial) in settlement of claims due to indemnity-based insurance policies. It is not out of place to mention that tax benefits from health insurance has been a key driving force for many middle class individuals. **A cashless health policy with least exclusions and flexible enough to suit the needs of insurer would make health insurances much more lucrative and logical for the potential consumers**.
- Another reason for reluctance on part of the potential consumers of health insurance is the shortage of supply of health services in rural areas, in general, and tertiary healthcare (expensive, making most sense for having insurance) in most cities. **It is believed that with increase in supply of high-end healthcare services there will be increase the penetration of health insurance and *vice versa*.**
- In India, communicable diseases have traditionally been highly prevalent. According to one estimate more than 20 percent of claims by insured were that of communicable

[40] This portion heavily depends upon the Chapter on health insurance in the Report of the National Commission on Macroeconomics and Health, by Sujata Rao

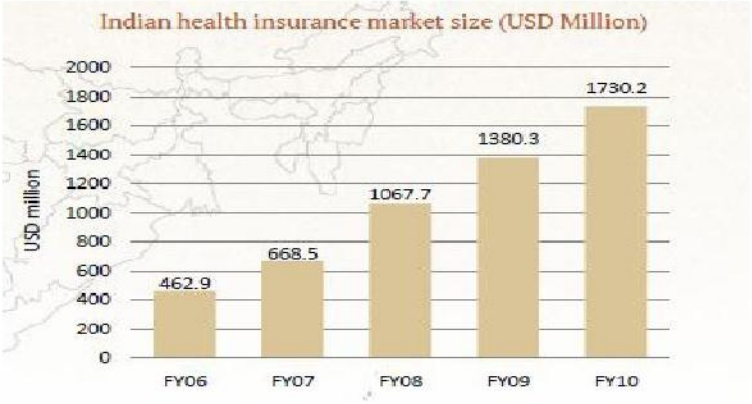
diseases. The fact that communicable diseases affect majority of people at the same time makes it unviable for the insurance company, even if forming a large pool. This could also result in higher premiums and hence less attractive for consumers.

Market structure

The discussion above, substantiate the fact that at present[41] the penetration of health insurance in India is very low, estimated to be between 2 to 5 percent , however with the advent RSBY the figure may go have gone beyond 10 percent. According to the National Family Health Survey 2005-06, only 10% of households in India had at least one member covered by medical insurance. This is despite the fact that there is a plethora of medical insurance schemes operated by the Central and state governments, public and private insurance companies and several community-based organisations. The benefits of insurance coverage so far has accrued only to a privileged few and mostly to those working in the organised sector.

However, the situation is changing fast as in recent years the growth of health insurance has been significant, between 20 to 25 percent per annum. In the first half of the financial year 2011-12, the health insurance industry recorded 21.3 percent growth in gross premium compared to the same period of the previous financial year[42]. According to one source health insurance industry has grown at a CAGR of 39 percent during the period[43] 2006-10 (see figure 14) and is likely to penetrate to 20 percent of Indian population by 2015 . Many companies are offering health insurance to their employees and this is driving the market penetration of insurance players, along with the recent GOI's scheme Rastriya Swasthya Bima Yojna (RSBY).

Figure 14



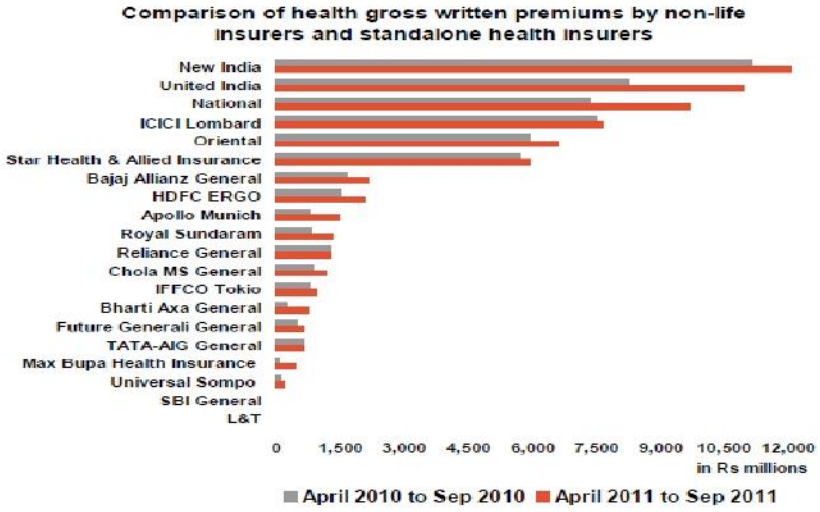
Source: IBEF

At present, the four public sector undertakings (PSU) operating in the non-life insurance sector has a market share of 60 percent (see figure 15), which was revolving around 90 percent just a few years back. Therefore, the market share of PSUs is on a fast decline because private insurance companies are making significant inroads. This goes by the National Health Policy,

[41] *Supra 37*
[42] India Market Health Insurance Update, Issue 13, December 2011; Towers Watson
[43] IBEF, 2011

2002, which "encourages the setting up of private insurance instruments for increasing the scope of the coverage of the secondary and tertiary sector under private health insurance packages"[44].

Figure 15



Source: Health Insurance Update, December 2011

There are more than 20 companies providing health insurance coverage, which include: PSUs like New India Insurance, United India Insurance, National Insurance, Oriental Insurance; and private players like ICICI Lombard, Star Health and Allied Insurance, Bajaj Allianz General, HDFC ERGO, Apollo Munich, Royal Sundaram, Reliance General, Chola MS General, IFFCO Tokio, Bharti Axa General, Future Generali General, Tata-AIG General, Max Bupa Health Insurance, Universal Sompo, SBI General and L&T. Two more private players are in pipeline to get IRDA approval. They are joint venture of Cigna (US major) and TTK group, and Religare Finvest, a subsidiary of Religare Group.

Apart from the above, PSUs and private companies offering health insurance, there are also government health insurance schemes and community-based health insurance schemes. They are being discussed briefly below.

Government Health Insurance Schemes

1. Universal Health Insurance Scheme[45] (UHIS)

For providing financial risk protection to the poor, the Government announced a UHIS in 2003. Under this scheme, for a premium of Rs 365 per year per person, Rs 548 for a family of five and Rs 730 for a family of seven, health care for an assured sum of Rs 30000 was provided. BPL families were given a premium subsidy of Rs 200 per annum. The scheme was redesigned in May 2004 with higher subsidy and restricting eligibility to BPL families only. The subsidy was increased to Rs 200, Rs 300 and Rs 400 to individuals, families of five and seven, respectively.

[44] Para 4.16.1.1 of NHP, 2002

[45] The brief of UHIS is substantially based on Chapter 2 of Report on Commission on Macroeconomics and Health.

To make the scheme more saleable, the insurance companies provided for a floater clause that made any member of the family eligible as against the Mediclaim Policy which is for an individual member. However, it failed to attract the desired number of potential consumers. The reasons for failing to attract the rural poor are many. First, the public sector companies who were required to implement this scheme find it to be potentially loss-making and do not invest in propagating it, resulting in very low levels of awareness, reflected in the low enrollment and very poor claim ratios. To meet the targets, it is learnt that several field officers pay up the premium under fictitious names.

Second, a major problem has been the identification of the eligible families. Identification became cumbersome as the family needed to have some form of certification, which is difficult to obtain from revenue authorities. Third, the procedures are cumbersome and difficult for the poor—the premium has to be paid in a lump sum; the paperwork required for enrolment as well as getting claim amounts is very time consuming. Fourth, in most places there is a deficit in the supply or availability of service providers, particularly because government hospitals are not eligible. Fifth, there was a set-back due to health insurance companies refusing to renew the previous year's policies. Finally, the Third Party Administrators (TPAs) are also not willing to implement this scheme at 5.5% of premium amount as their administrative costs of covering rural populations in dispersed villages makes it unviable.

Besides the most discouraging factor for potential consumers is the exclusion list, which generally includes:

- All pre-existing diseases.
- All diseases contracted during the first 30 days from the commencement date of the policy Provided that in the opinion of the panel doctor/s the insured person could not have known about the existence of disease or its symptoms at the time of making the proposal and had not taken any consultation, treatment for the disease prior to taking the insurance.
- Some of the diseases such as Cataract, Benign Prismatic Hypertrophy, Hysterectomy, hernia, Hydrocele, Fistula in anus, piles, sinusitis, ongenital internal disease are not covered in the first year of the policy.
- Corrective, cosmetic or aesthetic dental surgery or treatment.
- Cost of spectacles, contact lens and hearing aid.
- Vaccination, inoculation, change of life or cosmetic treatment or surgery HIV, AIDS, Sterility, Venereal Disease, Intentional Self injury, use of Intoxicating Drugs/ Alcohol.
- Primarily diagnostic expenses not related to sickness/ injury.
- Treatment for Pregnancy, Childbirth, Miscarriage, abortion etc.

2. Rashtriya Swasthya Bima Yojna[46] (RSBY)

RSBY has been launched by Ministry of Labour and Employment, Government of India to provide health insurance coverage for Below Poverty Line (BPL) families and it started rolling from 1st April 2008. The objective of RSBY is to provide protection to BPL households from financial liabilities arising out of health shocks that involve hospitalization. Beneficiaries under

[46] The brief on RSBY is substantially based on information available at www.rsby.gov.in

RSBY are entitled to hospitalization coverage up to Rs.30000 for most of the diseases that require hospitalization. Government has even fixed the package rates for the hospitals for a large number of interventions. Pre-existing conditions are covered from day one and there is no age limit. Coverage extends to five members of the family which includes the head of household, spouse and up to three dependents. Beneficiaries need to pay only Rs.30 as registration fee while Central and State Government pays the premium to the insurer selected by the State Government on the basis of a competitive bidding.

RSBY provides the insured with freedom of choice between public and private hospitals and makes him a potential client worth attracting on account of the significant revenues that hospitals stand to earn through the scheme. The scheme has been designed as a business model for a social sector scheme with incentives built for each stakeholder.

The insurer is paid premium for each household enrolled for RSBY. Therefore, the insurer has the motivation to enrol as many households as possible from the BPL list. A hospital has the incentive to provide treatment to large number of beneficiaries as it is paid per beneficiary treated. Even public hospitals have the incentive to treat beneficiaries under RSBY as the money from the insurer will flow directly to the concerned public hospital which they can use for their own purposes. Insurers, in contrast, will monitor participating hospitals in order to prevent unnecessary procedures or fraud resulting in excessive claims (moral hazards). By paying only a maximum sum up to Rs.750 per family per year, the Government is able to provide access to quality health care to the below poverty line population. It will also lead to a healthy competition between public and private providers which in turn will improve the functioning of the public health care providers.

Every beneficiary family is issued a biometric enabled smart card containing their fingerprints and photographs. All the hospitals empanelled under RSBY are IT enabled and connected to the server at the district level. This will ensure a smooth data flow regarding service utilization periodically. The key feature of RSBY is that a beneficiary who has been enrolled in a particular district will be able to use his/ her smart card in any RSBY empanelled hospital across India. This makes the scheme truly unique and beneficial to the poor families that migrate from one place to the other. Cards can also be split for migrant workers to carry a share of the coverage with them separately.

A beneficiary of RSBY gets cashless benefit in any of the empanelled hospitals. He/ she only needs to carry his/ her smart card and provide verification through his/ her finger print. Any hospital which is empanelled under RSBY by any insurance company will provide cashless treatment to the beneficiary. For participating providers it is a paperless scheme as they do not need to send all the papers related to treatment to the insurer. They send online claims to the insurer and get paid electronically.

RSBY is evolving a robust monitoring and evaluation system. An elaborate backend data management system is being put in place which can track any transaction across India and provide periodic analytical reports. The basic information gathered by government and reported publicly should allow for mid-course improvements in the scheme. It may also contribute to

competition during subsequent tender processes with the insurers by disseminating the data and reports.

For RSBY, the majority of the financing, about 75 percent, is provided by GOI, while the remainder is paid by the respective state government. GOI's contribution is 90 percent in case of North-eastern states and Jammu and Kashmir.

State governments engage in a competitive public bidding process and select a public or private insurance company licensed to provide health insurance by the Insurance Regulatory Development Authority (IRDA) or enabled by a Central legislation. The technical bids submitted must include a number of elements as per GOI requirements. All the bids which are technically qualified go to the financial evaluation stage. The insurer with the lowest financial bid is then selected for providing health insurance in the state for a particular district/ set of districts. The financial bid is essentially an annual premium per enrolled household. The insurer must agree to cover the benefit package prescribed by GOI through a cashless facility that in turn requires the use of smart cards which conform to certain specifications and must be issued to all members.

Each contract is specified on the basis of an individual district in a state and the insurer agrees to set up an office in each district. While more than one insurer can operate in a particular state, only one insurer can operate in a single district at any given point in time. After the insurance company is selected, they need to empanel both public and private health care providers in the project and nearby districts. The empanelment of the hospitals is done based on prescribed criteria. Empanelment of hospitals shall be done as soon as the insurer gets the contract and it can continue simultaneously with the enrollment of the beneficiaries. The insurer shall empanel enough hospitals in the district so that beneficiaries need not travel very far to get the heath care services. For empanelment of the public hospitals, the insurer needs to coordinate with respective health department of the state.

These hospitals should install necessary hardware and software so that smart card transactions can be processed. They should also set up a special RSBY desk with a trained staff. The hospital list should allow for both public and private hospitals who agree to participate. The insurer must also provide a list of RSBY empanelled hospitals, to the beneficiaries at the time of enrollment. This list can be revised at periodic intervals as more and more hospitals are added in the list. When empanelment takes place, a nationally unique hospital ID number is generated so that transactions can be tracked at each hospital.

The transaction process begins when the member visits the participating hospital. After reaching the hospital, beneficiary will visit the RSBY help desk at hospital where his identity will be verified by his photograph and fingerprints which are stored on his/her smart card. If a diagnosis leads to a hospitalization, the assistant at the help desk checks whether the procedure is in the list of pre-specified packages. If the procedure is in the list, the appropriate prescribed package is selected from the menu. If the procedure is not in the package list, the help desk assistant checks with the insurer regarding the price for that procedure. Upon release of the beneficiary from the hospital, the card is again swiped along with finger print verification and the pre-specified cost of the procedure is deducted from the amount available on the card. The beneficiary is also paid by

the hospital Rs.100 as transportation expense at the time of the discharge. However, total transportation assistance cannot exceed Rs.1000 per year and it is part of Rs.30000 coverage.

Information relating to transactions that take place each day at each hospital is sent through a phone line to a district server. A separate set of pre-formatted tables are generated for the insurer and for the government respectively. This allows the insurer to track claims, transfer funds to the hospitals and investigate in the case of suspicious claim patterns through on-site audits.

It seems that the Central Government has designed RSBY after analysing the near failure of the UHIS. It has dropped certain problematic elements and has adopted certain pro-competitive elements. The result, therefore, is encouraging. At present, in less than four years of the rolling of the scheme, nearly 27.7 crore people have active smart cards with around 3.2 crore hospitalisation cases been dealt under RSBY.

3. Employees' State Insurance Scheme (ESIS)

Enacted in 1948, the Employees' State Insurance (ESI) Act was the first major legislation on social security in India. The scheme applies to power-using factories employing 10 persons or more, and non-power and other specified establishments employing 20 persons or more, with employees earnings up to Rs.7500 per month being covered, along with their dependants.

The benefit package is quite comprehensive in its coverage of health-related expenses, going beyond the cost of medical care to include cash benefits (sickness, maternity, permanent disablement of self and dependant) as well as other benefits such as funeral expenses and rehabilitation allowance. However, the actual package of benefits available is determined more by the type of facility accessed rather than the type of cover. Medical care comprises outpatient care, hospitalization or specialist treatment as well as services of the Indian systems of medicines. These services are provided through a network of ESIS facilities, public care centres, NGOs and empanelled private practitioners.

Corresponding to these arrangements, a variety of payment mechanisms are employed from salaries for ESIS staff to capitation fees for private doctors. The ESIS is financed by a three-way contribution from employers, employees and the State Government.

4. Central Government Health Scheme (CGHS)

Established in 1954, the CGHS covers employees and retirees of the Central Government, and certain autonomous, semiautonomous and semi-government organizations. It also covers Members of Parliament, governors, accredited journalists and members of the general public in some specified areas. The families of the employees are also covered under the scheme. Benefits under the scheme include medical care at all levels and home visits/care as well as free medicines and diagnostic services. These services are provided through public facilities (including CGHS-exclusive allopathic, ayurvedic, homeopathic and unani dispensaries) with some specialized treatment (with reimbursement ceilings) being permissible at private facilities.

Of the total expenditure, about a third is spent on wages and salaries of the CGHS staff. Most of the expenditure is met by the Central Government as only 12 percent is the share of contributions, which may eventually fall further to 5 percent viewing the stagnancy of contributions. Furthermore, due to increasing instances of CGHS beneficiaries accessing to private hospitals, and in absence of any regulation regarding treatment protocols and prices, budgetary implications for GOI is becoming a concern.

Table 8: Features of Selective Existing Insurance Schemes & Proposed Under UHC Scheme

Risk Pooling	Voluntary Health Insurance	RSBY[16]	Rajiv Arogyasri[17]	The proposed UHC system
Risk Pooling	Yes	Yes	Yes	Yes
Risk Pooling Vehicle	Insurance Company	Government	Government	Government
Purchase of Healthcare	Insurance Company	Insurance Company	Insurance Company	Government
Cashless	Yes	Yes	Yes	Yes
Hospital Network	Very Large number of hospitals	Very large number of hospitals	Very large number of hospitals	Limited number of hospitals based on assessed need
Financial Protection	Limited to insured amount	Limited to Rs.30,000 per year, per family upon hospitalisation only	Limited to Rs.100,000 per year, per family upon hospitalisation only	No financial Limits. Covers all essential healthcare needs at all levels both in and out of the hospital.
Primary Care Network	Limited to OPD at hospitals	Limited to OPD at hospitals	None	Extensive
Likelihood of Waiting periods for non-emergency hospital admissions	Low	Low	Low	High
Integrated Care	No	No	No	Yes
Focus on Prevention and Wellness	No	No	No	Yes
Dominant Payment model to health provider	Fee for service[18]	Fee for service	Fee for service	Capitation[19]
Regulation of Quality	Largely focussed on financial fraud prevention	Largely focussed on financial fraud prevention	Largely focussed on financial fraud prevention	Much more detailed input and outcomes based regulation
Private Sector Engagement	Yes	Yes	Yes	Yes
Primary Care	Extremely Limited	Extremely Limited	No	Yes. Unlimited
Secondary Care	Within Financial Limits	Within Financial Limits	No	Yes. National Health Package. No Financial Limits
Tertiary Care	Within Financial Limits	No	Within Financial Limits	Yes. National Health Package. No Financial Limits
Gatekeeping Function[20]	Third Party Administrator[21]	Third Party Administrator	Third Party Administrator	Primary care provider

Source: HLEG on UHC for India

Regulation of Health Insurance

Health insurance was introduced in 1912 when the first Insurance Act was passed. The current version of the Insurance Act was introduced in 1938. Since then there was little change till 1972 when the insurance industry was nationalized and 107 private insurance companies were brought under the umbrella of the General Insurance Corporation. Private and foreign entrepreneurs were allowed to enter the[47] market with the enactment of the Insurance Regulatory and Development Act (IRDA) in 1999 .

[47] *ibid*

The IRDA allows entry of private sector in Indian insurance sector, including health insurance. The Act, which establishes a regulatory authority called Insurance Regulatory and Development Authority, aims at protecting interests of policyholders, promoting efficiency in the conduct of insurance, regulating the rates and terms and conditions of the policies offered by insures and directing the maintenance of solvency margins.

There is an entry requirement of a minimum capital of Rs.100 crore, which for some can act an **entry barrier**, because it is estimated to take around 13-15 years to breakeven. In addition, the Insurance Act, 1938 does not allow the insurers to undertake additional business that is not directly linked to insurance.

The IRDA provides for a code of conduct for the insurance agents, surveyors and loss assessors and also allows for a Tariff Advisory Committee to oversee premium rates, insurance plans and to prevent discrimination. But there is no window for consumer redress and complaints under IRDA, leaving consumers to use Consumer Protection Act, 1986. Furthermore, the IRDA does not deal with relationship between insurer and the provider. It also does not have much say about rating of premiums and benefit packages. IRDA's two functions are maintaining market standards and overseeing solvency and financial regulations. In sum, there is very little focus on the consumer of insurance products as well as health policy objectives of curbing risk selection, consumer protection and promotion of health maintenance organisations[48]. It is pertinent to note that nowhere in the IRDA, 1999 or the Insurance Act of 1938 there is any mention of either health sector or health insurance.

As far as regulatory independence of IRDA is concerned, it is in negative. It is mandatory under the Act for the regulator to adhere to any government order. Although the Act says that the government would only intervene on policy matters and not on technical and administrative matters, but it goes on to provide that "what constitutes a policy matter" is Central Government's prerogative (S.18). The Act provides powers to Central Government to even supersede the Authority in certain circumstances, including that in public interest and failure of the Authority in complying with directions given by the government (S.19). Furthermore, according to the IRDA there can be certain situations where one or more members of the Authority can be removed even without being given an opportunity to be heard (S.6).

One of the pro-competitive measures that IRDA has adopted is its recent decision to allow health insurance portability. Please see Box for details.

Box 6: Health insurance portability
The IRDA has issued vide its Circular dated 10th February 2011, the guidelines on health insurance portability to all non-life insurers. This means, a policyholder can switch from one health insurer to another without losing any benefits he/she has earned on his existing health cover. Portability will allow policyholders, dissatisfied with their insurer's services, to migrate to another insurer without losing the credit gained for pre-existing disease cover and no-claims bonuses. A few key features as outlined in the guidelines are as follows: • A policyholder will have to approach an insurer 45 days before his policy with the old insurer expires, to enable the new company to consider his application. In a circular, the IRDA said that the acquiring insurer

[48] *Supra 37*

would verify the claims, based on the experience data from the previous insurer. The acquirer will decide whether to accept the proposal and at what price in accordance with the underwriting policy filed with the IRDA.

- Individual members, including the family members covered under any group health insurance policy of a non-life insurance company shall have the right to migrate from such a group policy to an individual health insurance policy or a family floater policy with the same insurer.

The prime developments in this regard include the following:

- A web based facility is being developed by the IRDA, where all the relevant information relating to the issued health insurance policies, will be available to the insurers to provide easy access to data on the health insurance history of the policyholder wishing to switch.
- The rules are being (or have been) framed taking into account issues relating to data sharing, pricing, and exclusions in coverage and applicability of portability to different types of policies.

A customer can submit the application for portability and the insurance company will furnish the customer with portability form, proposal form and the relevant product literature. The customer will submit the same to the insurance company. The new insurer within 7 days will then seek the medical records and claim history of the customer from the previous insurer through IRDA web portal. The previous insurer will apprise the new insurer all the required details within 7 days. After getting the details, the proposal form will be sent for underwriter's approval. If there is no response regarding acceptance of proposal form with 15 days from the insurer, the proposal will be considered accepted by default.

In the interim period when the customer has applied for health insurance with the new insurer, the customer can extend existing health insurance for minimum period of one month (short period) and premium will be charged accordingly. The customer should not cancel the policy until he has obtained health policy from the new insurer. The policy cover of new insurer will begin from date of expiry of short period. The insurer has the right to continue with the existing insurer and no penalty will be imposed.

Source: Health Insurance Updates; and Policybazaar.Com

In light of the discussions regarding the nuances of health insurance dealt earlier, it can be said that a different kind of regulation of health insurance may be needed. There is a thinking going on this line to create a separate regulatory regime for health insurance. The present regime under IRDA is for insurance business in general and doesn't specifically apply to health insurance. Even though, insurance regulations meant to ensure fairness, efficiency, and financial accountability in health insurance are similar to those applicable to general insurance business, health insurance business always involves additional regulations. These relate to meeting social objectives of access, adequate benefits, and consumer responsiveness. From competition policy point view also, regulation of healthcare service providers and regulation of health insurance providers would require close synergies and convergence for optimum benefits to consumers and health insurance providers, which might be difficult in the present regime. The Ministry of Health & Family Welfare would need to play an important role in any new regulation.

[49] *Supra 36*

CHAPTER 4: CONCLUSION & AGENDA FOR COMPETITION POLICY

In light of the discussions in Chapters 2 and 3, the following issues can form the agenda for competition policy advocacy.

Health services

1. GOI to amend Section 10A of the Medical Council Act, 1956 to include entities other than university and trust, such as private hospitals, who can establish medical colleges.

2. Medical Council of India (MCI) to amend The Establishment of Medical College Regulations, 1999 so that it provides a eligibility criteria allowing entities other than universities and trusts, such as private hospitals to enter into medical education, and also facilitate establishment of new medical colleges by making qualifying criteria quality-centred rather than quantity-centred.

3. Indian Nursing Council to reformulate Minimum Standard Requirement for school for training ANMs so that it is more relaxed in quantitative terms in order to facilitate establishment of more nursing schools.

4. MCI to be more proactive in implementing the Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002, in general, and its Clauses 1.5 and 3.1 in particular, and begin invoking penal clauses in cases of violation by physicians and highlight such action through local media for its optimum deterrence.

5. In case, MCI fails to act in the (4)-above, Centre/state governments should intervene.

6. GOI (D/o Pharmaceuticals) to notify and enforce "Code of Conduct for Market Promotion by Pharmaceutical Companies" as soon as possible. Reduce the review period from five years to one year in the Code, and make it a statutory obligation if desired result is not availed.

7. State governments to adopt the Clinical Establishment Act, 2010 at the earliest.

8. GOI may like to adopt the Standard Treatment Guidelines, prepared by the WHO India Office in collaboration with Ministry of Health.

9. GOI to grant health sector an 'infrastructure' status.

Pharmaceuticals*

1. Induce the Patent Controller (and DIPP, GOI), so that patent offices begin strictly implementing the available public health safeguards in the Patents Act, in general, and

* As the paper has limited coverage on pharmaceuticals, hence limited advocacy agenda

Section 3(d), (e) and (i), in particular. A guideline may be considered to be implemented by GOI in this regard, to include it in the Patent regime. Furthermore, an institutional mechanism for the coordination of Patent Controller (DIPP) and DCG(I) (MOHFW) to enhance the quality of pharmaceutical patents.

2. GOI (DIPP/Patent Controller) to adopt a suitable strategy to deal with "Markush Claims" in a patent application, particularly those related with medical science.

3. GOI to ensure that flexibilities available in TRIPS Agreement is not eroded or diluted through ongoing negotiations on international norm-making agreements.

4. GOI may like to establish a suitable coordination mechanism between CCI, MOHFW and DIPP to deal with recent spurt of M&As in pharmaceutical sector, which has anti-competitive motives of futuristic nature.

5. CCI (D/o Company Affairs) may like to investigate (look into) the seemingly concerted effort by few global pharmaceutical companies to acquire major Indian companies with objective of reducing generic competition in future.

Medical Devices

1. GOI to rectify import duty structure for medical devices, so that it doesn't indirectly rewards trading by charging higher duties on raw materials than on finished goods, whereby dis-incentivising local manufacture of high-end medical devices.

2. GOI (MOHFW) to soon bring the new Bill under consideration for regulating medical devices and move away from the present approach of including them as 'drugs' (through notifications) under Drugs & Cosmetics Act, which gives an uncertain policy environment.

3. GOI, States and other statutory bodies to avoid notifying differential price ceiling based on different approval agencies of the world, as has been reportedly done by CGHS and ESIC.

4. DCG(I)/MOHFW to amend the "Guidelines for import of medical devices" so that it do not act as 'entry barriers' and provide '*ad hoc* and arbitrary' standards and evaluation protocols.

Public Health Procurement

1. All state governments to adopt Tamil Nadu type model for the procurement of health products for public health system.

2. Centre, State Governments and their (statutory) agencies to avoid putting anti-competitive conditions based on "market standing" and 'turnover" in their notifications inviting tenders for supply of medical products.

Health Insurance

1. GOI may like consider increasing 26 percent cap on FDI in health insurance market.
2. IRDA may like to consider reducing an entry requirement of a minimum capital of Rs.100 crore for health insurance business.

3. Centre/States to adopt regulation (including Clinical Establishment Act) to regulate health service providers in order to mitigate 'moral hazards' and increase penetration of health insurance.

4. GOI may like to consider a separate regulation (from IRDA) for health insurance, which may be in conjunction and synergy with regulation of health service provider.

5. Promote Government's health insurance scheme Rashtriya Swasthya Bima Yojna (RSBY) for its pro-competition model. Not only this scheme be extended beyond BPL household in calibrated manner (and with lesser subsidy), but the pro-competition elements of the scheme can also serve as model for other government welfare schemes outside health insurance.

In conclusion, it is only said that most of the issues mentioned in this study are not new and have been raised on many occasions and in many studies. There is hardly anything new that this study has brought to the notice. It is hoped that the present effort would induce to rectify such issues and make the heath system efficient enough and accessible to all.

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CHAPTER 3: IDENTIFICATION, LISTING & ANALYSIS OF ANTI-COMPETITIVE PROVISIONS AND PRACTICES

S No	Title[1]	Responsible Agencies[2]	Text of the Provision (section/clause)	Code[3]	Analysis[4]	Remarks & Recommendation[5]
1.	S.10 A of Medical Council Act, 1956	Medical Council of India (MCI)	**PERMISSION FOR ESTABLISHMENT OF NEW MEDICAL COLLEGE, NEW COURSE OF STUDY ETC**. 10.A (1) Notwithstanding anything contained in this Act or any other law for the time being in force:- (a) no person shall establish a medical college or (b) no medical college shall:- (i) open a new or higher course of study or training (including a postgraduate course of study or training) which would enable a student of such course or training to qualify himself for the award of any recognised medical qualification; or (ii) increase its admission capacity in any course of study or training (including a postgraduate course of study or training), except with the previous permission of the Central Government obtained in accordance with the provisions of this section.	A3 D1	S.10A gives Central Government discretion to grant the permission to establish a medical college to a "person". MCI's recommendation is, however, needed in this regard. "Person" for the purpose of this section includes only university or trust. Therefore, it can act as an entry barrier for entities "other than universities or trusts" to establish a medical college. It is to be noted, however, that Central Government is not included in "person" under this section. Does this mean that Central Government cannot establish a new medical college? If yes, then this is a self	There is huge need of quality Doctors in India and Government should increase facilitate establishment of medical colleges. In this regard, allowing entities other than trusts and universities to set up medical collages in India, would be a positive step. India's average annual output is 100 graduates per medical college, which should be increased.

[1] Of Acts/rules/regulations/policy/actions/practices
[2] Ministry/Department/statutory bodies responsible for enforcement
[3] Checklist Codes in Annexure 3 of TOR; annexed herewith as **Annexure II** for ready reference for the readers
[4] Analysis of anti-competitive effect or market distortion
[5] Recommendation(s), if any, to rectify the situation

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			Explanation 1-. For the purposes of this section, "person" includes any University or a trust but does not include the Central Government. Explanation 2.- For the purposes of this section "admission capacity" in relation to any course of study or training (including postgraduate course of study or training) in a medical college, means the maximum number of students that may be fixed by the Council from time to time for being admitted to such course or training.		restriction imposed on the Central Government. There is scope for relaxation the said restriction in order to allow entities other than trust and universities to open medical colleges do that more doctors are passed every year. Because shortage of doctors has been understood to create entry barriers for establishment of new hospitals or expanding the existing ones.	
2.	S.19A(1) of Medical Council Act, 1956	Medical Council of India	**MINIMUM STANDARDS OF MEDICAL EDUCATION**. 19. A (1) The Council may prescribe the minimum standards of medical education required for granting recognised medical qualifications (other than postgraduate medical qualifications) by universities or medical institutions in India.	-*	MCI has been bestowed with the power of prescribing the minimum standards required for medical education. For this purpose MCI has devised the Establishment of Medical College Regulations, 1999.	The prescription of minimum standard need to be such that it facilitates creation of more and more health human resource, without compromising on quality. The prescription need to be quality-oriented rather than quantity- oriented.
3.	The Establishment of Medical College Regulations, 1999	MCI	**1. ELIGIBILITY CRITERIA -** The following organizations shall be eligible to apply in Form-1 for permission to set up a medical college, namely:- 1. A State Government/Union territory; 2. A University; 3. An autonomous body promoted by	A2 A3 D1	In commensuration of what has been provided under S.10A of the MCI Act, 1956, the eligibility criteria for applying to set up a medical college exclude private players and Central Government. Therefore creating entry barriers for setting up new medical college and consequently entry	There is huge need of quality Doctors in India and Government should increase its expanding of medical colleges by reforming the eligibility and qualifying criteria, *inter alia*, allowing private hospitals to enter into medical education,

* ~~As this is mere enabling provision, hen~~ce no 'code' given. It has bearing on provisions below this.

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			Central and State Government by or under a Statute for the purpose of medical education; 4. A society registered under the Societies Registration Act, 1860 (21 of 1860) or corresponding Acts in States; or 5. A public religious or charitable trust registered under the Trust Act, 1882 (2 of 1882) or the WAKFS Act, 1954 (29 of1954). **2. QUALIFING CRITERIA-** The eligible persons shall qualify to apply for permission to establish a medical college if the following conditions are fulfilled:- 1. that medical education is one of the objectives of the applicant in case the applicant is an autonomous body, registered society or charitable trust. 2. that a suitable single plot of land measuring not less than 25 acres is owned and possessed by the person or is possessed by the applicant by way of 99 years lease for the construction of the college. 3. that Essentiality Certificate in Form 2 regarding No objection of the State Government/Union Territory Administration for the establishment of the proposed medical college at the proposed site and availability of adequate clinical material as per the council		barrier for setting up new hospitals, as described in the study. Some of the qualifying criteria for applying for a medical college, such as single plot of 25 acre land have practical difficulties in modern era, particularly in big cities, and creates natural barriers to entry. This would not only increase the establishment costs, but also availability of such a big plot. More so, such land area and building needs to be owned and not hired or rented. These qualifications can be eased reasonably. Similarly qualifications regarding 300 beds and payment of huge bank guarantee (starting at rupees one crore for 50 admissions) could be reconsidered and eased.	making qualifying criteria quality-oriented rather than quantity-oriented, which is the case at present. There is also scope for reforming the fee requirements and making it non-discriminatory.

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			regulations, have been obtained by the person from the concerned State Government/ Union Territory Administration. players 4. that Consent of affiliation in Form-3 for the proposed medical college has been obtained by the applicant from a University. 5. that the person owns and manages a hospital of not less than 300 beds with necessary infrastructural facilities capable of being developed into teaching institution in the campus of the proposed medical college: Provided that in North Eastern State and Hill States, the beds strength required at the time of inception shall be 200 beds, which shall be increased to 400 beds at the time of recognition for a medical college having annual intake of 50 students and it shall be 250 beds at the time of inception which shall be increased to 500 beds at the time of recognition for a medical college having annual intake of 100 students. 6. that the person has not admitted students to the proposed medical college. 7. that the person provides two performance bank guarantees from a Scheduled Commercial Bank valid for a period of five years, in favour of the Medical Council of India, New Delhi, one for a sum of rupees one hundred lakhs (for 50 admissions), rupees one hundred and fifty lakhs (for 100 admissions) and		More so, there is differential treatment with regards to fees and bank guarantee between government and private (trusts etc.). This may not stand the test of competition neutrality. As stated above, any barrier on creation of new medical college would act as entry barriers for setting up of hospitals.	

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			rupees two hundred lakhs (for 150 annual admissions) for the establishment of the medical college and its infrastructural facilities and the second bank guarantee for a sum of rupees 350 lakhs (for 400 beds), rupees 550 lakhs (for 500 beds) and rupees 750 lakhs (for 750 beds) respectively for the establishment of the teaching hospital and its infrastructural facilities : Provided that the above conditions shall not apply to the persons who are State Governments/Union Territories if they give an undertaking to provide funds in their plan budget regularly till the requisite facilities are fully provided as per the time bound programme. 8. Opening of a medical college in hired or rented building shall not be permitted. The Medical college shall be set up only on the plot of land earmarked for that purpose as indicated. **4. APPLICATION FEE:** The application shall be submitted by registered post only to the Secretary (Health), Ministry of Health and Family Welfare, Government. of India, Nirman Bhavan, New Delhi - 110 011 along with a non-refundable application fee of Rs. 3.5 lakhs *for the Government Colleges (under Central Government and State Governments) and Rs.7.00 lakhs for private sector medical colleges/institutions* in the form of demand			

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			draft/pay order in favour of 'Medical Council of India' payable at New Delhi. The Fee is for registration, technical scrutiny, contingent expenditure and for five inspections. Beyond five inspections, the normal inspection fee prescribed by the Council will apply. The Schedule for receipt of application for establishment of new medical colleges and processing of the applications by the Central Government is given in the Schedule annexed with these regulations.			
4.	Indian Nursing Council Act,1947	Indian Nursing Council (INC)	**16. Power to make regulations.** (1) The Council may by notification in the official gazette, make regulations not inconsistent with this Act generally to carry out the provisions of this Act, and in particular and without prejudice to the generality of the foregoing power, such regulations may provide for- (g) prescribing the standard curricula for the training of nurses, midwives and health visitors, for training courses for teachers of nurses, midwives and health visitors, and for training in nursing administration; (h) prescribing the conditions for admission to courses of training as aforesaid ; (i) prescribing the standards of examination and other requirements to be satisfied to secure for qualifications recognition under this Act ;	-	The INC Act bestows power on INC, *inter alia*, to make regulations regarding curricula, admission criteria etc. for various nursing degrees. Deriving power from this Section, INC has provided Minimum Standard Requirement for schools for training of ANMs, which is discussed below.	It is recommended that the prescription of Minimum Standard Requirement under this section need to be quality-oriented and not quantity-oriented. It also need to be facilitative for creation of more nurses, which are in short supply creating bottlenecks in establishment of new hospitals.

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			(j) any other matter which is to be or may be prescribed under this Act			
5.	Minimum Standard Requirement for school for training ANMs	INC	**MINIMUM STANDARD REQUIREMENTS** • A school for training of the ANMS should be located in a community Health Centre (PHC annexe) or a Rural Hospital (RH) having minimum bed strength of 30 and maximum 50 and serving an area with community health programmes. The school should also be affiliated to a district hospital or a secondary care hospital in order to provide experiences of secondary level health care and an extensive gynae-obstertical care. • An organization having a hospital with 150 beds with minimum 30-50 obstetrics and gynecology beds, and 100 delivery cases monthly can also open ANM school. The should also have an affiliation of PHC/CHC for the community Health Nursing field experience. • Existing ANM schools attached to District Hospitals should have PHC annexe (accommodation facility for 20-30 students) for community health field experience **Physical Facilities**	A2 D1	The minimum standard requirements for ANMs/Nursing schools relating to hospitals having 150 beds etc. is not realistic and are onerous creating a natural barrier for many potential entrants.	The minimum standard for running a training school for nurses, as provided, can be more relaxed, without compromising on quality, so that more nurses/ANMs are created which can facilitate setting up of hospitals. Low availability of nurses and para-medics has been cited as entry barriers in setting up nursing homes and hospitals.

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			Office room 1Class-room 2Nursing laboratory 1Nutrition laboratory 1Library cum study 1Audio visual aid 1 **Clinical Facilities** • School has to be affiliated to district hospital or a secondary care hospital with minimum 150 beds. • Bed occupancy on the average to be between 60% -70%			
6.	S.20A(1) of Medical Council Act, 1956	MCI	**PROFESSIONAL CONDUCT** 20.A (1) The Council may prescribe standards of professional conduct and etiquette and a code of ethics for medical practitioners. (2) Regulations made by the Council under sub-section (1) may specify which violations thereof shall constitute infamous conduct in any professional respect, that is to say, professional misconduct, and such provisions shall have effect notwithstanding anything contained in any law for the time being in force.	-	The MCI Act bestows on the MCI the power of prescribing standards of professional conduct and etiquette and code of ethics for medical practitioners, and also to specify which one of those prescribed standards or code constitutes as a professional misconduct triggering penal provisions. This prescription of MCI is provided under Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002, described below.	The prescription of standard professional conduct and etiquette and code of ethics need to such that bring real changes on ground and should not be such that are meant to be violated at will, without any deterrence in this regard.
7.	Clause 1.5 of the Indian	MCI	**CHAPTER I**	A1 E3	Physicians' prescription practices in brand names virtually 'grant	There is need to proper enforcement of regulation

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	Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002		**1. CODE OF MEDICAL ETHICS** **1.5 Use of Generic names of drugs:** Every physician should, as far as possible, prescribe drugs with generic names and he / she shall ensure that there is a rational prescription and use of drugs. **CHAPTER 7** **7. MISCONDUCT :** The following acts of commission or omission on the part of a physician shall constitute professional misconduct rendering him/her liable for disciplinary action. **7.1 Violation of the Regulations**: If he/she commits any violation of these Regulations. **CHAPTER 8** **8. PUNISHMENT AND DISCIPLINARY ACTION** **8.2** It is made clear that any complaint with regard to professional misconduct can be brought before the appropriate Medical Council for Disciplinary action. Upon receipt of any complaint of professional misconduct, the appropriate Medical Council would hold an enquiry and give opportunity to the registered medical practitioner to be heard in person or by pleader. If the medical practitioner is found to be guilty of committing professional misconduct, the appropriate Medical Council may award such punishment as deemed necessary or may direct the removal altogether or for a specified period, from the register of the		exclusive rights' for a supplier to supply medicine and fundamentally changes information required by buyers to shop effectively. Therefore, it is a very important ethical code for physicians is that they should prescribe drugs with generic names. However, there is virtually universal breach of this code. Because of this the consumers/patients does not enjoy the fruits of competition in the Indian drug sector. It makes this market imperfect, where consumers do not have choice or options to choose. This is particularly important because the bulk of out-of-pocket expenditure is on drugs. Violation of clause 1.5 of the Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002 can clearly be construed as "misconduct" under its clause 7.1, and hence liable for punishment and disciplinary action under Chapter 8. In this regard, anyone can file a complaint before MCI, which would be disposed within 6	by Medical Council of India and issues such as use of generic drugs and violation of regulation should be enforced effectively. If MCI is not able to deal it, Centre or State governments may like intervene, so that this misconduct does not prohibit competition in Indian drug sector. Consequently making healthcare more accessible.

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			name of the delinquent registered practitioner. Deletion from the Register shall be widely publicized in local press as well as in the publications of different Medical Associations/ Societies/Bodies. **8.4** Decision on complaint against delinquent physician shall be taken within a time limit of 6 months. **8.5** During the pendency of the complaint the appropriate Council may restrain the physician from performing the procedure or practice which is under scrutiny.		months. If found guilty the punishment could constitute deregistration of the practitioner for a specified time period. However, despite these provisions there is flagrant violation of the said clause 1.5. There is need for proper implementation of this. If MCI is not able to deal it, Centre or State governments may like intervene, so that this misconduct does not prohibit competition in Indian drug sector. Consequently making healthcare more accessible.	
8.	Market promotion draft code of conduct by DOP (Clause 6 and 7)	D/o Pharmaceuticals	**6. GIFTS** 6.1 No gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to persons qualified to prescribe or supply by a pharmaceutical company. 6.2 Gifts for the personal benefit of healthcare professionals (such as tickets to entertainment events) also are not be offered or provided. **7. Hospitality, Sponsorship & Meetings** 7.1 Companies may legitimately provide assistance that is directly related to the bona fide continuing education of the healthcare professionals and which genuinely facilitates attendance of the healthcare professional for the duration of the educational aspect of the event held in India. Such support and assistance must however, always be such as to leave healthcare	A1 E3	The Market Promotion Code of Conduct is an attempt to regulate supply side nuances that result in collusion between medical practitioners and pharmaceutical companies, which results inter alia in doctors prescribing medicines under brand name, and hence fundamentally changing information required by buyers to shop effectively and virtually granting exclusive rights to a particular supplier. The Code is intended to be voluntary and would be reviewed after five years, and if need be it could be turned into an	The Code is yet to be notified and hence is not in force at present. It is recommended to enforce this Code as soon as possible. It is also recommended to reduce the review period from five years to one year, and if it is found after one year that the voluntary nature is not working it should be immediately be turned into an enforceable statute.

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			professionals' independence of judgment. 7.2 Where appropriate and depending on the time, location and length of the meeting, support to healthcare professionals may cover actual travel expenses, meals, refreshments, accommodation and registration fees. The events have to be organized in India only and all expenses mentioned above, must be incurred only for the events held in India. 7.3 Companies must not organise meetings to coincide with sporting, entertainment or other leisure events or activities. Venues that are renowned for their entertainment or leisure facilities or are extravagant must not be used. 7.4 Any hospitality offered to healthcare professionals must: (i) Be reasonable in level and be likely to appear to independent third parties, to be reasonable; (ii) Be secondary and strictly limited to the main purpose of the event at which it is offered; (iii) Not exceed the level that recipients would normally be prepared to pay for themselves; (iv) Not be extended to spouses or other accompanying persons, unless they are healthcare professionals who qualify as participants in their own right. Travel expenses are not to be paid for spouses or other accompanying persons, unless they are healthcare professionals who qualify as participants in their own right; (v) Not include sponsoring, securing, organising directly or indirectly any entertainment, sporting or leisure events. 7.5 Funding of healthcare professionals to compensate them for the time spent in attending the event is not permitted.		enforceable statute. According to Clause 6 and 7 of the Code, pharmaceutical companies are precluded from providing any gift and/or hospitality, sponsorship etc. to doctors, so that the latter is not influenced by the former for prescribing their products. It is believed that the Code along with the MCI Code of Ethics would help rectify prescription mal-practices by doctors.	

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			7.6 All promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (including, for example, advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies) (each, an "event") organized or sponsored by or on behalf of a company must be held at an appropriate venue in the country that is conducive to the main purpose of the event. 7.7 The companies must maintain a detail record of expenditure incurred on these events.			
9.	Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002 (Clause 3.1)	MCI	**CHAPTER 3** **3. DUTIES OF PHYSICIAN IN CONSULTATION** **3.1 Unnecessary consultations should be avoided**: 3.1.1 However in case of serious illness and in doubtful or difficult conditions, the physician should request consultation, but under any circumstances such consultation should be justifiable and in the interest of the patient only and not for any other consideration. 3.1.2 Consulting pathologists /radiologists or asking for any other diagnostic Lab investigation should be done judiciously and not in a routine manner.	A1 E1	The collusion between physicians and diagnostic/tests firms, whereby former recommends particular firm for tests for some commission and cuts, virtually amounts to granting exclusive rights for a supplier and also limits the ability of consumers to decide from whom they purchase. Despite penal provisions under Chapter 8 of the Ethics Code, this menace is going on unchecked.	If MCI is not able to deal it, Centre or State governments may like intervene, so that this misconduct does not prohibit competition in the pathology/diagnostic market, consequently making healthcare more accessible.
10.	Patents Act, 1970	Patent Controller	Public health safeguards available in the Patens Act, 1970, in general, and those included in	**?**	Such practices tend to limit competition that can happen from	Proper guidelines for patent examiners need to be

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	Non-implementation of available public health safeguards in the Patents Act, 1970	(DIPP, GOI)	Section 3(d), (e) and (i), in particular have reportedly not being implemented in spirit of the law by different Patent Offices. mechanism between patent		generic drug manufacturers in pharmaceutical market, consequently harming consumers.	developed. Some form of coordination on offices (DIPP) and DCGI (MOHFW) may be developed for proper implementation of public health safeguards available in the Patents Act, 1970. It is hard to correlate the given practice with any of the entries in the given Competition Checklist, which has understandably been developed by merging OECD Competition Impact Assessment Checklist and DFID Competition Assessment Framework. Therefore it is recommended to include an entry in the checklist that can correlate with the given practice.
11.	Import duty structure for medical devices	Government of India	The present import duty structure, in general, for medical devices and equipment favours imports, whereby reducing the competitiveness and growth potential of the local manufacturing units.	A3	The present import duty structure for medical devices dis-incentivise domestic manufactures, hence is biased in favour of foreign manufacturers, which in turn act as entry barrier to domestically establish manufacture units for medical	In some cases, this policy indirectly rewards trading by charging higher duties on raw materials than on finished goods. For instance, titanium sheet/ rod imported for making implantable pacemakers

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					devices. It is also to be noted that high prices of medical devices has been reported as an entry barrier for establishment of new hospitals.	attracts a total import duty of 23.89 %, while import of the pacemaker itself attracts a duty of 9.36 %. As a result, in many cases, cost of a finished product manufactured within the country remains higher than an imported product. There is a need to look into the matter.
12.	CGHS and ESIC tender notices prescribing three different ceiling of prices for medical devices	CGHS & ESIC (GOI - MOHFW & Labour Ministry)	Reportedly[6] CGHS and ESIC has invited procurement of medical devices through tender notice, which prescribes three different ceiling of prices for medical devices based on their approval from different regulatory authorities. A product approved by USFDA has been given highest ceiling, followed by that approved from any European regulator and lowest for that approved by Indian regulator (i.e. DCGI).	B4 B6 D1	Firstly it undermines the domestic drug regulatory regime by implying that the DCGI approval is not optimal. Secondly, in the absence of a clear rationale and justification for favouring foreign regulatory approvals it seems *prima facie* discriminatory and a regulatory barrier against the domestic medical device manufacturers. Thirdly, if without basis and justification, it influences consumer minds that are victims of asymmetrical information in the relevant market to choose foreign medical devices over purely domestic medical devices on baseless grounds.	This needs to be looked into by GOI, and such differential treatments be removed. This also dis-incentivise the domestic players.

[6] As reported in Business Standard, 23rd December 2011

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13.	Regulation of medical devices under Drugs and Cosmetics Act, 1940	DCGI (MOHFW) India only when	There is no definition for medical devices. A medical device falls under regulation cover in it is notified to be included within the definition of "drugs" under sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940.	D1	This creates 'policy uncertainty', mainly due to frequent changes in definition of 'drugs', in absence of a clear cut definition of 'medical device'.	So far only 14 medical devices have been notified for regulation, where as more than 3000 medical devices are available in the market. MOHFW need to bring facilitate the new Bill, that it is considering to bring in near future to rectify this situation.
14.	Guidelines for import of medical devices	DCG(I) (MOHFW)	For the time being and for a period upto six months, until an application is approved or rejected, whichever is earlier, the devices which are currently in use will be permitted to be sold. In case of stents or drug eluting stents, the import will not be permitted if the applicant has sold less than one thousand stents of the particular specification prior to the date of issue of these guidelines. Separate committees consisting of subject experts and representative of DCGI office would be setup for their expert advice for evaluation of specific categories of devices. The expert committees would formulate their own benchmarks and procedures for evaluations and the standards to which such devices should conform.	A2 D1	The requirement for an applicant "to have sold at least one thousand stents of particular specification prior to the date of issue of the guidelines" *prima facie* seems to create an **'entry barrier'** in absence of any valid justification. The fact that the "expert committees would formulate their own benchmarks and procedure for evaluations and the standards to which devices should conform" *prima facie* seems **'arbitrary'** in nature creating regulatory uncertainty.	The requirement with respect to the imports of stents may like to be reviewed. More certainty may need to there in form of well defined procedure for evaluation and standards. The present situation seems *ad hoc* in nature.
15.	Procurement of drugs in Tamil Nadu / Delhi and other states as	Tamil Nadu Medical Services Corporation Ltd; states	In order to ensure the procurement of only quality drugs at competitive prices, an open tender system is followed and purchases are made only from manufacturers who have GPM certificate and not through agents or distributors.	B4	Conditions with respect to market standing and minimum turn over with the objective of sustainable supply of quality drugs creates entry barriers for new and smaller	There is need to ensuring competitive public procurement bidding system without creating hurdles for new entrants and hence need

ANNEXURE II

Competition Checklist

Competition Checklist: Competition Checklist (prepared after merging and incorporating OECD Competition Impact Assessment Checklist and DFID, UK Competition Assessment framework)

Check if a statute, regulation, policy statement and practice have any of the following effects:

(A) Limits the number or range of suppliers

This is likely to be the case if a clause:

1. Grants exclusive rights for a supplier to provide goods or services
2. Establishes a license, permit or authorisation process as a requirement of operation. Creates natural barriers affecting prospective entrants or significantly raises cost of entry or exit by a supplier. Do they affect different categories of prospective entrants differently (e.g. established vs. new firms, or domestic vs. foreign firms)?
3. Are there limits to the number of firms permitted to enter the market? (There could also be indirect limits to entry, through measures that reserve entry to particular groups, including through affirmative action policies.)
4. Limits the ability of some types of suppliers to provide a good or service
5. Are there any barriers, based on either regulations or custom, that prevent women from commencing business in the relevant market/s and/or expanding an existing business, or that make it difficult for them to do so?
6. Creates a geographical barrier to the ability of companies to supply goods services or labour, or invest capital

(B) **Limits the ability of suppliers to compete**

This is likely to be the case if a clause:

1. Limits sellers' ability to set the prices for goods or services
2. Limits freedom of suppliers to advertise or market their goods or services
3. Do any state-owned enterprise/s operate in the market/s being assessed? If so, do the enterprise/s receive any benefit/s or preferential treatment not available to other firms which appear to have the effect of limiting competition in the relevant market/s?
4. Sets standards for product quality that provide an advantage to some suppliers over others or that are above the level that some well-informed customers would choose
5. Does the under-development of transport or other infrastructure in some districts appear to give incumbent firms monopoly status?
6. If the government is a major buyer of the product/s, does it appear that government procurement policies have adequate safeguards for competitive bidding, for transparency and for fairness? If government is a significant purchaser, and its procurement policies lack transparency or fairness, how significant are the effects on competition in the relevant markets?
7. Significantly raises costs of production for some suppliers relative to others (especially by treating incumbents differently from new entrants)

(C) **Reduces the incentive of suppliers to compete**

This is likely to be the case if a clause:

1. Creates a self-regulatory or co-regulatory regime
2. Requires or encourages information on supplier outputs, prices, sales or costs to be published

3. Exempts the activity of a particular industry or group of suppliers from the operation of the general competition law

(D) Regulatory and policy barriers

1. Is the sector subject to any policies or regulations that are onerous, costly or time-consuming, or that frequently change, thereby creating 'policy uncertainty'? (Firms in the sector might be hindered by factors such as licensing restrictions, FDI restrictions or trade barriers. The possibility of achieving the stated objectives of the regulations in ways that are less onerous, costly or time-consuming should be considered.) Only proceed to the following questions in this section if there appear to be any inappropriate policies or regulations.
2. Do any firms in the market suffer from the unequal application of laws or regulations? (Examples of where this might occur include the unequal enforcement of taxes, labour regulations, health and safety regulations, access to land, access to key infrastructure, standards and intellectual property rights.)
3. Are there any trade or industrial policies that appreciably restrict competition in the market/s? If so, do these policies appear to have adequate justification, taking account of their effects on competition?

(E) **Limits the choices and information available to customers**

This is likely to be the case if a clause:

1. Limits the ability of consumers to decide from whom they purchase
2. Reduces mobility of customers between suppliers of goods or services by increasing the explicit or implicit costs of changing suppliers
3. Fundamentally changes information required by buyers to shop effectively

Conclusions required:

1. Are there any significant barriers to entry in the relevant markets? If so, what are their effects on competition? Do any law/policy-based reasons for these barriers appear justified?
2. Does the operation of state-owned enterprises, or the conduct of public procurement, or sector regulation, or the existence of trade and industrial policies, or the unequal enforcement of laws and regulations appear to limit the scope for competition? If so, how significant are the effects on the welfare of consumers or on the input costs of producers?
3. How does the extent of the impact on consumers and producers compare with any public benefits likely to result from the operation of any of these government policies?