

Sector Study: Healthcare

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 <u>person</u> 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- <u>For the purposes of this section, "person" includes any University or a trust but does not include the Central Government.</u> 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 <u>entry barriers</u> 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, <i>inter alia</i>, allowing private hospitals to enter into medical education,

* As this is mere enabling provision, hence 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 of 1954). 2. QUALIFYING 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 <u>single plot of land measuring not less than 25 acres</u> 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. 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 <u>hospital of not less than 300 beds</u> 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 <u>one hundred lakhs (for 50 admissions), rupees one hundred and fifty lakhs (for 100 admissions) and</u>	More so, there is differential treatment with regards to fees and bank guarantee between government and private players (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 <u>the above conditions shall not apply to the persons who are State Governments/Union Territories</u> 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 <u>medical college in hired or rented building shall not be permitted.</u> 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 <u>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</u> 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, <i>inter alia</i>, 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 <u>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</u>. 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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			<table><tr><td>Office room</td><td>1</td></tr><tr><td>Class-room</td><td>2</td></tr><tr><td>Nursing laboratory</td><td>1</td></tr><tr><td>Nutrition laboratory</td><td>1</td></tr><tr><td>Library cum study</td><td>1</td></tr><tr><td>Audio visual aid</td><td>1</td></tr></table> Clinical Facilities • School has to be affiliated to district hospital or a secondary care hospital with <u>minimum 150 beds.</u> • <u>Bed occupancy on the average to be between 60% -70%</u>	Office room	1	Class-room	2	Nursing laboratory	1	Nutrition laboratory	1	Library cum study	1	Audio visual aid	1			
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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	<u>CHAPTER I</u>	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	<u>1. CODE OF MEDICAL ETHICS</u> <u>1.5 Use of Generic names of drugs:</u> 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. <u>CHAPTER 7</u> <u>7. MISCONDUCT :</u> The <u>following acts of commission or omission on the part of a physician shall constitute professional misconduct</u> rendering him/her liable for disciplinary action. <u>7.1 Violation of the Regulations:</u> If he/she commits <u>any violation of these Regulations.</u> <u>CHAPTER 8</u> <u>8. PUNISHMENT AND DISCIPLINARY ACTION</u> <u>8.2</u> 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. <u>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</u>	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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			<u>name of the delinquent registered practitioner.</u> 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 <u>time limit of 6 months</u>. 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	<u>CHAPTER 3</u> <u>3. DUTIES OF PHYSICIAN IN CONSULTATION</u> <u>3.1 Unnecessary consultations should be avoided:</u> 3.1.1 However in case of serious illness and in doubtful or difficult conditions, the physician should request consultation, but <u>under any circumstances such consultation should be justifiable and in the interest of the patient only and not for any other consideration.</u> 3.1.2 Consulting pathologists /radiologists or asking for any other diagnostic Lab investigation <u>should be done judiciously and not in a routine manner.</u>	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.		generic drug manufacturers in pharmaceutical market, consequently harming consumers.	developed. Some form of coordination mechanism between patent 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 disincentivise 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 <i>prima facie</i> 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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	well as Centre	and centre (etc.)	Further, two conditions for manufacturer, which are generally put, are: (1) market standing for at least three years; and (2) minimum turnover (Rs.25-50 crore).		firms, and do not seem to be having proper nexus with the objective. More so, such conditions per se do not guarantee meeting the said objectives.	to be reviewed.
16.	FDI Policy	GOI	Restricts FDI in health insurance sector to 26 percent.	A2 D1	If more FDI is allowed there could be more players in market, hence more competition in health insurance market.	GOI may like to think allowing more FDI in health insurance.
17.	Insurance Development & Regulatory Act, 1999 Notifications made under it	IRDA	An entry requirement of a minimum capital of Rs.100 crore for insurance business	A2 D1	Entry requirement of a minimum capital of Rs.100 crore, may act as entry barrier, because it is estimated to take around 13-15 years to breakeven in health insurance business. This may also discourage non-government organisations to introduce Community-based Health Insurance with smaller capital requirement.	GOI may like review this regulatory requirement.
18.	Absence of regulation for health service providers	GOI & State Government	Absence of any regulation for health service providers creates asymmetry of information for health insurance companies and policy holders, and contributes towards “moral hazards”, which in turn act as an entry barrier for health insurance market.	E3 A2	If moral hazards are mitigated by regulating health service providers, it would do away with ‘asymmetry of information’ and ‘moral hazards’ prevalent in the sector.	A <i>de novo</i> regulation dealing health insurance and health service providers in conjunction could be thought of. MOHFW may like to take a lead in this regard.