

India-EU Relations in Health Services:
Issues and Concerns in an India-EU
Trade and Investment Agreement

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List of Abbreviations

AIIMS	All India Institute of Medical Sciences
BPO	Business Process Outsourcing
BS7799	British Standard for Information Security Management
BTIA	Bilateral Trade and Investment Agreement
BUPA	British United Provident Association
CAP	College of American Pathologists
CECA	Comprehensive Economic Cooperation Agreement
CHC	Community Health Centre
CPC	Central Product Classification
CRO	Contract Research Organization
DBT	Department of Biotechnology
DCGI	Drug Controller General of India
DPA	Data Protection Authority
EEA	European Economic Area
EHIC	European Health Insurance Card
EPHI	Electronic Protected Health Information
EU	European Union
FACT	Foundation for Accreditation for Cellular Therapy
FDI	Foreign Direct Investment
FIPB	Foreign Investment Promotion Bureau
GATS	General Agreement on Trade in Services
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMC	General Medical Council (of the UK)
GMP	Good Manufacturing Practice
GTP	Good Tissue Practice
HIPAA	Health Insurance Portability and Accountability Act
HR	Human Resource
HSMP	Highly Skilled Migrant Program
ICH	International Conference on Harmonization
ICMR	Indian Council for Medical Research

IPHS	Indian Public Health Standards
ISO17799	International Information Security Standard
ISQuA	International Society for Quality Assurance in Healthcare
ITeS	Information Technology-enabled Services
JCAHO	Joint Commission on the Accreditation of Healthcare Organizations
EHIC JCI	Escorts Heart Joint Commission International
JETCO	Joint Economic and Trade Committee
MCI	Medical Council of India
MHRA	Medicine and Healthcare Products Regulatory Agency
MRA	Mutual Recognition Agreement
NABH	National Accreditation Board for Hospitals and Healthcare Organizations
NABL	National Accreditation Board for Laboratories
NCI	Nursing Council of India
NHS	National Health Service
NIMHANS	National Institute of Mental Health and Neurological Sciences
PHC	Primary Health Centre
PHI	Protected Health Information
QCI	Quality Council of India
TCS	Tata Consultancy Services
TRIPS	Trade Related Aspects of Intellectual Property Rights
VAT	Value Added Tax
WHO	World Health Organization

Trade in Health Services: Issues and Concerns in an India-EU Trade and Investment Agreement

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1. Introduction

In recent years, India has been increasingly entering into bilateral and regional agreements within and outside the Asian region. Whether this trend is due to the lack of progress in the WTO negotiations, particularly in areas of interest to India, or a result of competitive regionalism to counter similar agreements that are being framed by other developing countries, or whether this is on account of strategic commercial and geopolitical interests that India wishes to pursue, is open to question. But the potential gains in terms of increased market access for Indian goods and services, for factor flows to and from India and partner countries or regions, and for speeding up required internal reforms, are considerable.

The India-European Union (EU) Trade and Investment Agreement (TIA) is of significance given that it is India's first agreement with a major developed country bloc, which would involve discussions on several complex issues, some not currently in the WTO mandate. This prospective agreement is also significant in view of India's growing bilateral trade and investment relations with the EU and the scope for these relations to grow further.

The healthcare sector constitutes a significant and growing share of GDP in the EU. Health is seen as a public good of vital national interest in the EU. There are national health systems and trusts in individual EU member countries that are the main providers of healthcare, with the private sector constituting a small though growing part of healthcare delivery in these countries. In India, the healthcare sector is growing rapidly and its share in GDP as well as employment is significant, with the private sector accounting for around 80 per cent of healthcare delivery.

Several factors make this a sector conducive to expanding bilateral trade and investment relations between India and the EU, across a wide range of segments and activities. However, there are numerous regulatory challenges posed by the public nature of health services. This paper examines the main opportunities for India in the EU's health services market and the various barriers affecting India-EU trade and investment relations in this sector. Its objective is to outline the main issues that need to be discussed in the TIA to promote bilateral commercial interests in the health services sector.

Section 2 provides a brief overview of the sectoral and sub-sectoral coverage in this paper based on the Central Product Classification (CPC) system that is used in the General Agreement on Services (GATS). Section 3 describes the health services sector in the EU, focusing on recent trends and developments, key characteristics of this sector in the EU, and important EU regulations. Section 4 provides a similar brief overview of this sector in India with a focus on trends, developments, regulations, and the extent of liberalization. Section 5 is an overview of trade and investment prospects

in health services for the EU and India. Since neither trade and investment data on health services for either India or the EU nor bilateral trade and investment information are available, this section provides a general discussion of emerging opportunities, segments, and modes.

Section 6 describes the barriers faced by Indian healthcare providers in the EU market, based on interviews with practitioners, senior management in Indian healthcare companies, and health industry experts, following which secondary evidence is used to corroborate these findings. The constraints are highlighted for individual opportunity areas in the health sector, where there is a perceived scope for expanding bilateral relations. This section also identifies the main barriers and regulatory issues faced by Indian healthcare providers which have affected their realization of export opportunities in other markets, and the barriers faced by the EU in the Indian healthcare market. A distinction is made in this section between barriers at the EU-wide level and barriers faced in individual Member States.

Section 7 discusses the EU's position in multilateral and regional/bilateral negotiations in the health services sector and on relevant regulatory and other issues to analyze the likely outcome for the India-EU TIA negotiations in this area. The section examines the EU's commitments in the Uruguay Round, its revised offer of 2005, and in selected bilateral FTAs. It compares the multilateral, bilateral, and unilateral liberalization undertaken by the EU as well as India.

Section 8 outlines issues and proposals pertinent to the health services sector which should be pursued by the Indian government in the India-EU TIA talks to promote bilateral relations in health services. These proposals are based on the concerns expressed by Indian industry as well as on an analysis of what the EU may be able and willing to negotiate, as evident from its other agreements and its internal mandate. A negotiating strategy in terms of a list of priority areas to address in the negotiations is outlined.

Section 9 discusses domestic reforms required to overcome internal constraints in exporting health services to the EU and other markets more generally. It also highlights regulatory and other shortcomings that need to be addressed to improve the competitiveness of India's health services sector.

The paper concludes with a brief note on the pragmatic approach that India needs to follow in this sector when negotiating with the EU. It is worth noting that although the paper focuses on health services, given the interdependence between the services and goods segments in healthcare delivery, where required, issues pertaining to healthcare products, chiefly medical equipment and pharmaceuticals, are highlighted.

2. Sectoral coverage of the health services sector

The broad coverage of the health services sector in this paper is in line with the coverage of this sector under the WTO. Health services are covered in two separate sectors under the GATS. These are the Health-related and Social services sector and the Professional Services in the Business Services sector. The coverage of the health services sector (professional- and establishment-related and other) along with the associated Central Product Classification (CPC) is provided in the table below. The associated activities under these sub-sectors are also summarized.

Table 1: Health and Social Services in the GATS Scheduling Guidelines and CPC

Sectoral Classification List	Relevant CPC No.	Definition/coverage in provisional CPC
1. Business Services		
A. Professional Services		
[...]		
h. Medical and dental services	9312	Services chiefly aimed at preventing, diagnosing and treating illness through consultation by individual patients without institutional nursing...
i. Veterinary Services	932	Veterinary services for pet animals and animals other than pets (hospital and non-hospital medical, surgical and dental services).
j. Services provided by midwives, nurses, physio-therapists and paramedical personnel	93191	Services such as supervision during pregnancy and childbirth ... nursing (without admission) care, advice and prevention for patients at home.
k. Other ^a	n.a.	n.a.
8. Health-Related And Social Services		
A. Hospital Services	9311	Services delivered under the direction of medical doctors chiefly to in-patients aimed at curing, reactivating and/or maintaining the health status...
B. Other Human Health Services	9319 (other than 93191)	Ambulance Services; Residential health facilities services other than hospital services; Other human health services n.e.c. ^b
C. Social Services	933	Social services with accommodation; ^c social services without accommodation ^d
D. Other	n.a.	n.a.

Source: WTO, *Background Note on Health and Social Services, September 18, 1998, Table A1, p.22.*

Notes:

n.a. Not available

a. Relates to all professional services (including sub-sectors (a) to (g)).

b. Services in the field of: morphological or chemical pathology, bacteriology, virology, immunology, etc., and services not elsewhere classified, such as blood collection services.

c. Welfare services delivered through residential institutions to old persons and the handicapped (PPC 93311) and children and other clients (93312); other social services with accommodation (93319).

d. Child day-care services including day-care services for the handicapped (93321); guidance and counselling services n.e.c. related to children (93322); welfare services not delivered through residential institutions (93323); vocational rehabilitation services (excluding services where the education component is predominant) (93324); other social services without accommodation (CPC 93329).

The scope of this paper is limited to the following sub-sectors.

- Medical and dental services (CPC 9312)
- Services provided by midwives, nurses (CPC 93191)
- Hospital services (CPC 9311)

Although the paper does not explicitly discuss the segments using the CPC-based nomenclature, this classification is implicit in the discussion. The interviews with the various healthcare providers also highlight the significance of these activities in their current and prospective relations with the EU market.

3. Overview of the Health Services Sector in the EU

Healthcare is considered a vital and strategic sector in EU countries. The following discussion highlights key features of the healthcare sector in the EU, such as expenditures, insurance provision, and IT integration, which could be important drivers in the India-EU negotiations in this sector.

3.1 Trends and developments

3.1.1 Healthcare spending

The health sector constitutes around 8 to 9 per cent of GDP in the EU and employs almost 10 per cent of the total work force. One of the most important characteristics of the EU healthcare sector (goods and services) is the large volume of expenditure in this sector. The following table shows the total expenditure in this sector in selected member countries for 2000-03.

Table 2: Total healthcare expenditure in selected EU countries, 2000-2003

Country	2000	2001	2002	2003
EU 25	484.9	505.7	543.8	614.6
Denmark	8.7	9.5	10.1	11.7
Finland	5.3	5.8	6.4	7.3
France	80.1	86.4	92.8	108.5
Germany	130.4	138.7	144.8	161.8
Italy	57.1	62.3	66.6	75.4
Netherlands	20.1	23	25.9	30.6
Poland	6.2	7.8	7.7	NA
Sweden	13.4	13.4	14.8	NA
UK	67.3	74.4	82.7	92.1

Source: Yuen, Compendium of Health Statistics 2005-06, Radcliffe Publishers, 2005.

Note: All numbers are in £ billion.

The WHO and European Observatory on Health Care Systems statistics indicate that healthcare expenditure per capita was around \$1,848 with some countries spending

between \$2,000 and \$2,500 per capita.¹ The UK is a particularly important market within the EU. Amongst the OECD countries, the UK has experienced the most rapid growth in healthcare spending as a proportion of GDP since 1990. Total health expenditures rose to over £100 billion in 2005, representing 9 per cent of GDP, up from 8.3 per cent of GDP in 2003 and 6.6 per cent in 1997.

Although health services are excluded from the scope of the EU services directive, there are several initiatives to promote cross-border cooperation among member countries in healthcare and to harmonize internal systems to the extent possible while also giving room to individual member governments to retain their national legislation and regulatory frameworks to address concerns of consumer safety, standards, and accountability.

3.1.2: Health coverage

EU Member States provide universal or near-universal public coverage for health as part of a wider system of ‘social protection’. It is extended to health services that are prescribed by health professionals or institutions that are registered with the health insurance system or which figure on the country’s positive list of approved procedures or of drugs and medical devices.

Private insurance offering ‘supplementary’ cover accounts for less than 20 per cent of total financing of healthcare in most EU countries and mostly complements the coverage provided under statutory insurance. (Further details on the public-private breakdown of healthcare financing are provided in Section 3.2). Private insurance covers services such as dental or alternative treatment that may be partially covered by statutory user charges or excluded altogether, and also provides supplementary coverage for options elected by the patients. In recent years, the EU has moved from a heavily regulated insurance market with controls over prices and products towards a subsidiary principle of insurance where governments are free to decide on the appropriate form of regulation depending on the context. The aim has been to give patients more choice of provider and faster access to services.

Coverage of alternative treatments by the statutory healthcare system tends to be excluded. Treatments such as homeopathy and spa treatment are not covered by most statutory healthcare systems in EU countries. Even costs in other areas such as dental care, physiotherapy and pharmaceuticals are only partially covered by the health insurance trusts. Statutory reimbursement of pharmaceuticals tends to be based on a positive list of drugs drawn up by National Medicines Agencies in these countries.

Within the EU, Member States have the right to healthcare for emergency treatment in another member country or an EEA member country. EU nationals can also elect to get treated in another member country for pre-approved procedures or cases of undue delay if they carry a European Health Insurance Card (EHIC), also called the EU Medical Card (which has replaced the earlier E111 form). The EHIC lasts for 3-5 years and entitles its holders to receive free or reduced cost emergency healthcare when visiting European Economic Area (EEA) countries. It authorizes reimbursement by the home country of the patient in such cases. There is also an initiative to

¹ Scottish Parliament (September 19, 2001), p.8.

standardize health cards across member countries by providing an interoperable format that would help a patient prove entitlement to healthcare from different national health services or to medical insurance schemes in Member States. Treatment is also possible in other countries under reciprocal agreements (see Section 5.1).

3.1.3 Integration of IT in healthcare

An important aspect of the healthcare system in EU countries is the role of IT and the extent to which member countries have adopted IT in their healthcare delivery. This has implications for the market potential of cross-border delivery of healthcare services to the EU in segments such as teleradiology, telediagnosics, medical coding, transcriptions, and back-office support functions.

The e-health industry in the EU was estimated at €21 billion in 2006. This includes a wide range of areas, including the ICT infrastructure of organizations belonging to the health delivery system though it does not cover the ICT systems and services of the wellness sector. According to recent estimates, Europe could potentially account for one-third of the global health ICT industry of €50-60 billion, although there are problems of market fragmentation, lack of interoperability across countries in the EU, lack of legal certainty, inadequate financial support, and issues of procurement.

Healthcare IT infrastructure varies widely across EU member countries. The main push for adoption of technology in healthcare delivery comes from ageing populations and rising operational costs coupled with the need to improve service access and quality. The UK spends the most money on health IT at €2.4 billion compared to the EU's total of €8 billion under its 'National Programme for IT' (NPfIT). France and Germany are next with spending of about €1.2 billion each. (The US comparably spends twice as much as Europe on IT for healthcare). In per capita terms, the highest spenders are Sweden (€62), the UK (€43), the Netherlands (€31), and France and Germany (€19 and €17, respectively). Countries that have barely started to modernize their health services (such as Italy and Poland) spend about €10 per person.

The most widely perceived opportunity is the electronic patient record (EPR) and the interoperability between the record-keeping systems of different doctors and hospitals to improve patient safety and cut costs. Member countries have also launched e-health initiatives. However, there are concerns about patient privacy, whether citizens can trust their government and its privacy laws. The UK is in favor of centralized control of patient records to safeguard privacy, whereas other governments such as Sweden, the Netherlands, Germany, and France favor a more decentralized system.

Different countries have different priorities in the adoption of IT and are at different levels of adoption. While cost control and efficiency dominate Sweden's IT strategy, in Germany the consolidation of records across different providers is seen as the main problem to be addressed through IT. Some countries like Sweden have gone farthest in the health informatics area by facilitating the use of IT in information provision and transaction support, including electronic prescriptions and telediagnosics. The German government has launched an IT strategy for various public services including health which proposes a program of coordinated IT investment to bring Germany to the level of its main competitors. This includes issuance of health insurance smartcards on an optional basis, issuance of 300,000 ID cards for health professionals,

electronic trade in medicines, and electronic prescription. Security and telemedicine are other high-priority areas for local IT investment in Germany. But in other EU countries, such as Spain and Poland, there is no coordinated IT strategy for healthcare and the level of spending remains low.

3.2 Structure of the sector

The public segment dominates the healthcare sector in the EU, although the private segment has been growing in recent years due to the gradual privatization of health services in several EU countries. Three-quarters or more of healthcare expenditure is in the public sector, while only a small share of spending, ranging from as low as 15 per cent in the case of the UK to as much as 38 per cent in the case of the Netherlands, occurs in the private segment. The distribution of healthcare expenditures in selected EU member countries is shown in the following table.

Table 3: Share of public health spending in total healthcare expenditure in selected EU countries, 2000-2003

Country	2000		2001		2002		2003	
	Public	Private	Public	Private	Public	Private	Public	Private
EU 25	76	24	77	23	77	23	76	24
Denmark	82	18	83	17	83	17	83	17
Finland	75	25	76	24	76	24	77	23
France	76	24	76	24	76	24	76	24
Germany	79	21	78	22	79	21	78	22
Italy	74	26	76	24	75	25	75	25
Netherlands	63	37	63	37	62	38	62	38
Poland	70	30	72	28	72	28		
Sweden	85	15	85	15	85	15		
UK	85	15	85	15	85	15	85	15

Note: Numbers are percentages.

Source: Yuen, Compendium of Health Statistics 2005-06, Radcliffe Publishers, 2005.

The following table also reflects the relative insignificance of private sector provision of healthcare in the EU. The share of such spending in GDP ranges between 1.3 per cent in the UK to 3.7 per cent in the Netherlands and is generally around 2 per cent of GDP in most EU countries. The share of public healthcare expenditure in GDP is significantly higher at around 6 per cent of GDP. It is also worth noting that there has not been any major shift in the composition of spending over this period, although there is a slight upward trend in private expenditure shares.

Table 4: Private Health Expenditure as % of GDP at Market Prices in selected EU countries, 2000-2003

Country	2000	2001	2002	2003
EU 25	2	2	2.1	2.2
Denmark	1.5	1.5	1.5	1.5
Finland	1.7	1.7	1.7	1.7
France	2.3	2.3	2.3	2.4
Germany	2.3	2.3	2.3	2.4
Italy	2.1	2	2.1	2.1
Netherlands	3.1	3.2	3.5	3.7
Poland	1.7	1.7	1.7	
Sweden	1.3	1.3	1.4	
UK	1.1	1.2	1.2	1.3

Source: Yuen, Compendium of Health Statistics 2005-06, Radcliffe Publishers, 2005.

Three important things can be inferred from the above tables. First, any discussions with the EU in healthcare have to be predominantly with the concerned governments and through negotiations with public health authorities and institutions. Second, one needs to identify markets where there is a gradual shift towards private provision as these markets are likely to be compelled to open up their healthcare systems externally in the near future. Third, given the relatively stagnant share of the private sector in healthcare expenditures, the potential market in the EU may not open up very rapidly and there is likely to be resistance from internal stakeholders.

The following table shows the trends in the UK's healthcare expenditure during 2000-05 and its distribution between the National Health Service (NHS) and private providers.

Table 5: Total healthcare expenditure in the UK, 2000-2005

Year	UK Healthcare Expenditure (£ million)		UK Healthcare Expenditure as % of GDP		
	NHS	Private Healthcare	NHS	Private and Other	Total
2000	57067	4927	6	1.1	7.1
2001	62892	5719	6.3	1.2	7.5
2002	70196	6234	6.7	1.2	7.9
2003	78015	6755	7.1	1.3	8.4
2004	86610	7078	7.5	1.2	8.7
2005	94050	7561	7.7	1.2	9

Source: Yuen, Compendium of Health Statistics 2005-06, Radcliffe Publishers, 2005.

As shown above, the public sector or NHS share has grown while that of the private sector has remained static. More recent data indicate similar numbers and shares for

both segments.² Employment in the NHS has also grown, from 1.2 million in the 1990s to 1.4 million in 2003 indicating the continued importance of the public sector not only as a provider of healthcare but also as an employer.

3.2.1 Public vs. private health insurance

The significance of the public sector is also evident from the important role played by statutory public insurance trusts in financing healthcare expenditures in EU countries. The out-of-pocket and voluntary health insurance market in these countries is quite small. The following table shows the public versus private sources of healthcare funding in France. The trends for other EU countries, such as Denmark, Germany, the Netherlands, and the UK, are similar.

Table 6: Main Sources of Healthcare Funding in France, 2000

	National Current Expenditure (€ million)	% of Total	Healthcare Consumption (€ million)	% of Total
Health Insurance Schemes	102428	72.8	92290	75.5
State and Local Authorities	6110	4.3	1285	1.1
Private	32083	22.8	28623	23.4
- Mutual Associations	11004	7.8	9110	7.5
- Provident Institutions	2569	1.8	2569	2.1
- Commercial Insurers	3372	2.4	3372	2.8
- Households	13610	9.7	13571	11.1
- Other Private	1528	1.1	0	0
Total	140628	100	122197	100

Source: *European Observatory on Health Care Systems (April 2002), Table 3.4, p.39.*

3.3 Key regulations

As healthcare is dominated by the public sector, it is a highly regulated sector. Since health services fall outside the scope of the EU's services directive, the health services market is highly fragmented with different countries having their own sets of regulations, in addition to EU-wide guidelines.

Two areas of regulation are relevant to a discussion of trade and investment in health services in the EU: (a) data protection, data privacy, and information security, and (b) accreditation, registration, and standards. Both regulatory issues are briefly outlined here with further details provided in Section 6 when discussing specific barriers in the

² Smith (2006).

EU.

3.3.1 Data protection

Data protection is an important area of regulation with regard to trade in health services, particularly e-health delivery in the EU. The EU-wide Directive on Data Protection takes a regulatory and comprehensive approach to data privacy. (Precise rules are laid down in the EC Data Protection Directive 95/46/EC and in Directive 2002/58/EC on privacy and electronic communications and in the national laws of the Member States implementing these Directives). These regulations are intended to protect individuals with regard to the processing of personal information and to ensure the free movement of personal information outside the EU via the coordination of national laws. This directive is very broad as it applies to all data processing, on- and off-line, manual and automatic, and all organizations holding personal data. It establishes strict guidelines for processing personal information based on the guidelines for the protection of privacy and trans-border flows of personal data adopted by the OECD.

The EU's data protection law is governed by three directives, namely, the General Directive, the Directive on Privacy and Electronic Communications, and the Directive on Data Retention. Each EU member is required to enact national laws that give effect to these directives. The primary principles on which the General Directive is based include: (1) legitimacy – personal data may only be processed for limited and legitimate purposes; (2) finality – personal data may be collected only for specified, legitimate purposes and may not be further processed for any other purpose; (3) transparency – data subjects must receive information about the processing of their personal data; (4) proportionality – personal data must be relevant and not excessive relative to the purpose for which they are collected and processed; (5) confidentiality and security – technical and organizational measures must be in place to ensure the confidentiality and security of personal data; and (6) control – data protection authorities must enforce data protection laws.

Thus the Directive requires all personal information to be processed fairly and lawfully, such as requiring that the person whose personal information is being collected and used is informed of the proposed uses, or that the use of personal information is limited to the purpose first identified and to other compatible uses. The directive also established rules for legitimate data processing which include obtaining the consent of the data subject before the information is processed and also providing the subject with an opportunity to see the data, correct it, or know who will receive the data when it is being processed. Certain data may be deemed sensitive and is not permitted for processing. Technical and organizational measures are also required to protect the data against destruction, loss, change, or unauthorized disclosure or access. Users of e-health applications are required to ensure that they respect the fundamental rights of the individuals concerned and also comply with the legal obligations for the protection of personal data of patients.

The EU Directive also imposes certain institutional requirements on member countries and companies. It requires companies processing the data to appoint a data controller who must register with government authorities. The data controller must notify the government authorities before processing any data. This notification

includes informing the individual of the purpose of the processing, providing a description of the data subject and of the recipients to whom the data might be disclosed, proposed transfers to third countries, and a description to ensure that basic security requirements have been met. The EU directive on data protection also requires a government authority to oversee data processing activities. Individual EU member countries are required to establish an independent public authority, namely, Data Protection Commissions, to supervise the protection of personal data by investigating and monitoring data processing activities and intervening in these activities where required.

An important aspect of the EU data protection directive pertains to data transfers to countries outside the EU. The Directive requires that Member States enact laws that prohibit the transfer of personal data to countries outside the EU which fail to ensure adequate privacy protection. In such cases, member countries are required to take steps to prevent any data transfer to such a third country. (This issue is discussed in more detail in Section 6.1.1 (a)). The Data Protection Commissions and Member States are required to inform each other in such cases. This approach is different from that of the US which uses a sectoral approach to data privacy that relies on a mix of legislation, regulation, and self-regulation. In order to avoid the complications created by the EU's approach to data privacy, some countries such as the US have entered into a "safe harbor" agreement with the EU. Certification to the safe harbor ensures that EU organizations know that the company engaged in the data processing provides adequate privacy protection as required by the EU Directive. (Appendix A summarizes the key features of the EU's Directive on Data Protection).

3.3.2 Data Privacy

The EU's Privacy Rule establishes regulations for the use and disclosure of Protected Health Information (PHI), which refers to any information about health status, provision of healthcare, or payment for healthcare that can be linked to an individual. This is interpreted rather broadly and includes any part of a patient's medical record or payment history. Covered entities must disclose PHI to the individual within 30 days upon request. They also must disclose PHI when required to do so by law, such as reporting suspected child abuse to state child welfare agencies.

The Security Rule complements the Privacy Rule. While the Privacy Rule pertains to all Protected Health Information (PHI) including paper and electronic, the Security Rule deals specifically with Electronic Protected Health Information (EPHI). It lays out three types of security safeguards required for compliance: administrative, physical, and technical. For each of these types, the Rule identifies various security standards, and for each standard, it names both required and addressable implementation specifications. Required specifications must be adopted and administered as dictated by the Rule. Addressable specifications are more flexible. Individual covered entities can evaluate their situation and determine the best way to implement addressable specifications.

3.3.3 Information security standards

BS7799 is a well-known data security and privacy protocol that is followed by reputed companies engaged in cross-border provision of health services. The BS7799

is based on the premise that electronic commerce implicitly requires business partners to prove to each other that they are adequately secured. The lack of sufficient security countermeasures of an organization may threaten the security of its electronic business partners and vice versa. It is therefore necessary that an organization is evaluated and certified as complying with some international information security standard.

The British standard for Information Security Management (BS7799) –also known as the ISO17799 Standard – is an international code of practice that can be used when an organization wants to provide the necessary proof of adequate information protection; all trading partners are then required to conform to the same standard to ensure mutual trust between business partners.

The aim of the BS7799 standard is to:

- Provide common best practice guidance to organizations to develop, implement and measure information security
- Provide confidence in inter-organizational business
- Outline ten essential key controls which are either legislatively required or are considered fundamental building blocks for information security, namely:
 - Information security policy document
 - Allocation of information security responsibilities, i.e., security organization
 - Information security education and training, i.e., personnel security
 - Reporting of security incidents
 - Virus controls
 - Business continuity planning
 - Control of proprietary software copying
 - Safeguard of organizational records
 - Data protection
 - Compliance with security policy

BS7799 Part 1 serves as a reference framework for information security management and assists companies in developing a strong, structured strategy for information security that is internationally accepted as important. Part 2 of BS7799 provides the requirements specification against which an organization can be assessed for compliance to the control measures stipulated in Part 1. At present, this is the only internationally accepted scheme for formal information security certification. If an accredited and certificated BS7799 auditor successfully evaluates the company's information security management system against the BS7799 Code of Practice, an internationally accepted Certificate of Compliance is issued. Such a certificate is valid for three years.³

³ There are several other international codes of practice for Information Security Management available today, for example the Generally Accepted System Security Principles (GASSP) document, Control Objectives for Information and Related Technologies (COBIT), Guidelines for the Management for Information Technology Security (GMITS) and the Information Security Forum (ISF).

3.3.4 Registration, accreditation, and standards⁴

There are numerous regulations concerning standards and eligibility requirements for healthcare providers (persons and establishments) in the EU. These regulations concern who can provide services, what conditions he/she must fulfill, how the operations must be conducted, their liabilities, and various accountability issues. There are, for instance, registration requirements with concerned regulatory bodies, language certification requirements, insurance coverage requirements, and compliance requirements with EU-wide as well as national-level legislation in areas such as telemedicine, clinical trials and research activities. There are also requirements in some areas to adhere to established EU or international standards.

Health professionals are regulated at the level of Member States and, to some extent, at the EU level to ensure that only properly qualified professionals provide health services. EU legislation has established different systems of recognition of professional qualifications that would enable the migration of high-quality professionals within the region. There are two different regimes for recognition of qualifications:

- The sectoral system, based on common minimum training standards defined in the relevant sectoral directives. The minimum common criteria lead to the automatic recognition of the diploma, without any need for ad hoc evaluations of diplomas that meet the minimum requirements.
- The “general system”, which may require a case-by-case evaluation of the diploma by national authorities with the option to impose compensation measures. Ad hoc evaluation is a key obligation to allow recognition in Member States other than the one in which the diploma was awarded.

Dentists, medical doctors, midwives, nurses, pharmacists and veterinarians are covered by the sectoral system; all other health professionals are covered by the general system. These recognition requirements include competence assessment, certification requirements, specification of minimum training, and other conditions for the medical profession. Appendix B provides further detail on the sectoral and general systems for the recognition of professional qualifications in the EU.

3.4 Challenges facing the EU healthcare sector

The healthcare systems in the EU member countries are facing numerous challenges. In a comprehensive report, the European Observatory on Health pointed out issues facing the healthcare systems such as ageing populations and pressures on healthcare spending, the demography of the medical profession and limited human resources in healthcare, the need to modernize and redesign national health services, the need for improved management of the healthcare system, cost and sustainability of public health expenditures, the role of the private sector, long waiting times, and the need to give patients greater choice. Some countries have initiated reforms by undertaking quality assurance programs, providing guarantees of reduced local waiting times,

⁴ The discussion is based on the following sources: Eur-Lex Directives 2005/36/EC, 93/16/EEC, Healthcare Professionals Crossing Borders Agreement (2005), Polak, G., (2007), Gerlinger, T., and R. Schmucker (2007).

restructuring healthcare delivery, adopting IT strategies, and developing health plans for citizens. Regional agreements and collaboration are also being used to address supply-side constraints.

Cost escalation is evident in various healthcare systems. In the UK, the gross cost of the NHS in per capita terms more than doubled between 1989-94 and 1999-2004, from 23% to 44%. The gross cost of the NHS in real terms rose from 6% of GDP in 2000 to 8% of GDP in 2003.

Problems of access to public healthcare providers are evident from the long waiting times that characterize many of the national health services. For example, waiting lists for diagnostic processes and for treatment emerged as the main problem of the Dutch healthcare system in the late 1990s. In March 2000, there were around 150,000 patients waiting for treatment in general hospitals with more than 92,000 of them waiting longer than one month. In late 2001, this number stood at 185,000 with the largest waiting lists in specialties of orthopedics, general surgery, ophthalmology, and plastic surgery. A 2001 report put the total social costs of the waiting lists at €3.16 billion per year due to loss of welfare, income, productivity, long-term disability, and administrative costs.

Such long waiting lists exist in several other EU countries for consultations as well as treatments. In the UK, 22% of patients waited more than 13 weeks for their first outpatient appointment, 27% of patients waited six months or more for an in-patient admission. Patients wait for the first appointment with a general physician, for the initial consultation with a specialist, for diagnosis, and for treatment. Patients needing heart bypasses may have to wait over a year for treatment, one in four cardiac patients die while waiting, and one in five lung cancer patients wait so long that they become untreatable. Those with painful skin conditions, children needing speech therapy, or elderly patients needing hip replacements may have to wait several years for treatment. The following table shows the waiting time for consultation in selected EU countries

Table 7: Waiting Time for Consultation in Selected EU Countries

N = 6495 Days Waiting for Consultation (%)	Spain	Finland	Portugal	Sweden	Average
0-1 Day	92	39	50	37	57
2-4 Days	8	22	10	9	13
5-8 Days	0	33	15	27	18
> 8 Days	0	6	25	27	13
Patients/Week per Doctor (Average)	154	94	89	90	103
Duration of Consultation (%)					
< 5 Minutes	52	29	30	36	37
5-9 Minutes	24	27	25	27	29
10-14 Minutes	10	29	29	17	22
15 Minutes	3	15	16	20	13

Source: European Observatory on Health Care Systems (April 2002), Table 7.3, p.98.

In part, these waiting lists reflect shortage of healthcare personnel in EU countries. For example, the UK's NHS has faced severe shortages of capacity, with fewer doctors per head than many other EU countries. It has had to import nurses and doctors from the rest of the world. Some EU countries have initiated programs to expand their health workforce along with targets for service improvements.

Although some EU governments have introduced national legislation providing waiting time guarantees for critical illnesses and general waiting time guarantees to improve access to healthcare, and there are initiatives to facilitate intra-EU patient mobility and e-health, the problem still persists. Long waiting times have resulted in increased pressure from patients in several EU countries to access services across borders, and sickness funds in some EU countries have contracted hospitals across borders to alleviate this pressure. In addition, there is demand for unauthorized and non-contracted care in other EU countries.

These challenges facing the healthcare systems in EU member countries create opportunities for healthcare providers in non-EU countries, such as India. There are opportunities in various healthcare segments to alleviate the cost and accessibility pressures in these countries.

4. Overview of the health services sector in India

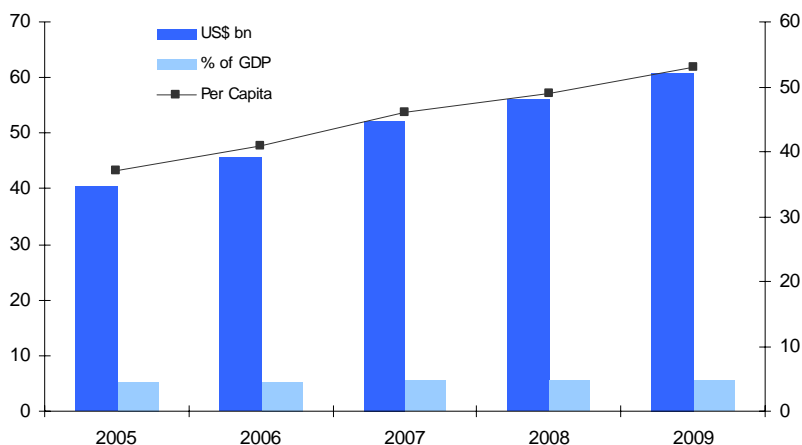
4.1 Trends and developments

The Indian healthcare delivery market is estimated at US\$18.7 billion and employs over four million people, making it one of the largest service sectors in the economy today. Total national healthcare spending reached 5.2% of GDP, or US\$34.9 billion in 2004 and is expected to rise to 5.5% of GDP, or US\$60.9 billion by 2009. The industry has grown at about 13 per cent annually in recent years and is expected to grow at 15 per cent per year over the next four to five years. According to a recent study, the industry will account for 6.1 per cent of GDP by 2012 and is projected to provide employment to around 9 million people.⁵ Per capita expenditure on healthcare is projected to rise from \$32 in 2004 to \$53 by 2009. At present there are more than half a million doctors employed in over 15,000 hospitals and 0.75 million nurses.

Hence, by all estimates, this is a rapidly growing sector with considerable potential. This growth and potential is due to the growing demand for healthcare services in the Indian market, which is driven by rising incomes, a growing propensity to spend on healthcare, a shift to lifestyle-related diseases, and demographics, among other factors. The following graph shows the projected growth in India's healthcare industry over the medium term.

⁵ These statistics are taken from IBEF, available at www.ibef.org.

Figure 1: Indian Healthcare Industry Projections



Source: IBEF (2007)

India's healthcare sector comprises many segments, which include medical care providers (physicians and nurses), medical care establishments (hospitals, clinics, nursing homes), diagnostic service centers and pathology laboratories, medical equipment and device manufacturers, contract research organizations that conduct clinical trials and research, pharmaceutical manufacturers, telemedicine providers, health insurance providers, and health services outsourcing providers.

Estimates and projections are available for some of these segments. The market for hospital services is estimated at over \$4 billion. The clinical trials segment is estimated to reach €740 million by 2010; by 2010, 2 million patients are expected to undergo clinical trials in India, which is about 20 million tests. The healthcare business outsourcing market is projected to grow to €5.4 billion by 2012, with an estimated growth of 11% per year, providing employment to around 200,000 people. The domestic pathology industry is estimated at \$500 million or 2.5% of the overall healthcare delivery market and has been growing at an estimated CAGR of 20% in recent years. There are 40,000 independent pathology laboratories in the country that are largely serviced by small, unorganized players. Other growth segments include the health imaging market, which is expected to double by 2010 from around \$350 million at present, and the hi-tech medical devices market, which is growing rapidly at between 12-15 per cent per year and is likely to be driven by changing disease profiles, clinical needs, and the growth of medical tourism.

4.2 Structure of the sector

A striking feature of India's healthcare system is the significant and growing role of the private sector in healthcare delivery and total healthcare expenditures. Public health expenditure accounts for less than 1 per cent of GDP compared to 3 per cent of GDP for developing countries and 5 per cent for high-income countries. The private healthcare sector in India accounts for over 75 per cent of total healthcare expenditure in the country and is one of the largest in the world. An estimated 60 per cent of hospitals, 75 per cent of dispensaries, and 80 per cent of all qualified doctors are in

the private sector. An estimated 95 per cent of new hospital beds in recent years have come up in the private sector. The growing spending power of the middle-class has been driving growth opportunities for corporate healthcare providers.

By and large, private healthcare delivery is highly fragmented with over 90 per cent of private healthcare being serviced by the unorganized sector according to a recent report.⁶ Some 2 to 3 per cent of hospitals are 200+ beds, some 6-7 per cent are 100-200 beds, and the bulk or 80 per cent of private sector hospitals have fewer than 30 beds.

Studies by the Central Bureau of Health Intelligence show that the majority of Indians trust private healthcare, despite a higher average cost of US\$ 4.3 compared to US\$ 2.7 in government-owned healthcare agencies. Only 23.5% of urban residents and 30.6% of rural residents choose government facilities, reflecting the widespread lack of confidence in the public healthcare system. The private sector's role is expected to grow in the future. It is estimated that out of the 1 million beds to be added by 2012, the private sector will contribute 896,000 beds. Government spending on healthcare infrastructure (excluding land) is projected to rise only marginally, by 0.12 per cent of GDP and is expected to meet only 12 per cent of the huge investment required in the healthcare sector, with the private sector providing some 88 per cent of investment requirements.⁷ Hence, the private sector will be a key player in driving the future growth of India's healthcare sector, including in segments such as hospitals.

4.3 Key regulations

The healthcare sector is both over- and under-regulated in India. Areas of regulation that are pertinent to trade concern standards for medical establishments, accreditation for medical professionals, and foreign direct investment. Regulations in some of these areas are still evolving, but there has been considerable streamlining in recent years to establish and improve standards and ensure governance in various segments of the healthcare sector.

*4.3.1 Medical establishments*⁸

The Ministry of Health & Family Welfare has developed Indian Public Health Standards (IPHS) for certain governmental clinical establishments, viz., Community Health Centres (CHC), Primary Health Centres (PHC) and Sub-Centres, which are implemented through administrative means. A few States and Union Territories have enacted laws for registration and regulation of nursing and clinical establishments, but so far these do not cover laboratories and diagnostic centers. (The shortcomings in India's regulations in this regard are discussed in greater detail in Section 6.2.1).

Standards are currently being evolved for medical establishments. Recently the Clinical Establishments (Registration and Regulation) Bill, 2007 was introduced in the Lok Sabha to fill existing gaps in regulation of medical establishments. Article 2

⁶ Technopak (February 2007).

⁷ Ernst and Young (2007) and IBEF.

⁸ Reproduced from the Report of the High Level Group on Services, Planning Commission, Government of India, New Delhi, March 2008.

of the Bill defines clinical establishments as:

- (i) 'a hospital, maternity home, nursing home, dispensary, clinic, sanatorium or an institution by whatever name called that offers services, facilities with beds requiring diagnosis, treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognized system of medicine established and administered or maintained by any person or body of persons, whether incorporated or not; or
- (ii) a place established as an independent entity or part of an establishment referred to in clause (i), in connection with the diagnosis or treatment of diseases where pathological, bacteriological, genetic, radiological, chemical, biological investigations or other diagnostic or investigative services with the aid of laboratory or other medical equipment, are usually carried on, established and administered or maintained by any person or body of persons, whether incorporated or not'.

The Bill aims at the compulsory registration of all clinical establishments in two stages, provisional at first and permanent thereafter. Clinical establishments are required to comply with the prescribed minimum standards at the time of permanent registration. There will not be any prior inspection of the establishment; however, before permanent registration is granted, the applicants have to submit evidence that they have complied with the standards which would then be displayed to the public for filing objections. Any objections are to be communicated to the clinical establishment for a response. Permanent registration can be granted to the applicant only after it has fulfilled the prescribed standards. Although there is no provision for periodic inspection, the registering authority has been given the power to conduct an inquiry or inspection of the clinical establishment at any time and to issue directions; it is also empowered to cancel the registration if it is satisfied that the conditions of registration are not being fulfilled. Further, it can restrain the clinical establishment from operating if there is imminent danger to the health and safety of patients. Penalties of up to Rs. 5 lakh are provided in case of contravention of the provisions of the Act. There is provision for appeal to the State Government from orders rejecting or canceling registration.

The Bill envisages the establishment of a National Council that has the responsibility of setting the minimum mandatory standards for all clinical establishments. The Bill indicates the functionaries and representatives who would constitute the Council.

*4.3.2 Licensing and accreditation*⁹

Medical professionals are regulated through Central legislation, viz., the Indian Medical Councils Act, the Dentist Act and the Nursing Council Act. These laws provide for the setting up of regulatory councils at the National and State levels. The National Councils prescribe norms and standards of education, while the State Councils deal primarily with registration and enforcement of these standards. There are rules for the registration of medical practitioners and separate regulations for

⁹ Reproduced from the Report of the High Level Group on Services, Planning Commission, Government of India, New Delhi, March 2008.

professional conduct, etiquette and ethics. The latter contain certain recommendatory rules, such as the use of generic names of drugs, but also mandatory rules, such as for the maintenance of medical records of indoor patients for a minimum period of three years and maintenance of a register of certificates issued.

In 2006, an accreditation program was initiated for secondary and tertiary hospitals by the National Accreditation Board for Hospitals & Healthcare Providers (NABH), which is a constituent board of the Quality Council of India. The objective is to improve the quality of healthcare establishments in the country. Accreditation is a voluntary process, involving evaluation of an organization's compliance with pre-established performance standards. The organization is granted accreditation if it is assessed to meet an acceptable level compliance, or it may be given conditional accreditation. NABH has so far granted accreditation to 11 hospitals and 43 are in various stages of evaluation. It has 120 qualified assessors on its panel, comprising senior clinicians, hospital administrators and nursing supervisors, who are assigned the task of carrying out the evaluation.

4.3.3 Foreign investment

Since January 2000, up to 100% FDI is permitted under the automatic route in hospitals in India. Thus no government approval is required as long as the Indian company files with the regional office of the RBI within 30 days of receipt of inward remittances and files the required documents along with Form FC-GPR with that Office within 30 days of issue of shares to the non-resident investors.¹⁰ Foreign investors are also permitted to hold a controlling stake in hospitals. Approval from the Foreign Investment Promotion Board (FIPB) is currently only required for foreign investors with prior technical collaboration, but is allowed up to 100%. Prior to January 2000, FDI in hospitals was permitted under the FIPB route; this meant that the FIPB would consider the investment proposals, take a decision, and thereafter filings would be made by the Indian company with the RBI. Current regulations also permit other forms of capital mobilization which are treated as FDI. For instance, Indian companies can raise foreign currency resources abroad up to 49% through ADRs and GDRs under the automatic route, subject to specified conditions; such investments are also treated as FDI.

4.4 Challenges facing India's healthcare sector

Notwithstanding the sector's rapid growth and potential, India's healthcare sector falls well below international benchmarks for physical infrastructure and manpower, and even falls below the standards existing in comparable developing countries. The total number of doctors (all kinds included) per thousand persons stood at only 1.27 in 2006 and 0.5 physicians per thousand persons in India, compared to a world average of 1.5. The number of nurses per thousand persons stood at 0.9 in 2006 compared to a world average of 1.2. Added to this deficiency is the maldistribution between rural and urban areas and shortages of specialized personnel. These ratios are projected to remain below the existing world averages even in 2016. The current ratio of beds per thousand persons is a mere 1.03 (well below WHO norms) compared to an average ratio of 4.3 for developing countries like China, Korea, and Thailand, and in the best

¹⁰ See RBI note on Foreign Investments in India (April 1, 2007).

of circumstances is projected to reach 1.85 per thousand persons by 2012. It is estimated that over a million beds have to be added to attain this 1.85 ratio, which translates into a total investment of \$78 billion (Rs. 350,830 crore) in health infrastructure. An additional 800,000 physicians are required over the next 10 years, which in turn translates into huge investments in training facilities and equipment. In order to reach even 50-75 per cent of the present levels of other developing countries, the sector will require an estimated investment of \$20-30 billion.¹¹ Thus, India's healthcare sector needs to scale up considerably in terms of the availability and quality of its physical infrastructure as well as human resources so as to meet the growing demand and to compare favorably with international standards.

5. Trade and investment flows in Health Services

As healthcare is not a commercial service sector, existing data sources do not provide information on the extent of trade or investment flows in this sector for either the EU or for India. Bilateral data are also not available to gauge the extent of India-EU relations in this sector. However, the factors that drive the EU's trade in healthcare services with non-member countries and the factors that are likely to facilitate India's trade and investment flows in health services can be deduced from a variety of primary and secondary sources.

5.1 EU's trade in health services

Many factors create opportunities for overseas healthcare providers (professionals and establishments) to service the EU market. Some of these driving forces include advances in information and communication technology that make possible the electronic delivery of healthcare; ageing populations, manpower shortages, rising demand, escalating costs, financing constraints, and long waiting lists for treatment in the EU.

The initiation of healthcare reforms by many EU countries in order to contain operational costs, improve efficiency, and redesign their health and technological infrastructure in order to give their populations greater choice and improved access to healthcare has created export opportunities for third countries like India whose private healthcare providers are increasingly aligning themselves with international standards and guidelines. Some opportunity segments in the EU include telemedicine, clinical trials and research, medical tourism, alternative treatments and therapies, collaborative ventures in research and training, and exchange of health manpower at various levels.

5.2 India's trade in health services

The high growth in India's healthcare sector and the emergence of reputed private players of international standard have created opportunities in trade, investment, and collaboration. According to health industry experts, India has considerable opportunities in many aspects of e-health, including teleradiology, telediagnosics, telepathology, intensive care, ophthalmology, dermatology, psychiatry and, to some extent, in continuous online remote monitoring. India's prospects in cross-border e-

¹¹ See, Ernst and Young (2007) and CRISIL Research (Feb 2007).

health are being driven by its cost advantages where Indian radiologists report salaries that are 70 to 80 per cent lower than those in the US. Moreover, while such work is done by technicians in many countries, in India value is added to such reporting work as doctors and specialized medical staff may be involved in reporting and interpretation work. There is growing interest among foreign players in entering India's medical devices, clinical research and trials, and pharmaceutical segments. Many are entering through joint ventures and through tie-ups in technology, training, and research. Indian players are also interested in exporting health services through various modes of supply, spanning segments such as telemedicine, medical value travel, and deployment of medical professionals to other countries.

Telemedicine is provided to other countries by independent telemedicine providers as well as reputed IT companies such as Wipro which is partnering with Manipal Hospital to combine their IT and network security and protocols capabilities with the core medical competence of reputed hospitals. The Apollo Group in India has begun exporting e-health services; it provides telemedicine services (consultation, diagnostic, telepathology, teleradiology, etc.) from its Apollo Gleneagles Hospital in Kolkata to patients in Bangladesh, Nepal, Bhutan, and Myanmar; it also provides tediagnostic and tele-consultation services from its center in Karaganda Oblastu in Kazakhstan to the Central Asian region; it has also partnered with Health Services America and Medstaff International in the US for billing, documentation of clinical and administrative records, coding of medical processes, and insurance claims processing for Mediclaim policy holders, and third party administrators.¹² India is among the main exporting countries for medical transcriptions. Employment in activities providing Mode 1 health services increased from 30,551 in 2000 to 242,500 in 2005. Outsourcing of pathology services is also emerging as a huge opportunity due to the high cost differential in India; the outsourcing market in the UK in the telepathology area is estimated to be around £450 million.

Some Indian research labs and contract research organizations provide sophisticated tests like molecular diagnostics for autoimmune disorders, cytogenetics and diseases related to abnormalities in chromosomes and hormones. Some laboratories are able to offer a wide test menu of over 1,500 tests under one roof. A partnership between Metropolis Labs and a US-based consortium, for example, secured US\$600 million worth of outsourced work in 2006 from the UK NHS and is aiming for US\$1 billion in 2007.¹³

India is also an attractive market for healthcare business process outsourcing, with potential cost savings of 20-30% for client companies. Apart from regular business processes, Indian companies help convert existing data to HIPAA format.¹⁴ At present, India's telemedicine exports are mainly to the US and Singapore. The client base in the US has expanded from a mere one hospital to 60 hospitals in a few years for leading Indian telemedicine providers. The National Healthcare Group of Singapore has tied up with telemedicine institutions in India to provide teleradiology services to designated hospitals in Singapore. Contracts have been signed with Malaysia and with Dubai.

¹² See <http://www.apollohospdelhi.com/news/html>.

¹³ Burrill Quarterly India Life Sciences, Volume 3 Number 1 – January 2007.

¹⁴ Health Insurance Portability and Accountability Act.

India also has promising prospects in the area of medical value travel. The medical tourism market in India was estimated at \$333 million in 2004 and is projected to reach \$2.2 billion by 2012.¹⁵ Most of the patients are from the SAARC region, the Middle East, and Africa, though there is potential for patients from the West. Private sector initiatives by corporate hospitals in India have been important in this regard. For instance, corporate hospital groups such as Apollo Hospitals, Fortis Healthcare and Wockhardt have partnered with international insurance and tourism companies, and hospitals and practitioners abroad. These prospects are driven by India's cost advantages, availability of world-class hospitals, and push factors in client markets. The cost of comparable treatment in India is on average one-eighth to one-fifth of those in the West. The following table shows the cost comparison between India and a competing exporting country, Thailand, as well as two important source countries for medical value travel, the US and the UK, to highlight this cost advantage.¹⁶

Table 8: Costs of selected procedures in India and other countries

Procedure	India	Thailand	US	UK
Heart bypass graft surgery	6,000	7,894	23,938	19,700
Heart valve replacement	8,000	10,000	2,00,000	90,000
Angioplasty	11,000	13,000	31,000–70,000	---
Hip replacement	9,000	12,000	22,000-53000	---
Hysterectomy	---	10,000	---	---
Bone marrow transplant	30,000	----	2,50,000-4,00,000	150,000
Liver transplant	40,000-69,000	----	3,00,000-5,00,000	200,000
Neurosurgery	800	----	29,000	
Knee surgery	2,000-4,500	8,000	16,000-20,000	12,000
Cosmetic surgery	2,000	3,500	20,000	10,000

Note: All figures are in US\$.

Source: Burrill India Life Sciences Quarterly-January 2007, Arunanondchai and Fink (December 2005), CUTS (2007), and various web sources.

There is also scope for India to export healthcare workers such as nurses and technicians on a temporary basis and through institutional tie-ups with overseas establishments given its cost advantage and manpower availability.¹⁷ The following

¹⁵ Clearstate (2007).

¹⁶ India's medical tourism exports, however, remain constrained by the lack of insurance portability and lack of accreditation of healthcare providers by overseas health insurance trusts or private insurance companies.

¹⁷ However, once again, there are barriers in the form of licensing and certification requirements, immigration restrictions, and cultural and social sensitivities.

two tables highlight India's importance as a source country for healthcare workers for selected host nations.

Table 9: Major nations providing physicians to the US, UK, Canada and Australia in 2004

Source country	% of US physician workforce	% of UK physician workforce	% of Canadian physician workforce	% of Australian physician workforce	Total no. from source country
USA	-	0	0.8	0	519
UK	0.4	-	4.0	8.6	10,838
Canada	1.1	0	-	0	8,990
Australia	0	0.5	0.4	-	1,119
India	4.9	4.9	2.1	4.0	59,523
Philippines	2.1	0	0.4	0.3	18,291
Pakistan	1.2	2.1	0.5	0.2	12,713
South Africa	0	1.2	2.0	2.3	4,987
Ireland	0	3.0	1.7	0.8	4,433

Source: Mullan (February 4, 2005). USA based on ECFMG, AMA (2004); UK based on NHS (adjusted); Canada based on Canadian Institute for Health Information, CAPER (2002); Australia based on Australian Institute of Health and Welfare, 1999 (adjusted).

Table 10: Top Five Countries for Nurse Applicants to the UK (based on new Work Permits), 2002

Country	No. of Work Permits Issued
Philippines	10,424
India	3,392
South Africa	2,835
Zimbabwe	2,346
Nigeria	1,501
Total	25,602

Source: Dovlo (September 2003), Table 5, p.9.

The clinical research and trials segment has grown significantly since the introduction of TRIPs¹⁸ in India and is estimated at around \$300 million today with projected revenues of \$1-2 billion by 2010 (though this is still small relative to the size of the overall global clinical trials industry estimated at around \$30 billion).¹⁹ Clinical trials

¹⁸ Trade Related Aspects of Intellectual Property Rights

¹⁹ Till 2005, clinical trials were not really happening in India. With the introduction of TRIPs, with Indian companies wanting to market generics overseas following the expiry of patents, some

and research are mainly conducted by Contract Research Organizations (CROs) and some of the major Indian pharmaceutical companies. Pharmaceutical companies from the developed countries have offices in India, whose clinical research and medical departments route such work to the CRO. Many foreign companies do bioequivalence studies in India where the Indian CRO is engaged to find equivalence of a molecule to a molecule that is already approved elsewhere. The business is mainly with the US at present. Healthcare providers such as Manipal have set up centers in specific areas such as stem cell research and clinical applications and also set up CROs (such as Acunova) to conduct clinical trials.²⁰ These companies have received approval from authorities of foreign governments (e.g., Malaysia) to conduct clinical trials, including fast-track clinical trials.

Given the growing demand, the emergence of reputed private players, and the huge investment needs in the healthcare sector, there has been growing interest in recent years among foreign players and non-resident Indians in entering the Indian healthcare market. In addition, domestic and international financial institutions, private equity funds, venture capitalists, and banks have begun to explore investment opportunities across a wide range of segments (drugs and pharmaceuticals, medical devices, hospitals, etc.). In the hospitals and medical devices segment alone, there are reportedly at least 20 international players competing for a share of the Indian healthcare market. These players enter mainly through joint ventures with Indian companies or through technology and training collaborations. Some examples include Singapore's Pacific Healthcare which has opened an international medical centre in Hyderabad in a joint venture with India's Vitae Healthcare; Singapore-based Parkway Group Healthcare PTE Ltd which has entered through a joint venture with the Apollo Group to set up the Apollo Gleneagles hospital in Kolkata; the Columbia Asia Group which has started its first US-style medical centre in Bangalore; and research, training, and other forms of collaboration between hospitals in India and abroad.

There is a high degree of involvement by foreign players in the hi-tech medical devices segment, accounting for \$770 million; 90 per cent of the demand in this segment is met by imports from the US, Japan, and Germany. Some foreign companies conduct the first 550 surgeries in India after the approval of a medical device or surgical treatment by the US FDA. In the health insurance segment, the FDI limit has been relaxed, resulting in growing health insurance premiums and joint ventures by leading global health insurance players.

5.3 India-EU relations in health services: Status and prospects

There is no bilateral trade and investment data to determine the extent of current engagement between India and the EU in health services. Discussions with

companies in India entered into drug discovery, safety and toxicology studies, and clinical trials. For generic products to be marketed overseas, a certain number of clinical trials need to be done. This is being done today by many Indian CROs. These drugs are then marketed in the US, Europe, Japan, Australia, South Africa, Brazil, and other countries. From an initial focus on generics, the industry has now moved to bioequivalence studies for registration in the US and Europe and to conducting trials for new chemical entities.

²⁰ Acunova supports the conduct of clinical studies for other companies and undertakes such studies and trials in India. It does dose finding, tolerance, and efficacy studies across Phase IB to Phase IV trials. It may also do additional work such as data management, data review, and answering queries.

stakeholders in India's healthcare industry indicate that bilateral commercial and other relations in this sector are limited at present. Several factors explain the limited relationship, including cultural, linguistic, social, and perception barriers, infrastructural constraints, and regulatory norms and conditions in both the EU and India (discussed in Sections 6.1 and 6.2 of this paper). Moreover, the health services sector differs from other services in that it falls outside the scope of the EU services directive and is thus not a single market in the EU. It is also currently in a state of flux within the EU, with member countries experimenting with cross-border cooperation amongst themselves and debating a wide range of issues concerning regulatory coordination, harmonization, consumer choice, safety, and national interest. Thus the health services sector poses special challenges due to its public good nature and its special status within the EU, which makes it difficult for a third country like India to look at the EU as a single export market.

However, discussions with stakeholders as well as information available from secondary sources indicate areas where India can expand its engagement with the EU. The six main opportunity segments are:

1. Telemedicine with particular stress on teleradiology and more generally the integration of IT with healthcare delivery (bioinformatics, continual monitoring, teliagnostics, etc.)
2. Conducting clinical trials and clinical research in India for EU-based pharmaceutical companies and CROs
3. Medical transcriptions, revenue cycle management, and other back-office support functions in health services
4. Medical tourism especially in elected and out-of-pocket expenditure cases and for alternative therapies and treatments
5. Temporary staffing by Indian health personnel, especially nurses, under establishment-establishment arrangements and through government-level agreements
6. Collaborative ventures between universities, hospitals, and research centers in medical education, research, training, and product development.

Among the identified opportunity segments, there is greater optimism about export prospects in areas that are non-intrusive and those with minimal patient contact and interface, i.e., the telemedicine, clinical trials and research, and back-office segments. There are mixed views about exploiting the medical value travel market in the EU given perception and regulatory issues and the predominance of the public sector in EU's healthcare delivery (discussed in Section 6.1.3). There is some scope for medical staffing and cross-border mobility of Indian health personnel, especially in the UK, but EU-wide prospects are perceived to be limited due to social, political, and regulatory challenges.

The markets of interest vary depending on the segment in question, with language- and culture-dependent segments being largely confined to the UK. The UK is the common market across all these opportunity areas. In the telemedicine area, the UK, in particular, the National Health Service is identified as the main client market for telemedicine exports from India. Clinical trials and clinical research are perceived to be among the most promising areas for commercial and collaborative work with the EU; Germany and the Scandinavian countries are seen as prospective markets, either

due to their pharmaceutical base or their inclination towards R&D and their acknowledgment of Indian expertise. In the area of personnel staffing and exchange, the UK (particularly the NHS) is identified as the main market, though some potential is also perceived in the more English language-inclined countries of Scandinavia, Germany, and the Netherlands. In medical tourism, apart from the UK, countries such as Germany, France, and the Scandinavian countries are also perceived to be potential client markets given their inclination towards rehabilitative and alternative treatments and tourist interest in India.

Several Trade Commissions from EU member countries, including the Dutch and Danish High Commissions, have shown interest in expanding telemedicine from India to their countries and could provide a platform for pushing these opportunities with their respective governments. Given the shortage of qualified persons in the EU and e-health initiatives under consideration in the EU, there are opportunities for outsourcing telemedicine services to countries like India.

1. **Telemedicine.** Some Indian companies are setting up a commercial presence and partnerships to enter the EU market for telemedicine since direct outsourcing of such work outside the EU membership is not allowed at present (discussed in Section 6.1.1(a)). Teleradiology Solutions has incorporated a subsidiary in the EU called Teleradiology Europe, which has a US-trained Dutch radiologist who is reading from the Netherlands for hospitals in the US. The subsidiary can also undertake work within the EU by bidding for contracts in the EU since it is not subject to the outsourcing restrictions on patient data as long as the work is delivered from its local company in the EU. Thus, commercial presence in the EU is one way in which telemedicine providers can access the EU market. In anticipation of future changes in data protection legislation enabling outsourcing of such work to India, Teleradiology Solutions is trying to gain a first-mover advantage in the EU market through its EU-based subsidiary and is meanwhile also investing in a separate segment at its Bangalore office to cater to business in the EU. Manipal Health Services is similarly using its overseas presence in the UK to tap the emerging business in telemedicine; it has got a subcontract from the private consortium of bidders that have an NHS contract for radiology reporting within the UK. This work is being done in collaboration with a UK-based company called 4 Ways Healthcare. The consortium takes care of the physical aspects of the delivery while Manipal, through a local delivery center that it has set up in the UK, does the reporting work. It sends its radiologists on a rotational basis to staff this UK office.
2. **Clinical research and trials.** Companies in India, such as Biocon and Clinigene, are doing clinical trials for European pharmaceutical companies.²¹ Some Indian Contract Research Organizations (CROs) have set up marketing offices in other countries, including in the EU, while others are acquiring companies in the EU and elsewhere to build their image and credibility. Business with Europe is, however, very small; whereas Eastern European countries are doing \$3 billion in

²¹ Clinigene is a subsidiary of Biocon and does clinical trials. It started by doing work for Biocon and clinical trials for registration of drugs and then moved on to do work for MNC pharma companies primarily based out of the US. It is now extending its services to other clients with such work now accounting for around 60 per cent of its business. It has some clients from Europe.

clinical trials for Europe, India is doing only \$100 million worth of business. Some Indian CROs are, however, holding discussions with companies in Europe, mainly from the UK, Germany, and Italy. Sweden, Denmark, Germany, and Finland have inquired about conducting clinical research and trials in India for a faster turnaround. Some areas of interest are Phase I and II studies on diabetes, oncology, neuropsychiatry, gastroenterology, and stem cell research. There are also ongoing discussions with European biopharma companies for proof of concept for new drugs. The breakup of India's engagement with the EU in this area is not available but the countries with the strongest pharmaceutical sectors, namely the UK and Germany, are seen to be the most important markets for India within the EU; the UK constitutes half the clinical trials market in Europe, followed by Germany. There is scope for research in experimental therapies for clinical trials that could be conducted by Indian companies or research centers in collaboration with European institutions and universities. There is also potential for partnerships between Indian and EU laboratories to get international certification for evaluation and testing.

In the developed world, drug development is expensive as the patient pool is limited and the recruitment rate is slow. Several factors make India an ideal market for conducting clinical trials and research and explain the enormous potential for doing such work for the EU. India is cost-effective for doing clinical trials given its huge population, diverse genetic pool, wide range of diseases, drug-naïve population, trained medical and technical manpower, and good hospitals where such trials can be undertaken. As drug development is highly capital-intensive and the R&D costs of MNCs for developing drugs and bringing them to the market have increased significantly, delays in clinical trials can be very expensive for a pharmaceutical company. Indian CROs can help pharmaceutical companies lower their costs and reduce the time to market drugs. It was noted that while the US is mainly outsourcing clinical trials to India because of its large market, the main motivation for European companies is to reduce their own costs.

3. **Health Tourism.** Health tourism into India from the EU is mostly limited to out-of-pocket patients at present. However, there are some potential markets in the EU to which India could expand its exports in the medical value travel segment. These include the UK, given colonial, linguistic, and social ties, and some countries in Eastern Europe, such as Poland, which are facing challenges in their healthcare system following their transition from socialism. According to a survey conducted by the Treatment Abroad website, in 2007 over 70,000 British citizens traveled abroad for medical treatment, with India being the destination of choice.²²

Indian providers perceive Eastern Europe as a good market for establishing commercial presence or for tie-ups between institutions given the region's lower costs and need for affordable healthcare, its shortage of quality medical infrastructure, the exodus of medical personnel from Eastern Europe to Western Europe following accession, and their possible affinity to India (due to good political relations in the past). There is also some potential in the alternative medicine area, given growing interest in the West for treatment of chronic

²² Business Standard,, March 4, 2008, p.16.

disorders where allopathy fails to deliver. India has the potential to provide various streams of alternative medicine, including panchkarma, ayurveda, unani, siddha, and homeopathy.

4. **Back-office processing.** Another segment where India could export health services to the EU is in back-office business process and support services. Although such work is at present being done for the US market, Indian health industry experts see scope for doing high-end, back-office work in healthcare for the EU market. Specific activities include revenue cycle management, which involves taking patient bills and records for processing reimbursements from insurance companies; such work involves specialized expertise and can be done for hospitals and physicians. Germany has recently expressed an interest in outsourcing medical transcription as well as other IT-enabled services to India to overcome its high costs and labor shortages in healthcare.

Another segment is medical coding and analysis of patient charts. For example, companies are examining procedures and assigning codes to these procedures for later analysis to ease reimbursement by insurance companies. Such coding work can be offered to the EU for data analysis and diagnostic purposes. There is an European Procedural Terminology that Indian companies can use for such coding work. This work could also be done using the data from clinical trials.

5. **Staffing.** Given the shortage of personnel in most EU countries, particularly in areas like nursing, there is scope for India to export medical personnel on a temporary basis to staff the national health systems of those countries. The main potential is in the UK and the key areas of staffing are nursing and paramedics. Medical management services is another area where India is seen as having the inherent technical capabilities to serve the EU market.
6. **Collaboration.** There is a lot of scope for collaboration on various fronts between India and the EU in the healthcare sector (services and products). Potential areas include medical education and training, staffing and exchange of personnel, and research and product development. The earlier discussion of opportunities in clinical trials and research or telemedicine is also illustrative of segments where there is scope for collaboration and tie-ups between Indian and EU -based institutions.

While the EU has shown little interest in setting up medical education campuses in India, there are possibilities for collaboration through technical tie-ups, dual degrees, and twinning programs, which could be combined with a period of deployment and practical training in the EU following coursework. Since the EU has excellent hospitals with trained personnel and established processes in subspecialty care, collaboration in post-graduate training would help raise Indian standards while also addressing labor shortages in those countries. The Danish authorities have expressed some interest in such collaboration. In addition, EU companies that are engaged in healthcare delivery, for example the delivery of medical equipment and devices, could be part of this academic-cum-commercial relationship to impart training. However, language and lack of mutual recognition remain critical barriers to expanding such collaborative efforts

There is also scope to collaborate in knowledge process outsourcing of specialized and technical services for the healthcare industry, such as the design and production of medical devices and the testing of medical equipment; this would be facilitated by the emergence of corporate hospitals in India and the entry of foreign players in these segments.²³ Companies such as Siemens and Philips, which are engaged in the development and production of medical equipment, are looking at India for research, design, and prototype testing, both as a global delivery center and as a market for such products. There are, however, constraints in the form of ethical regulations, liability and compensation-related concerns, and lack of international standards for registration of medical devices and technologies in India.

6. Trade and Investment Barriers affecting India-EU Relations in Health Services

Indian healthcare providers, both establishments and personnel, face several barriers in doing business with the EU. The first part of this section deals with barriers in the EU due to regulations in EU Member States or at the EU-wide level; the second part describes barriers associated with regulatory and institutional frameworks in India.

The discussion is based on interviews with practitioners in the healthcare sector (including doctors, researchers, radiologists, and biotechnologists), senior management at leading Indian hospitals, and industry experts, based in Bangalore, Delhi, Kolkata, Mumbai, and the UK, and corroborated by information from secondary sources. The interviews were held during December 2007- January 2008 and were conducted in person and over the phone. The aim of these discussions was to understand the work being done by Indian healthcare providers for EU-based clients, the emerging opportunities realized or perceived in the EU region, and the main barriers to doing business with the EU in the healthcare sector. To validate these views and to get alternate perspectives, views were also solicited from industry association representatives, economic counselors of the German and French embassies in New Delhi and experts at the British High Commission and the European Commission. A total of 26 interviews were conducted. The companies and institutions that were interviewed and the number of persons with whom discussions were held are given below.

- Acunova (1)
- Apollo Gleneagles (1)
- Clin Tech International Pvt. Ltd. (1)
- Clinigene International Ltd. (a division of BIOCON) (2)
- Columbia Asia (1)
- FICCI (1)
- Fortis (2)
- Fortis Clinical Research Ltd. (2)
- Healthcare Magic (1)
- Institute of Clinical Research (ICRI) (1)

²³ Overseas companies are looking at corporate hospitals such as Escorts and Fortis to provide such tests.

- Manipal Health Systems (1)
- Medical Systems, Philips Electronics India Ltd. (1)
- Omega Health and Management Services (1)
- Stempeutics Research Pvt. Ltd. (2)
- Teleradiology Solutions Pvt. Ltd. (2)
- Wipro Health Science (1)
- Legal expert in the UK (1)
- British High Commission (2)
- German Embassy in India (1)
- French Embassy in India (1)

Most respondents emphasized three points that have a bearing on barriers in the EU and in India that affect bilateral relations in health services.

First, European markets are not well understood; within the EU and Indian providers only have an understanding of the UK's NHS. There is only generic knowledge about the healthcare sector in other EU countries, and that too only in terms of awareness about existing shortages of personnel and waiting times. Since each EU country has its own complex and evolved healthcare system, this lack of awareness automatically constrains the scope for providing healthcare services to the EU market.

Second, linguistic, social, and cultural barriers constrain India's potential for delivering healthcare services to the EU. Healthcare is a highly personalized service where perceptions, attitudes, and social and linguistic affinity play an important role. Thus, India's prospects are mainly limited to the UK market and a few EU countries that have English-speaking capabilities and are more progressively inclined on the cultural and social front.

Third, the existing barriers to India's exports of health services to the EU are not really barriers but regulations that would be justified in any country to ensure safety, quality, consumer protection, etc. Thus, the onus is on India to adopt a variety of regulatory measures, introduce reforms, and align its own standards and regulations to international ones so as to leverage its capabilities in the health sector in the EU or for that matter in any other developed region. Thus, often the constraints are not due to external regulations but the lack of domestic regulatory frameworks or lack of enforcement of necessary regulations in this sector, and at times with the operational and administrative aspects of the regulations in the EU countries than the regulations per se.

6.1 Barriers in the EU

The previous section identified six major opportunity segments for India with regard to the EU market: telemedicine, clinical trials and research, healthcare, business process outsourcing, medical tourism, exchange and movement of personnel, and collaboration in education, research, and training. Associated with each of these opportunity areas are several regulatory and other barriers. These are: (1) restrictions on outsourcing certain kinds of health services to providers outside the EU territory; (2) data protection and data exclusivity issues; (3) accreditation and certification requirements for healthcare establishments and compliance issues with international

or EU standards and guidelines; (4) insurance portability restrictions and coverage issues; (5) recognition of professional qualifications and registration requirements; and (6) immigration and visa regulations affecting mobility of providers. Many of these barriers are inter-related. Below, the barriers affecting each of the six identified segments of opportunity are summarized (with additional details provided where required in the Appendices).

Many of these regulations cannot be perceived as barriers as they are warranted on the grounds of consumer protection, safety, and national interest. Hence, whether or not these act as market access barriers has more to do with the way in which some of these are implemented administratively, as in the case of recognition issues, or with the underlying justification for certain regulations not being in line with ground realities, as in the case of restrictions on outsourcing or data security issues. There are also national treatment barriers, where Indian health providers are not on a level playing field with EU-based providers, which undermines market access for India vis-a-vis competitor countries within the EU, particularly in Eastern Europe.

(1) Telemedicine

There are four constraints in doing telemedicine for the EU: data protection regulations, recognition of provider qualifications, contractual issues, and perception issues regarding India as a healthcare provider. The key aspects of these barriers and how they affect telemedicine exports from India to the EU are highlighted in the table below (for specific details, see Appendix C).

Table 11: Barriers affecting Telemedicine between India and the EU

Problem	Features and Implications
Data protection, privacy, and information security issues ²⁴	<ul style="list-style-type: none"> • Bureaucratic EU data protection laws • Cumbersome database registration requirement with data protection authorities • Lack of harmonization in data protection legislation among members • Data on EU patients cannot be sent outside the EU unless legal basis for transfer, i.e., official adequacy finding to determine country has national laws to provide adequate level of data protection • India has not received adequacy determination from EU authorities, so needs to legalize data transfer • Imposes additional compliance costs of security audits, fines, registration, contracts with client companies • Overcoming constraint by setting up commercial presence in EU and doing telemedicine from within

²⁴ Much of the discussion in this part is based on “Data Protection Law in the European Union”, Elizabeth Johnson, The Federal Lawyer, September 2007, pp.44-48. See Appendix A for a summary of the selected features of the EU Directive on Data Protection and highlights the most restrictive features.

Problem	Features and Implications
	EU
Recognition and accreditation requirements	<ul style="list-style-type: none"> • Very expensive and time-consuming certification process • Multiple levels of verification • Stringent certification requirements for teleradiology companies and providers • Registration required with each country's healthcare commission and concerned authorities • Compliance with EU directives on data protection, consumer safety, etc. • Indemnity/insurance requirement • Cumbersome evaluation and documentation requirements • Competence determination tests • Language requirements • Residency requirements • Requirement to appear in person for registration • Recertification, revalidation, relicensure, regular appraisal requirements • Lack of harmonization within EU • Implicit discrimination against non-EU providers
Contractual issues	<ul style="list-style-type: none"> • Practical problems with malpractice insurance and liability policies in EU countries • Handling of breach of contract and jurisdictional issues in enforcing compliance • Costs imposed due to service line agreement clauses on prior consent, indemnity, non-disclosure, liability • Delays in executing contracts
Perception, attitudes, and stakeholder resistance	<ul style="list-style-type: none"> • Resistance to electronic delivery of healthcare in EU • Cultural and social barriers • Linguistic barriers, translation requirements for reports • Resistance from professional associations in EU due to concerns over employment losses

Source: Based on interviews.

(2) Clinical trials and research

The constraints on outsourcing clinical trials and research work from the EU to India pertain to the rigor and standards of trials and analyses, data protection, accreditation

and certification of laboratories and organizations conducting the trials, and contractual obligations. There are also issues of perception regarding India as a destination for clinical trials and research. As in the case of telemedicine, there is a lack of awareness in Europe about India’s capability as a destination for clinical trials and research; India has not been marketed sufficiently in Europe in this segment as the focus has been on the US. Many of these regulations are perceived as necessary and not as barriers per se. In fact, the onus lies on India in addressing some of these concerns (as discussed in Section 9 of this paper on domestic reforms). The following table summarizes the main constraints affecting clinical trials and research by India for EU countries (while further details are provided in Appendix D).

Table 12: Constraints affecting clinical trials and research

Problem	Features and Implications
Standards and Accreditation	<ul style="list-style-type: none"> • Requirement to conform with client country guidelines often cumbersome • Accreditation of Indian labs required even if they conform to accepted global standards • Compliance costs of meeting documentation, audit, infrastructure, qualification, training requirements
Norms for clinical trials	<ul style="list-style-type: none"> • Stringent requirements for informed consent, transparency, adherence to prescribed norms
Data Protection	<ul style="list-style-type: none"> • India not perceived as data-secure • Data exclusivity contracts have to be signed • Detailed audits required • Costs of litigation
Manpower mobility	<ul style="list-style-type: none"> • Problems in getting visas for technical persons sent by Indian CROs to clients in EU-- short duration, single entry

Source: Based on interviews

(3) Medical Value Travel and Alternative Therapies/Treatments

Although there is scope for medical tourism by India, several factors limit the potential for medical value travel from the EU to India. These mainly pertain to the lack of insurance portability from the EU to India, which in turn is due to a variety of reasons such as:

- (i) Restrictions on reimbursement of patients from the EU if travel to the exporting country exceeds a certain duration, effectively negating the possibility of India as a medical destination;
- (ii) The relatively low share of non-insured and out-of-pocket paying patients in the EU that automatically limits the pool of patients who would opt for treatment in India;
- (iii) The dominance of the public sector as a provider of insurance which creates problems of political acceptability in allowing medical value travel to India and getting reimbursed by the national health insurance trusts in EU

- countries;
- (iv) The lack of accreditation of Indian hospitals and the lack of recognition of Indian medical qualifications which affect the scope for reimbursement for treatment in India.

In addition, there are linguistic, cultural, and social barriers as well as perceptions regarding India as a healthcare provider. Given that health is a perception-based sector and medical value travel involves a close interface between the doctor and the patient, attitudinal factors and India’s lack of credibility as a medical tourist destination will constrain the extent of trade under this mode between India and the EU. These issues fall under several categories, namely, insurance portability, competition from within the EU, perception, and standards and quality of healthcare within India. Each of these issues is summarized in the table below (while further details are provided in Appendix E and issues internal to India are discussed later in Section 6.2 on barriers in India).

Table 13: Constraints to India’s Medical Value Travel Exports to the EU

Problem	Features and Implications
Insurance portability regulations	<ul style="list-style-type: none"> • State insurance trusts and private insurance companies do not accept treatment in India for reimbursement • Flight time restrictions for UK patients (limited to 3 hours) for reimbursement from NHS • Restrictions on reimbursement of alternative medicines and therapies for lack of scientific evidence and registration
Growing competition	India at disadvantage relative to Eastern European countries on qualification, e-health delivery, movement of persons, insurance portability
Perceptions	<ul style="list-style-type: none"> • Nationally sensitive issue, resistance to medical value travel by national health providers • Cultural, social, linguistic perceptions about India • Perceptions about India as a suitable destination for medical value travel

Source: Based on interviews

(4) Back-office Support Functions

While India can provide the EU with various support services in the healthcare sector, including revenue cycle management, medical coding, and analysis, there are three main constraints to tapping the EU market: accreditation and certification, the limited scope of the market in the EU, and data privacy and restrictions on international data transfer. These constraints are summarized in the following table (while further details are provided in Appendix F).

Table 14: Constrains on India’s provision of support services in healthcare to the EU

Problem	Features and Implications
Accreditation	<ul style="list-style-type: none"> • Certification required by concerned regulatory bodies in various segments (medical coding, analysis) • Additional requirements of continuing certification and evaluation
Limited scope of the EU	<ul style="list-style-type: none"> • Resistance to outsourcing of back-office functions in the EU
Data privacy and restrictions on international data transfer	<ul style="list-style-type: none"> • India is not empaneled as data-secure by EU authorities • Restricts scope for data transfer and related outsourcing • Compliance costs of meeting EU and individual countries’ data protection legislation

Source: Based on interviews.

(5) Collaboration in education, training, research, and staffing

While there is scope for collaboration with the EU on various fronts within the health services sector, it is also felt that the EU has not been open to collaboration with India. The following table highlights constraints affecting specific areas for collaboration, such as in staffing, research, and medical device testing (further details are provided in Appendix G).

Table 15: Constraints to collaboration in healthcare between India and the EU

Problem	Features and Implications
Political and social sensitivities	Affect staffing and temporary movement of health personnel from India to EU countries
Recognition of qualifications	<ul style="list-style-type: none"> • Qualifications and experience of Indian health personnel not recognized in EU member countries • Re-certification and registration requirements impose additional costs on Indian doctors
Other regulatory issues	Regulatory differences between India and the EU on ethics, liability, and production and testing

Source: Based on interviews.

6.2 Summing up the constraints

Clearly, the most significant barriers relate to accreditation and standards, data protection regulations, consumer protection and safety norms, and detailed specifications for compliance with internationally accepted or EU member country specific norms. It is also evident that Indian healthcare providers not only need to be compliant with EU-level directives but also with country-specific regulations, which

complicates the provision of healthcare to the EU. Furthermore, it is not clear to what extent acceptance in one EU member country translates into acceptance in other member countries. There are eligibility issues at the establishment level and at the individual provider level, which can complicate the certification and registration process with EU authorities. It is also worth noting that there are requirements for registration and certification with multiple institutions and regulatory authorities, including healthcare commissions, local agencies, and specialist registers. Adding to these constraints are social, linguistic, cultural, and perception factors which are very important in health services which is human resource-intensive and involves close customer-service provider relations, trust, and quality assurance.

6.3 Barriers in India

Several internal constraints affect India’s trade in health services with the EU. These constraints mostly relate to standards and accreditation, and inadequacies in India’s legal and regulatory framework for health services. The following table summarizes the main constraints within India which affect its ability to export health services to the EU. Further details on each of these domestic issues are provided in Appendix H.

Table 16: Domestic Constraints in India’s Health Services Exports to the EU

Constraint	Features and Implications
Accreditation and standards	<ul style="list-style-type: none"> • Absence of mutual recognition agreements with key markets, requiring Indian providers to undergo cumbersome certification and registration processes • Lack of recognition prevents Indian companies from drawing on overseas pool of medical manpower • Lack of standardization in medical and nursing training in India • No regulatory body in some areas (paramedics) • Authentication systems not perceived to be credible • Lack of international accreditation by most Indian healthcare establishments, preventing medical value travel, insurance portability, clinical trials outsourcing • Lack of registration, standardization and overseas recognition of alternative medicines and therapies • Lack of central laboratory accreditation that is recognized internationally (CAP)
Legal and regulatory framework	<ul style="list-style-type: none"> • Bureaucracy and delays in approval process for clinical trials • Delays in clearance for drug and sample shipments for testing • Multiple clearances required by CROs for undertaking clinical trials (from multiple Ministries) • Ethics approval process cumbersome as multiple committees involved • Absence of legislation in certain areas (movement of drugs within India, lack of procedural controls on use of medical devices)

Constraint	Features and Implications
	<ul style="list-style-type: none"> • Poor enforcement of registration for clinical trials • Slow regulatory clearances for bioequivalence studies • Lack of clarity in guidelines for biotechnology products • Jurisdictional issues about dispute resolution as lack of credible and efficient legal system in India • Gaps between India's clinical trials legislation and that of EU countries (e.g., requirement for pharmaceutical person for issuing drugs in the EU, not in India) • Concerns over violation of ethics by Indian CROs
Data protection	<ul style="list-style-type: none"> • Concerns over possible breach of data confidentiality after data submission to Indian regulatory body • Lack of strict firewalls for data leakage, guidelines on data exclusivity lacking, not strictly enforced
Insurance and litigation	<ul style="list-style-type: none"> • Lack of insurance portability, public or private from EU (related to lack of recognition of Indian qualifications and establishments) • Malpractice liability issues: concerns over dispute resolution, jurisdiction, appropriate compensation • Absence of insurance in India in emerging areas: clinical trials requiring insurance abroad at high cost
Other	<ul style="list-style-type: none"> • VAT and service tax charged on services of consultants monitoring clinical trials and reporting to client (export-oriented services usually exempt from service tax) • Delays in getting multiple entry visas for consultants monitoring clinical trials, short duration visas typical • Delays in bringing certain medical devices into India affecting medical device testing, research-related outsourcing

Source: Based on interviews.

7. EU's Multilateral and Regional Commitments Relating to Health Services

The two preceding sections have highlighted regulatory and other factors affecting relations between India and the EU in health services and issues that need to be addressed in the India-EU TIA negotiations. Before examining possible strategies and measures to address these barriers, it is important to assess the extent to which the EU has committed in the health services sector under the GATS and in its other preferential trade or economic cooperation agreements (PTAs and ECAs). The EU's willingness to negotiate in this sector and on some of the regulatory issues affecting this sector, in its multilateral and bilateral talks, could indicate what India can expect from its negotiations with the EU. It is unlikely that the EU will offer anything substantially more to India than what it has already committed to other countries or in the WTO. Given the special status of health services in the EU, which is excluded from the scope of the EU services directive (although there are initiatives to promote cooperation in cross-border healthcare on issues such as patient mobility, e-health, and recognition of qualifications), this becomes an even more difficult sector to negotiate with the EU as a whole.

7.1 Multilateral commitments and offers by the EU

The health services sector is captured in two parts of the GATS schedules, i.e., in the health and social services sectoral schedules and in a sub-sector called medical, dental, and midwives services under the business services sectoral schedule. The discussion assesses the status of EU commitments and offers in this sector.

7.1.1 Comparison of commitments and offers in Modes 1,2,3

The following table shows the EC's revised offer in the health and social services sector, classified by the nature of these commitments in each mode and sub-sector.²⁵

Table 17: Revised Offers of EC Members in Health Services and Social Services

		Hospital Services	Other Human Health Services	Social Services	Other (Health Related Services)
Total		25	25	25	25
<i>Market Access</i>					
Mode 1	Full	1	1	2	1
	Partial	0	0	0	0
	Unbound	24	24	23	24
Mode 2	Full	19	4	17	2
	Partial	0	0	0	0
	Unbound	6	21	8	23
Mode 3	Full	6	4	16	2
	Partial	13	0	1	0
	Unbound	6	21	8	23
<i>National Treatment</i>					
Mode 1	Full	1	1	2	1
	Partial	0	0	0	0
	Unbound	24	24	23	24
Mode 2	Full	17	4	17	2
	Partial	1	0	0	0
	Unbound	7	21	8	23
Mode 3	Full	16	4	17	2
	Partial	3	0	0	0
	Unbound	6	21	8	23

Source: Author's compilation based on EC Revised Offer.

The following table shows the revised offers in the sub-sector of the business services schedule that is relevant to health services.

²⁵ Hospital services are defined as services delivered under the direction of medical doctors chiefly to in-patients aimed at curing, reactivating, and/or maintaining health status. Other human health services refer to ambulance services, residential health facilities services other than hospital services, and services in the field of pathology, and other non classified services. Social services refer to welfare services delivered through residential institutions to old persons and the handicapped and children and other clients, and other social services with accommodation. And other services refer to child day care services, counseling, etc.

Table 18: Revised Offers of EC Members in Medical, Dental and Midwives Services

Medical, Dental and Midwives Services		
Total		25
<i>Market Access</i>		
Mode 1	Full	2
	Partial	5
	Unbound	18
Mode 2	Full	17
	Partial	5
	Unbound	3
Mode 3	Full	5
	Partial	16
	Unbound	4
<i>National Treatment</i>		
Mode 1	Full	2
	Partial	5
	Unbound	18
Mode 2	Full	17
	Partial	5
	Unbound	3
Mode 3	Full	16
	Partial	5
	Unbound	4

Source: Author's compilation based on EC's revised offer

Note: The offers combine the three categories of service providers in this sub-sector pertinent to healthcare services under the business services sector. In Modes 2 and 3, while some countries have indicated no restrictions for medical and dental professionals, they have indicated unbound for midwives. Generally, the midwife category is the most restricted in all the modes. Thus partial may mean that some categories are unbound and others are open, rather than access being subject to conditions. Only Mode 3 is clearly subject to various kinds of listed limitations.

It is evident from the above tables that the EC has made a very restrictive offer in the health services sector and in the sub-sector of health professionals under business services. Most of the offers are unbound in Mode 1. This effectively means that outsourcing of health services, such as telemedicine work, clinical trials, back-office support like medical coding and imaging, and telepathology are not permitted cross-border by the EU, either on an institutional basis such as by hospitals and laboratories or on an individual provider basis such as by doctors or radiologists. Yet it was seen in the preceding sections on opportunities and barriers that some of the most promising segments for expanding relations with the EU are in the cross-border delivery area such as in teleradiology and clinical trials. The only EU country that has unrestricted access under Mode 1 for hospital and other human health services is Hungary and the two countries that have made unrestricted offers in the social services sub-sector are Latvia and Lithuania. None of the major countries in the EU has provided market access for cross-border delivery of health and social services. The only two countries to have given unrestricted access for medical, dental, and midwives services in the case of Mode 1 are Poland and Sweden and again the main markets in the EU have not.

In Mode 2, market access is unrestricted in most countries under hospital services,

which is the most pertinent for medical value travel. But as noted earlier, the potential of this market depends on the extent of insurance portability by public or private insurance providers and the out-of-pocket paying population. Likewise, while Mode 2 is relatively unrestricted for the professional services sub-sector in healthcare, issues of recognition and portability of insurance remain. Thus, the liberal market access in Mode 2 under both schedules may not translate into real market access for Indian providers unless insurance and perception issues are addressed. In Mode 3, the offers are for the most part unrestricted in the main segment of concern, namely, hospitals, but restrictive and subject to limitations in the case of medical professionals under business services.

The following box highlights the nature of the limitations applicable to Mode 3 in the EU's professional services and health and social services offers.

Box 1: Limitations on market access in Mode 3 for health and related professional services

Health Services and Social Services

Hospital Services

Spain - Prior authorization is required by the "Comunidades Autónomas" based on an economic needs test taking into account the population and already existing health services in the given health regions.

France and Italy - The number of beds authorized is limited by a health services plan established on the basis of needs; Equipment of heavy material is limited by a health services plan established on the basis of needs.

Italy - Private health and sanitary services need authorization by local health authorities. Criteria are based on a ratio in function of population.

Poland - Head, or his deputy, of the health facility should meet qualifications of medical doctor. All the limitations pertaining to medical, and dental services, as well as services of midwives, nurses are applicable.

Netherlands - Quantitative economic needs test fixed by a health plan allowing for a maximum number of beds related to the population of each health region.

Medical, Dental and Midwives Services

Germany – Access restricted to natural persons only. Economic needs test. The economic needs tests, when applies, sets a limit on the number of services suppliers (for medical doctors and dentists) who are authorized to treat members of public insurance schemes. Main criteria: local demand and population criteria.

Spain – Access restricted to natural persons only.

France – Provision through SEL (Société d'Exercice Libéral) or SEP (Société Civile Professionnelle) only.

Italy – Access is restricted to natural persons only. Professional association (no incorporation) among natural persons permitted.

UK – Establishment for doctors under the National Health Service is subject to medical manpower planning.

Source: Author's compilation based on EC's Revised Offer.

The main limitations are in the form of economic needs tests, authorization requirements, and associated quantitative restrictions based on local needs assessment. There are implicit restrictions relating to standards, qualifications, certification, etc.

The following tables show the changes in the EU's commitments and offers in the health and social services sector and in the professional services sub-sector for health. The idea is to examine whether there are any discernible changes in the extent of liberalization the EU is willing to bind in this sector across all modes.

Table 19: EC Commitments and offers in Health and Social Services

Sector / Sub-sector	Uruguay Round Commitments (1994) (Limitations on market access)	Conditional Initial Offer (2004)	Revised Offer (2005)
Hospital Services	1) Unbound 2) Majority of the states have made full commitments in this sub-sector. 3) Most member countries have restricted market access by imposing limitations on the availability of beds and also demanding an economic needs test.	No major changes.	No further changes.
Other Human Health Services	1) Unbound 2) Most member countries have not made any commitments. 3) As above.	No major changes.	No further changes.
Social Services	1) Unbound 2) Barring a few members, the majority of the member states have full commitments. 3) As above.	No major changes.	No further changes.
Other Health Related Services	1) Unbound 2) Unbound 3) Unbound		No further changes.

Source: Author's compilation based on EC's commitments, initial, and revised offers.

Table 20: EC Commitments and Offers in Business Services related to Health Sector

Sector / Sub-sector	Uruguay Round Commitments (1994) Limitations on market access)	Conditional Initial Offer (2004)	Revised Offer (2005)
Medical, Dental and Midwives Services	<p>1) Unbound</p> <p>2) Most of the Member States remain unbound for midwives services while they have made almost full commitments in medical and dental services.</p> <p>3) Most member countries have restricted market access in medical and dental services by demanding an economic needs test along with a nationality requirement while almost all the members have their market unbound for midwives services.</p>	No major changes.	No further changes.

Source: Author' compilation based on EC's commitments, initial, and revised offers

It is evident from the above two tables that the position of the EU has not changed between the Uruguay Round Commitments and the revised offer. The lack of progressive liberalization in this sector shows that the EU sees this as a sensitive sector where it is not willing to remove regulations pertaining to standards, qualifications, and consumer protection.

7.1.2 Comparison of commitments and offers in Mode 4

The following tables provide the nature of the EU's revised offers in Mode 4 for both the health services and health professionals sectors.

Table 21: EC's Revised Offers in Mode 4 for Health and Social Services

	ICT			BV			CSS			IP		
	N	P	U	N	P	U	N	P	U	N	P	U
Market Access												
Hospital Services	0	5	20	0	5	20	0	0	25	0	0	25
Other Human Health Services	0	4	21	0	4	21	0	0	25	0	0	25
Social Services	0	2	23	0	2	23	0	0	25	0	0	25
Other (Health-related Services)	0	1	24	0	1	24	0	0	25	0	0	25

	ICT			BV			CSS			IP		
	N	P	U	N	P	U	N	P	U	N	P	U
<i>National Treatment</i>												
Hospital Services	0	19	6	0	19	6	0	2	23	0	0	25
Other Human Health Services	0	4	21	0	4	21	0	1	24	0	0	25
Social Services	0	8	17	0	8	17	0	2	23	0	0	25
Other (Health-related Services)	0	1	24	0	1	24	0	1	24	0	0	25

N: None; P: Partial; U: Unbound

Source: Author's compilation based on EC's Revised Offer

Table 22: EC's Revised Offers in Mode 4 for Medical, Dental and Midwives Services

	ICT			BV			CSS			IP		
	N	P	U	N	P	U	N	P	U	N	P	U
<i>Market Access</i>												
Medical, Dental and Midwives Services	0	12	13	0	12	13	0	0	25	0	0	25
<i>National Treatment</i>												
Medical, Dental and Midwives Services	0	9	16	0	12	13	0	2	23	0	0	25

N: None; P: Partial; U: Unbound

Source: Author's compilation based on EC's revised offer

The enumeration tables above indicate the highly restrictive offers in Mode 4. For the two categories of service providers that are pertinent to India, namely, contractual service suppliers and independent professionals, all the offers are unbound. The same is true for national treatment which implies that there is differential and more restrictive treatment of foreign medical professionals in the EU in these two categories. The other two categories are important for India only to the extent that Indian companies may make acquisitions overseas or set up establishments in the EU, but such a presence is likely to be limited in the EU. Also, if one takes the Mode 4 offers under hospital or other health services, which are mostly unbound, and the various limitations imposed on Mode 3, effectively no market access has been provided for medical professionals even in the intra-corporate transferee and business visitor categories.

If one examines the progression in the EC's horizontal commitments and offers in modes, then as with the other three modes, there is no change pertinent to the health services sector. Some of the improvements seen in the EU's Mode 4 horizontal offer, such as the inclusion of additional categories like graduate trainees, are not pertinent to the healthcare sector given the unbound entries in the sectoral Mode 4 offers.

7.2 Regional and bilateral commitments by the EC

It is worth examining whether the EC has gone beyond its multilateral commitments and offers in its PTAs and, if so, whether India can expect the same in its own talks. In various EC agreements including the EU-South Africa Trade, Development and Cooperation Agreement, the EU-Mexico and the EU-Chile Agreements, there is a general declaration of the importance of facilitating trade in services through all four modes. There are provisions specific to the health services sector in two of the bilateral agreements namely the EU-South Africa agreement and the EU-Mexico agreement. In the other bilateral agreements, various regulations and cross-cutting issues that are pertinent to the health services sector and which have been highlighted earlier as affecting India's exports of health services to the EU, are highlighted.

7.2.1 Health sector and cross-cutting provisions

The provisions on health mainly pertain to increasing collaboration between the two sides with a view to improving access to healthcare. The focus is on cooperation and exchange of information rather than commerce per se. For example, the EU-South Africa agreement states that the two sides will cooperate to "improve the mental and physical health of populations by promoting health, and preventing disease." In the area of public health, the agreement calls on both sides to cooperate through knowledge and experience sharing on programs and improving education and training of public health professionals. Cooperation is also proposed in the pharmaceutical sector, including support in the evaluation and registration of medicinal products. In the EU-Mexico agreement, a similar thrust is evident on collaboration in research, preventive medicine, and other such public health-related areas, and bilateral engagement in projects to improve public health and develop vocational training programs.

There are also provisions on cross-cutting issues. For instance, the EU-Chile agreement specifically mentions the need to cooperate on standards, technical regulations and conformity assessment to avoid and reduce technical barriers to trade. There are provisions for regulatory cooperation, compatibility of technical regulations based on international and European standards, and technical assistance to create a network of conformity assessment bodies on a nondiscriminatory basis. Cooperation is envisaged to reduce gaps in standards, regulatory practices, and business practices and operation of systems on both sides. Likewise, in the EU-South Africa agreement, there are provisions to promote greater use of international technical regulations, standards and conformity assessment procedures including sector-specific measures. There are also provisions calling for cooperation in quality management and assurance in selected sectors of importance to South Africa, facilitation of technical assistance and capacity-building initiatives in accreditation, and developing practical links between South African and European standardization, accreditation, and certification organizations. Such provisions are very relevant in the area of health services as some of the main problems for Indian healthcare providers in accessing the EU are due to differences in standards and regulations requiring conformity with European or international practices. As these agreements call for harmonization of standards and the establishment of regulatory and other mechanisms to enable such harmonization, these provide important cues for the Indian negotiations and what could be included in India's agreement with the EU.

On movement of persons, there is nothing concrete, except for a provision to review rules and conditions applicable to Mode 4 after some time in order to achieve further liberalization. There are, however, several provisions on mutual recognition and domestic regulation regarding qualifications and licensing. One relevant provision on recognition included in the EU-Chile agreement is that “where a Party recognizes, unilaterally or by agreement, education, experience, licenses or certifications obtained in the territory of a third country, that Party shall afford the other Party an adequate opportunity to demonstrate that education, experience, licenses or certifications obtained in the other Party’s territory should also be recognized or to conclude an agreement or arrangement of comparable effect.” This implies that if there is mutual recognition among two EU member countries, then if the non-member country with which the EU signs a bilateral agreement is accorded recognition by one of the two EU member countries, it should be given the opportunity to prove equivalence and receive recognition in the other EU member country. Thus, transitivity of recognition is implicit in such a provision, which is again relevant to the health services sector. The provisions on mutual recognition of qualifications in the EU’s bilateral agreements, though general in nature, provide grounds for institution regulatory mechanisms that accord recognition to partner countries’ service providers with greater transparency and speed and, if required, call for temporary licensing provisions. Some of the bilateral agreements also call for cooperation between institutions of higher learning and in education and vocational training as well as links between specialized bodies in the EU and the partner country to facilitate the recognition of degrees and diplomas and the pooling and exchange of experience and technical resources. Such provisions create room for negotiating collaboration in research and training and movement of personnel, which are relevant for India in the health services sector.

All the bilaterals contain a separate article on data protection, which includes provisions for cooperation to improve the level of protection accorded to the processing and transfer of personal data, taking into account international standards (which are provided in the Annex to the agreements). The provisions also call for technical assistance, exchange of information, and joint initiatives in this area. There is nothing more concrete, however. But it is evident that personal data and issues of choice, notice, transfer, and processing of sensitive personal data are a matter of concern for the EU in all its agreements and will also be important in the negotiations with India.

Thus, the specific and general provisions for the health sector contained in the EU’s bilateral agreements with countries such as Chile, Mexico, and South Africa refer to all the issues that are important to India in health services. This gives some negotiating basis for India in this sector as some of these provisions could also be adapted to suit India’s interests in the health services sector when framing its bilateral agreement with the EU.

7.2.2 Relevant features of the India-Singapore CECA ²⁶

The bilateral CECA between India and Singapore contains several provisions that are relevant to health services. Apart from guaranteeing market access and national

²⁶ India-Singapore Comprehensive Economic Cooperation Agreement (CECA), Information Kit, FTA website, Government of Singapore, Singapore’s Schedule of Specific Commitments- Annex 7B, India’s Schedule of Specific Commitments, Annex 7A.

treatment in each other's markets, the agreement also specifies that domestic regulations governing the provision of services will be reasonable, impartial, and objective. There is also a provision for MRAs to facilitate the freer movement of people across five professions, including the medical, dental, and nursing profession in both countries. There is an understanding to negotiate MRAs within a year of signing the CECA to recognize each other's education and professional qualifications. Professionals employed in 127 specific occupations, including the healthcare profession, will be allowed entry and stay for up to a year or the duration of the contract, whichever is less. This list contains 35 occupations that fall under the health services sector (numbers 72 to 107 of the list of occupations in the CECA), as shown in the following table.

Table 23: List of health services related occupations in the India-Singapore CECA

Serial Number	Occupation title
1.	Biologist (general)
2.	Zoologist
3.	Anatomist
4.	Biochemist
5.	Physiologist
6.	Neurologist
7.	Medical pathologist
8.	Clinical pathologist
9.	Veterinary pathologist
10.	Pharmacologist
11.	Animal Scientist
12.	Microbiologist
13.	Bacteriologist
14.	Immunologist
15.	General physician
16.	General surgeon
17.	Specialised surgeon
18.	Anaesthetist
19.	Psychiatrist
20.	Obstetrician and gynecologist
21.	Endocrinologist
22.	Paediatrician
23.	Dermatologist
24.	Ophthalmologist
25.	Cardiologist
26.	Radiologist
27.	Industrial Physician
28.	Medical Service Physician (school)
29.	Public Health Physician
30.	Dentist (general)
31.	Specialist dentist
32.	Veterinarian
33.	Veterinary epidemiologist
34.	Pharmacist (dispensing)
35.	Other pharmacists

Source: India-Singapore Comprehensive Economic Cooperation Agreement (CECA), Annex 9A.

The CECA also contains an education cooperation chapter to facilitate joint post-graduate programs between reputed institutions in the two countries. This chapter provides that degrees specified by the University Grants Commission of India or an institution of national importance in India and by universities in Singapore shall be recognized for admission purposes into each other's universities. Although medical training institutions are not explicitly covered under this education cooperation chapter (while engineering institutions such as IITs are), these provisions provide scope for facilitating linkages between reputed medical colleges in India and Singapore.

Commitments made by Singapore in the medical services sub-sector under professional services are the most unrestricted. Modes 1, 2, and 3 are unrestricted except for medical services and for services provided by midwives, paramedics, nurses, and physiotherapist where Mode 1 is left unbound. Singapore's commitments for sub-sectors such as hospital services, and other health services under the health and social services sector are restrictive. Modes 1 and 3 are largely unbound and only Mode 2 is unrestricted. Hence, apart from medical value travel, other segments such as telemedicine, health services outsourcing, and foreign direct investment in hospitals, where there is scope for India to export to the Singapore market, have not been committed (though unilaterally such trade is being permitted as in the case of telemedicine).

India's commitments in health services are very liberal, with entries of "none" for Modes 1, 2, and 3 in both professional services sub-sectors pertinent to healthcare and under the health and social services sector. There are, however, some exceptions on the grounds of relevant technology and for publicly subsidized healthcare being limited to Indian nationals. It is worth noting that India's commitments in health services under the CECA are more liberal than under the GATS, though India has progressively liberalized even under the GATS in its initial and revised offers, with full commitments in Modes 1 and 2 and raising its FDI ceiling in Mode 3. India's willingness to make liberal commitments under CECA or the GATS reflects its autonomous liberalization in this sector since 2000.

Overall, the CECA provisions and commitments do provide for increased cooperation and exchange between India and Singapore in the health services sector, in both the professional and the establishments segments. The commitments also indicate that both countries have been more willing to provide market access on a bilateral basis than under the GATS. The provisions regarding MRAs and cooperation among training institutions are elements that India would seek to incorporate in its other bilateral agreements to address its interests in the health services sector.

8. Proposals for the India-EU Negotiations in Health Services

Several specific issues emerge from the preceding discussion, which should be included in India's negotiating agenda with the EU to promote its interests in health services. The negotiating agenda, in order of priority, is given below. This includes a cross-cutting approach to the health sector through a focus on cooperation and joint initiatives as well as efforts to remove specific restrictions.

8.1 Cooperation chapter: collaboration, partnerships, affiliations in education, research, training

In the health sector, commercial market access issues are less important than collaborative opportunities; hence, cooperation is the most important issue to pursue. This has positive implications for all of India's opportunity segments in the EU. A cooperation chapter, either of a general cross-cutting nature or a chapter on cooperation specific to health services along the lines of the India-Singapore CECA chapter on cooperation under education services, should be negotiated. This chapter should include elements such as institutional tie-ups, exchange of faculty, students, and trainees, research collaboration, cooperation on standards and recognition issues, and launching of joint programs and pilot projects between India and EU countries. It may be useful to have a separate cooperation chapter on education as in the India-Singapore CECA since many issues need an understanding of education and training.

The text of the cooperation chapter should cover all broad aspects of collaboration in the healthcare sector.

- Institutional tie-ups to help in the areas of telemedicine and medical value travel.
- Partnerships and affiliations among labs and research centers to facilitate work in the area of clinical trials, and global recognition and certification of Indian labs.
 - There can be tie-ups between laboratories in India and the EU, or Indian laboratories and EU universities to conduct clinical trials. Such partnerships would enable Indian companies to learn the procedures followed by EU companies. One example is the tie-up between India and Canada under a joint Indo-Canadian project on tissue engineering to work on stem cell therapy. The company wants to do experimental therapy in the EU and conduct autologous experiments; a similar partnership with an EU university or institution would enable the company to have clarity on the procedures required in the EU.
- India could negotiate a reciprocal health agreement with selected markets in the EU, along the lines of the agreements some of these countries have with non-member nations for treatments required during visits on emergency grounds.
- There should be provisions to facilitate partnerships and collaboration among medical education and research institutions in India and the EU. Today, hardly any medical institutions, private or public have a relationship with EU countries. However, the EU has many hospitals with good processes and personnel with good subspecialty training which would benefit Indian institutions.
 - Specific institutional linkage possibilities in the area of training, as in the case of the India-Singapore education cooperation chapter which covers technical and engineering colleges of repute, should be included. The India-EU BTIA cooperation chapter could explicitly include provisions for tie-ups with reputed Indian institutions. Some possibilities include a tie-up between NIMHANS and the neuropsychiatric hospitals in EU countries, between Escorts or AIIMS and the Karolinska Institute in Sweden for a

joint program in cardiology, and between the Rajiv Gandhi Institute for Cancer Research and selected institutions in the EU in oncology. Pilot programs on research and training on a joint basis would also facilitate the certification of Indian medical professionals. While language is an issue in such joint programs, the negotiations could consider the scope for EU universities to offer post-graduate training to overseas professionals; this would increase the latter's exposure to higher standards, and allow them to impart that learning when they return to their home countries.

- Collaboration in education and training should provide for launching of pilot programs for staff deployment and exchange or medical value travel between select institutions on both sides. Thus, exchange of doctors and personnel deployment on a selective basis could be explored, which would be supported by collaborative programs in education, research, and training between selected prestigious hospitals, medical colleges, and centers in India and the EU.
 - One could negotiate pilot programs with the NHS wherein Indian doctors would get additional training and certification from the UK Medical Board and go to the UK on a three- or six-month rotation basis, do radiology reporting or undertake clinical duties, and then return to their parent institution in India. If there is a tie-up in the education and training area, it would become easier for the EU country's authorities to recognize the qualifications and allow them to work in their institutions in the EU.
 - Temporary exchange of personnel could involve sending surgical teams or nurses to the EU for limited periods.
 - Twinning programs could be considered with coursework being done in India and the research and clinical work being done in the EU institution.
 - Visiting faculty could be brought to India for short periods to impart training at the Indian partner institution.
 - Research-oriented Indian professors could be taken to the EU institution for training and further capacity-building and on their return to India could impart training to others.
- There could also be tie-ups between Indian hospitals/research centers and EU companies such as Siemens and Philips that develop medical devices and equipment, for commercial and academic reasons. Such partnerships can help Indian establishments undertake testing of medical devices. Indian companies, research centers, and labs could also help partner in the engineering and design services work for the development of medical equipment.

The win-win outcome of such arrangements needs to be highlighted to the EU authorities. Not only will this enable the Indian practitioners to get relevant skills and further the EU's aim of improving the healthcare system of its partner country (as seen in its other bilateral agreements), but would also address its own manpower shortages and supplement its skill sets. Equivalence of qualifications could be ensured through twinning programs, partnerships in education, and affiliation between institutions on both sides in continuing education and research. Again, tiering of Indian institutions and negotiations with the EU on criteria for the selection of which institutions should be partnered with will be required. This personnel exchange could also be done for labs, pharmacists, radiologists, paramedics, and any health

professionals where there are huge shortages in the EU countries. In addition to the government's discussions on these issues, private providers will also need to proactively push for such partnerships with EU institutions. A case in point is the tie-up between Max and clusters of hospitals in the US to send nurses to those hospitals for work on a temporary basis. Contractual arrangements through temporary visas and strict return conditions could ensure that the personnel return on completion of their contracts.

8.2 Restrictions on cross-border delivery

An important issue to press in the negotiations is to remove the existing restrictions on outsourcing clinical data and patient information to India for services such as teleradiology, teleconsulting, tele-imaging, and medical coding. The Indian government must lobby with concerned EU governments to enable such outsourcing outside the EU region. Given the high levels of IT security compliance of Indian healthcare providers engaged in e-health delivery, restrictions on such outsourcing on the grounds of data privacy and IT security are not warranted.

Several things can be done to address this issue. One step is to make the EU governments aware of the IT security systems in place in Indian companies; their compliance with internationally accepted protocols such as BS7799 should be highlighted. It is also useful to impress on the EU that since Indian IT providers are already doing software development work and outsourced IT work for EU countries in many sectors, including healthcare, telemedicine providers in India should also be allowed to do reporting and analysis of this data. Awareness also needs to be created that the data does not necessarily cross borders as it sits in the client country server and that the data is morphed and anonymized. The benefits from such outsourcing in terms of cost reduction and reduced wait time for EU public health systems need to be stressed. Apart from dialogue with EU governments, other ways to create greater awareness about India as a telemedicine provider would be to publish information about such providers in India in academic and popular publications and to demonstrate that telemedicine from India is safe and effective.

The model adopted by the Singapore National Health Care Group in outsourcing teleradiology work to India is an approach that could be suggested to the EU authorities. Singapore, which also has stringent quality assurance standards, has outsourced work from its national healthcare system to India. This was done through a proper accreditation and auditing process where Singapore brought teams of doctors from the National Healthcare Group to make sure of the processes followed by Indian teleradiology providers and went through their Quality Assurance policy at the Indian establishment. The assessment results were put to the Singapore Board which then gave accreditation to the Indian company to undertake telemedicine work for select Singaporean hospitals. The Singapore Ministry of Health gave the Indian company interpretation tests, checked to ensure that the processes were robust, and checked the credentials of the physicians at the Indian establishment. The success with the Singapore model, with turnarounds being reduced from 3 days to a few hours for X ray reports, reduced costs, and increased referrals has proven to be a win-win for both sides. Such a case needs to be flagged to the EU authorities and the model followed by the Singapore government in accrediting the Indian telemedicine provider could be followed by interested EU countries with select Indian companies. Efforts could be

made to affiliate hospitals in the national health systems of selected EU countries with telemedicine companies that meet all quality standards and data security norms, as in the Singapore model. Such an institutional affiliation could be done on a small-scale basis initially and then expanded to include more telemedicine companies and more procedures if the certification process is found to be robust and the outcomes are found to be beneficial. Periodic and random audits, reviews, quality assurance, and IT security systems would have to part of this certification process.

It is also important to explicitly include provisions regarding cooperation in healthcare to improve the public health systems of both countries. Such a provision would give scope to India to negotiate institutional affiliations between Indian and EU institutions for cross-border delivery and benefit both countries by reducing waiting times and alleviating shortages in the EU countries and by creating the capacity for undertaking telemedicine within India and thus greater access to healthcare for all.

8.3 Cross-border mobility of patients and insurance portability

It is important to negotiate and remove the three-hour limit on flying time which is imposed by the NHS for reimbursement. As was pointed out by most respondents, it will be important to highlight to EU authorities through these negotiations, through trade and industry delegations, the gains the EU could realize in terms of lower costs and reduced waiting lists by allowing their patients to get treated in India. In addition to getting such restrictions on flight time removed, the Indian government would need to get the public health systems of the EU countries, in particular the UK and perhaps others such as the Netherlands, Denmark, and Germany to accept treatment in India for reimbursement by their national health insurance trusts.

One way to address this issue is to get the NHS and other public health systems to select certain Indian healthcare establishments for reimbursement, for selected procedures such as cardiac surgeries, joint replacements, and cosmetic surgeries where such a third country can be easily justified given long waiting lists and shortage of personnel. Information needs to be disseminated about the Indian medical system, reputed institutions, and procedures being done in India. The selection of institutions could include those that have received accreditation from internationally recognized sources, such as JCI, coupled with additional audits by the authorities of the concerned government. Based on this, a final list of selected institutions can be created. There could be understandings on per procedures, volumes, and cost plus - based arrangements between the NHS and these selected institutions.

Another way to address the publicly insured pool of persons in the EU for medical tourism is to launch pilot projects on an institutional tie-up basis on a very limited scale. This tie-up can be made part of a larger institutional link, such as staff exchange, research and development, training, and telemedicine, to give more credibility and accountability to the Indian healthcare provider. Over time, the scale of such initiatives could be expanded to cover more institutions and procedures. Once again, the criteria for selecting institutions in India for such tie-ups will depend on some form of recognition of their existing standards with any additional checks and controls being required by the EU authorities. The NHS or relevant public health authorities can set the standards and select the procedures and providers. The understanding with the public health authorities could also involve insurance

providers such as BUPA who could act as third-party administrators in such government-government schemes.

In addition to the publicly-insured patients and getting some understanding on reimbursement from national health systems, it is also important to arrive at an understanding with private health insurance companies. Although the share of privately-insured patients is relatively small in EU countries, this segment can be tapped by making private health insurance companies such as BUPA aware of the benefits that would accrue to them from covering treatments in India, especially for the higher-risk groups and permit them to come for critical treatments to India, or areas where the cost differential is much larger. The savings to the insurance company needs to be articulated for different procedures. As many respondents pointed out, private health insurance companies have to be given an incentive to pay for patients to be treated in cheaper places like India and for this the government along with private healthcare providers needs to do some promotional work. Patients in the EU could be given the option of selecting procedures where their insurance would be mobile and the premium or co-payments for treatment could be linked to the place where treatment is done in order to account for additional risks, legal liability and malpractice concerns. The maximum amount to be reimbursed could be capped. Again, through trade and industry delegations, the insurance companies can be incentivized to accept establishments that have international accreditation and do an additional audit of the providers' clinical and privacy policies to decide whom to certify and for what kind of coverage. This approach has worked for Bumungraad hospital in Thailand where there are differentiated products and elective treatments are reimbursed by private insurance companies. The same can be worked out with private insurance companies in the EU.

Another means of getting more EU patients to India would be for corporate hospitals in India to tie up with MNCs from Europe, who could provide choice to their employees to elect and get covered for treatment in India. Again, this will require the recognition of Indian hospitals by the private insurance companies with which the MNCs are affiliated.

Thus, one has to do some sensitization and promotion of India's potential as a medical tourism destination for EU patients to EU authorities and private insurance providers. More information dissemination is required about our medical system, establishments, and procedures to gain credibility. Following this, the government and Indian private providers need to negotiate with public health authorities and the insurance companies' mechanisms to select the right institutions and areas for reimbursement so as to tap both the public- and privately-insured patient pool. At present medical tourism from the EU is limited to out-of-pocket patients, who are unlikely to choose India as a destination given their affluent status, thus limiting the size of the market that is being tapped.²⁷ Of course, such schemes to select institutions would also require more Indian healthcare providers to get international certification. Once India's own standards such as the NABH are accepted by international certification

²⁷ Canada is leveraging the possibility for medical tourism in India as authorities there are allowing people to come to India for surgeries. Lifeline hospital in Chennai, Apollo, and Manipal are the main providers to this group, but the bulk of patients are tourists or out-of-pocket patients. The US is seen as the biggest potential market for medical value travel as there is a substantial chunk of non-insured persons in the US.

bodies such as ISQA, this process of getting acceptance from overseas authorities and insurance companies will become easier.

8.4 Recognition issues

Issues related to accreditation and standards are among the most important barriers to India-EU relations in health services. Whether it is medical tourism, telemedicine, movement of personnel, or clinical trials, the central issue is recognition of standards and qualifications. On issues of establishment (hospitals, labs, and telemedicine companies) standards which concern adherence to various protocols, one needs to create awareness among EU authorities about those which have international accreditation or affiliations through a tiering approach among healthcare establishments (as proposed above in Section 8.2) while also raising and harmonizing internal standards (as discussed in the next section on domestic reforms). There should also be negotiations to facilitate the extension of such accreditation, once accorded by one EU member country, to other EU countries, with minimal additional requirements of bridging, registration, etc.

In the area of recognition of professional qualifications, negotiations on mutual recognition are required for doctors, nurses, radiologists, medical coders, etc. This will again require tiering of medical training institutions in India and providing a select list of high-quality institutions to the EU authorities and for a select list of occupations (along the lines of the occupation list in the India-Singapore CECA), which can be supplemented with additional requirements to bridge any gaps in training (apart from internal issues of reducing disparity in standards of medical education and training). Negotiations are required to accept this principle as a starting point for mutual recognition discussions following which there will need to be a lot of cooperation among regulatory authorities to decide on these training institutions, sets of qualifications, occupations, and bridging mechanisms. There should also be an understanding with concerned EU authorities that if recognition is achieved in one EU country, there should be facilitation of recognition with other EU authorities, by the principle of transitivity, given that mutual recognition with bridging mechanisms are also operational in the EU.

It will be important to negotiate for streamlining of registration and certification processes in the EU. As highlighted earlier in the section on barriers to telemedicine from India to the EU, the registration process is cumbersome and time-consuming. The current process needs to be looked at and made more efficient, such as by reducing requirements of maintaining a log book of all procedures undertaken by the professional or the exact formats (including even the file boxes) for submission, etc. More efficient and streamlined accreditation processes coupled with outsourcing of work from the EU would enable India to undertake many more activities, including telemedicine, staff exchange and deployment, coding, and lab work for the EU healthcare market.

As regards Mutual Recognition Agreements (MRAs) pertaining to the health sector, it would be useful to negotiate for MRAs covering medical devices and on clinical and manufacturing practices pertinent to the health sector. The format of the MRAs the

EU has with the US, Australia, and New Zealand in this area, could be followed.²⁸

8.5 Specific issues for negotiation

There are some issues that were specifically highlighted by those interviewed in the course of this study, which are worth highlighting during the negotiations.

One issue is investment. It was evident that given certain restrictions in the EU on outsourcing of health services, commercial presence in the EU through a local subsidiary or a front end marketing office is one way around the problem. Similar work can then be undertaken from within the EU region, although such a model is not seen to be scalable. Given the importance of organic or inorganic investments, it is worth negotiating the streamlining of investment regulations for the establishment of healthcare institutions – labs, hospitals, subsidiaries, marketing, and other kinds of offices in the EU. Related taxation, accreditation, and movement of personnel issues could also be examined in case there is any differential playing field for non-EU countries. While no specific issues were raised by the respondents regarding the ease of investment in healthcare within the EU, this may reflect the lack of such investment presence in the EU at present. But more inorganic investments are likely by Indian companies through acquisitions of EU companies in segments such as clinical trials, and thus any procedural impediments need to be examined.

Some points were also made regarding visas. It was noted that temporary resident visas could be given to Indian nurses in areas where EU countries have shortages. Specially classified visas could be created (as the US has done). The issue of an uneven playing field for Indian medical personnel due to the preference given to EU nationals by potential export markets like the UK was also highlighted. Industry associations in India are trying to lobby the governments there to remove the first preference in recruitment to EU nationals. This issue could be raised in the discussions. It was also suggested that technical and senior personnel in CROs who may need to go to the client country in the EU when undertaking a clinical trial project need to be given longer duration multiple-entry visas and without much delay as drug trials need to maintain strict timelines.

8.6 Summary of key areas for negotiation in health services

To sum up, the priority should be to negotiate a chapter on cooperation that covers various regulations that have a bearing on the health services sector. In addition, three specific issues need to be focused on, both in the context of the chapter on cooperation and otherwise.

The first area of focus pertains to specific restrictions maintained by the EU and using the negotiations to remove them.

The second area of focus pertains to larger issues such as equivalence, recognition,

²⁸ The EU's MRAs with the US, Australia, and New Zealand touch upon medical devices and manufacturing practices in the pharmaceutical sector, which have a bearing on areas like clinical trials and research, and medical devices testing, that could be export opportunities for India in the EU market. However, none of the MRAs cover health personnel.

standards and establishing mechanisms to either harmonize or agree on a selective basis for greater linkages between EU and Indian establishments and providers.

The third area pertains to administrative and operational issues in the way regulations are implemented and administered in the EU, which if streamlined could smoothen existing relations in these areas.

These negotiating efforts also have to be supported by active lobbying and promotional work by Indian industry associations and trade delegations to market India as a healthcare provider as well as consumer. For example, it was suggested that India should highlight its importance as a healthcare market given its large population, its 21 per cent share in the world's diseases, and thus the need for studies to be conducted on Indian patients for drug development so that these products are also marketed in India. It should be impressed on other governments that Indian companies would not merely provide the testing services for drugs, devices, and diagnostic agents, but would also provide the necessary evidence for companies to sell their products in the large Indian market. Thus, India's potential as an exporter of health services needs to be linked with its potential as a consumer of healthcare to further justify why it is in the EU's interest to expand its relationship with India in this sector.

8.7 Implications of a government procurement agreement

As the healthcare sector is primarily publicly funded in the EU and member governments play an important role in the procurement of health services, it is important to consider the implications of signing a Government Procurement Agreement (GPA) for India's commercial interests in this sector.

An examination of the relevant EU rules in this regard, which include the EC Public Procurement Directive, 2004/18/EC, the EC Remedies Directive, 89/665/EC, and national regulation such as the Public Contracts Regulation, 2006 in the UK, suggests that there may be some benefit to India from signing a GPA as far as its interests in health services are concerned. One reason is that health services fall under Part B services, to which the EU rules on public procurement apply only to a limited extent and are subject to lighter regulation. EU rules would only apply to technical specifications and filing a contract award notice with the Official Journal of the European Union. It would provide for equality of opportunity, national treatment, transparency, proportionality, and mutual recognition. Moreover, the provisions would ensure a "degree of advertising sufficient to enable the services market to be opened up to competition and the impartiality of procedures to be reviewed", unless the economic importance of the contract is such that it will not be of interest to organizations in other EU member countries. Another important provision pertinent to health services is that the concerned government cannot reject a tender which does not comply with a technical specification or standard if the tendering party can prove that its proposal meets the client's functional requirements in an equivalent way or shows that the technical specification of standard meets the client's specified requirements. Thus, there are clearly benefits in terms of transparency, fair chance, and clarity in procedures for tendering which could benefit Indian healthcare providers such as teleradiology companies or medical coding and business support companies interested in procuring government contracts in the EU.

However, India will need to weigh these benefits against what it would have to commit under a GPA in terms of opening up its tendering procedures and contracts for public works and public services. The benefits from signing a GPA are not guaranteed for Indian healthcare providers given the continued regulatory impediments in other areas which would still limit the scope in the EU market. For instance, there is some private outsourcing by national health authorities of some EU member countries, but so far this is permitted to private parties based within the territory of the EU. There remain restrictions on data transfer outside the EU to countries like India which have not received “data adequacy” determination. Thus, while signing the GPA may help Indian providers to get contracts within the EU, the basic requirement of setting up local commercial presence in order to obtain the contract would continue, unless India can get empanelled by EU data authorities or enter into a safe harbor arrangement with the EU along the lines of the US. Thus, it would be important to simultaneously address these other constraints if a GPA is to be translated into meaningful market access.

9. Domestic Reforms and Policy Measures in India

Much of what has been outlined above for the negotiations needs to be supplemented and at times preceded by domestic reforms and the introduction of regulatory frameworks and measures. Some of these issues that need to be addressed internally are highlighted here.

9.1 Standards and recognition

The Medical Council is a regulatory bottleneck when it comes to standards and recognition matters. This body is not considering cross-certification of degrees with other countries. Mutual recognition would also need to be supported by a credential or ranking system of different medical institutions and colleges. Mutual recognition and tiering of institutions would not only facilitate outsourcing of work to India, medical value travel, and other partnerships, but would also enable India to draw on Indian medical personnel who are trained in the EU, particularly the UK, and to get them to work in India, serving both the Indian and the EU markets. There are a sizeable number of radiologists who have been trained overseas; they could be hired in India, but as their credentials are not recognized by the Medical Council of India, they are deterred from returning as they cannot practice here. The strategy should be to get one’s personnel empanelled by the concerned authority in the UK or other country in order to provide the services, whereas mutual recognition would have obviated the need to undergo the current cumbersome registration and certification procedures. Recognition of Indian medical degrees on a mutual basis would enable the exchange of consumers and cooperation among institutions in India and the EU.

Attempts at mutual recognition on a wider basis will need to be preceded by internal measures to raise standards in our own medical colleges and institutions. There is considerable divergence at present in our standards of training, qualifying exams, and extent of clinical practice and exposure across different Indian medical training institutions, nursing and paramedic schools and colleges, unlike the US or UK where there is a set standard and common qualifying exam. Thus, quality has to be standardized internally. The UGC has been talking of standardizing the syllabi and training imparted Without such raising of standards and harmonization internally, it

will not be possible to get recognition for our nursing schools or to affiliate our nursing colleges to hospitals in the EU, to enable the rotational temporary deployment of nurses to EU institutions. Better governance mechanisms would also be required in our training institutions. Newly-introduced quality assurance norms such as the NABH and NABL will need to be globally recognized and accepted, and put on par with others such as the JCI.

In other areas too, there needs to be an alignment of India's norms and practices with the ICH guidelines. There are supposedly some small differences at present, though by and large India's legislation is almost at par with international standards in these areas. International accreditation from concerned authorities is required in various segments of clinical trials (such as cellular therapy and stem cell research). Although there are national guidelines on these segments, these national standards are not internationally recognized. Global affiliations have to be forged such as between the Indian establishment and an overseas lab or hospital and the establishment has to get certified by an international body. The Indian lab accreditation system has to be aligned with the globally recognized CAP certification in the US, which is also recognized in Europe. Conformity is also required in the area of medical devices with the introduction of more effective procedural controls and their enforcement. Respondents also noted that there is no legislation on the movement of drugs from one point of the country to another which affects the clinical trials business.

Today, Indian companies are getting certification by getting their staff to take such exams or by tying up with universities in Europe and the US for giving joint degrees or diploma courses.²⁹ Thus, again the issue is of getting international certification and aligning Indian standards with internationally accepted ones. It was also noted that Indian companies have little knowledge about the regulatory conditions in the EU, which makes such alignment more difficult.

Once a company has been accredited, it becomes easier to get accreditation from other governments. It was felt that either CAP certification or getting lab certified by one of the EU countries would make it easy to get lab certification from other EU member countries given broad equivalence in standards within the EU. The critical issue is awareness and sensitization of EU countries regarding Indian CROs and labs. Thus more Indian labs and CROs need to be accredited internationally by getting CAP certification which is universally accepted and meanwhile efforts need to be made to get our NABL recognized by international standard-setting bodies. Given that a substantial part of India's work is for the EU, India should align its legislation with that of Europe by building in additional provisions that are missing in its legislation.

9.2 Insurance sector

Several problems have to be addressed internally in our health insurance sector. Further opening up of the insurance sector is part of the solution as this would enable more joint ventures between Indian and overseas insurance companies but would also make possible the provision of insurance by Indian companies to foreigners to cover

²⁹ The University of Cranfield has tied up with Indian Clinical Research Institute to give a joint degree. Clinical research centers have come up with affiliations with universities in Europe and the US to give diplomas.

treatment in India.

In addition, several transparency issues have to be sorted out in India. One of the main problems affecting the take-off and penetration of health insurance in India is the lack of standardization and proper classification of services for payouts. Health insurance companies and providers need to arrive at a common nomenclature and classification of diseases and procedures and agree on a tiering of institutions and products to arrive at a differential pricing model based on facilities, standards, personnel, treatments, etc. There has also been a problem with Third Party Administrators and repayments. For these problems to be sorted out, quality benchmarking and its enforcement through the accreditation process of hospitals will need to take off. Insurance companies must accept the accreditation process of Indian hospitals.

To tap the out-of-pocket market for patients, there is also a need to develop attractive packages, such as in the area of alternative treatments and medicines. This will, however, require getting certain procedures and drugs registered with the DCGI. State governments will need to take these initiatives jointly with private providers and promotional campaigns will also be required.

Malpractice insurance is also important. This has to be bought in the client country at present. Opening up the insurance sector could create possibilities for purchasing the policy in India and reduce this cost. Clinical trials insurance is another area which needs to emerge in India to cover CROs engaged in clinical trials work. Such policies are very expensive at present and again more joint ventures and liberalization of the insurance sector could see the emergence of Indian companies entering this segment of insurance.

9.3 Administration and operational issues

The need for administrative and operational streamlining and improvements in efficiency were also pointed by several respondents, especially in the clinical trials area. It was felt that the approval process for a CRO that wishes to undertake clinical trials work is very slow, due to the lack of sufficient and qualified human resources in the DCGI, the cumbersome ethics committee approval process, and the multiple government agencies (ICMR, DCGI, Ministry of Commerce, Ministry of Environment) involved in giving approvals. As noted by one respondent, there is need for a centralized office that clears these approvals quickly and is better equipped technically to evaluate the applications for clinical trials. The ethics framework also needs to be streamlined. It was suggested that India look at the framework for the USFDA or the EMEA and copy that set up in terms of the institutional apparatus for granting approvals for clinical trials. More clarity is also required on what kinds of studies are permitted and under what conditions.

The Medical Council of India was seen as major bureaucratic hurdle, which needs a change in mindset. In some areas such as paramedical training, it was felt necessary to establish some kind of regulatory body to standardize and regulate the standards of training and output of paramedics.

9.4 Human resources

The lack of sufficiently trained and quality manpower and the lack of a research mindset were highlighted by many respondents. These problems have to be addressed through improved training, setting up more training institutions, aligning the curriculum to international standards, and gearing research and training to the needs of particular sectors and specialties. For example, in the clinical trials area, it was felt that India lags behind the US and Europe due to personnel and skill issues and because training is not geared towards the needs of the pharmaceutical sector or emerging research areas. Scalability of operations is constrained by the shortage of trained personnel combined with growing attrition.

9.5 Regulation of clinical establishments

There is a need to stipulate minimum standards for clinical establishments to enable effective regulation. These standards must be comprehensive and cover all aspects of medical establishments, from the standard of infrastructural facilities to professional standards. In line with international best practices, licenses should be granted initially based on some form of external evaluation and compliance with these minimum standards. The constitution of a National Council has been recommended and representatives from quality assurance organizations such as NABH need to be inducted into this council. More clinical establishments in the country need to take advantage of the accreditation system that is being put in place by regulatory bodies such as NABH and NABL. Eventually, international recognition should be sought for these national standards.

10. Conclusion

This report has outlined the opportunity segments as well as constraints in India-EU relations in the health services sector based on primary as well as secondary evidence. The corroboration of the discussions with sector specialists and experts based on secondary sources clearly show that it will be difficult to realize any major breakthroughs in the India-EU negotiations in this sector. The lack of an internal mandate to form a single market in health services is itself a reflection of the difficulties in negotiating greater market access to the EU in this area. Therefore, the most pragmatic approach is to launch joint programs with selected countries in the EU on a pilot basis in all possible segments of opportunity and to scale these initiatives depending on the outcome. A cooperation-based approach would be more applicable in this sector. Also, stakeholder buy-in will be essential and thus a limited and gradual approach is appropriate. Meanwhile, a variety of internal measures and regulatory reforms need to be adopted in India if these opportunities are to be scalable and sustainable in the long run. A chapter on cooperation that covers various aspects of domestic regulations pertinent to health services would be important to negotiate.

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Appendix A

EU Data Protection Directive

Box A1: Selected features of the EU Directive on Data Protection

The Directive has two basic objectives: first, to protect individuals with respect to the “processing” of personal information; and second, to ensure the free movement of personal information within the EU through the coordination of national laws (Article 1).

Personal information is defined as information relating to an identified or identifiable natural person. An identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity (Article 2).

The scope of the Directive is very broad. It applies to all processing of data, on-line and off-line, manual as well as automatic, and all organizations holding personal data. It excludes from its reach only data used “in the course of purely personal or household activity” (Article 3). The Directive establishes strict guidelines for the processing of personal information. “Processing” includes any operations involving personal information, except perhaps its mere transmission (Article 2). For example, copying information or putting it in a file is viewed as “processing.” The substantive aspects of the Directive’s privacy protections are based on the Guidelines on the Protection of Privacy and Transborder Flows of Personal Data adopted by the Organization for Economic Cooperation and Development (OECD) in 1981.

Data Quality. The Directive requires that all personal information must be processed fairly and lawfully, so that, for example, a person whose personal information is at issue knows that it is being collected and used and must be informed of the proposed uses. Furthermore, the use of personal information must be limited to the purpose first identified and to other compatible uses, and no more information may be collected than is required to satisfy the purpose for which it is collected. In other words, the theory is that if a person provides information to obtain telephone service, that information should not be used to target that person for information about vacation trips, nor should information relevant to a customer’s interests in vacation trips be required to get, for instance, telephone service. Information must also be kept accurate and up to date (Article 6).

Legitimate Data Processing. The Directive sets forth rules for “legitimate” data processing. Most basically, this requires obtaining the consent of the data subject before information is processed unless specific exemptions apply (Article 7). In addition, certain information must be provided to data subjects when their personal information is processed (Article 10), such as whether they have rights to see the data, to correct any information that is inaccurate, or to know who will receive the data (Article 12).

Sensitive Data. “Sensitive” data, such as that pertaining to racial or ethnic origins, political or religious beliefs, or health or sex life, may not be

processed at all unless such processing comes within limited exceptions, for example if the individual gives explicit consent (Article 8).

Security. The Directive requires that “appropriate technical and organizational measures to protect data” against destruction, loss, alteration, or unauthorized disclosure or access be taken (Article 17).

Data Controllers. The Directive requires those processing data to fulfill very specific requirements. Specifically, they must appoint a “data controller” responsible for all data processing, who must register with government authorities (Article 19) and notify them before processing any data (Article 18). Notification must at a minimum include: the purpose of the processing; a description of the data subjects; the recipients or categories of recipients to whom the data might be disclosed; proposed transfers to third countries; and a general description that would allow a preliminary assessment of whether requirements for security of processing have been met (Article 19).

Government Data Protection Authorities. The Directive also mandates a government authority to oversee data processing activities. Each Member State must establish an independent public authority to supervise the protection of personal data. These “Data Protection Commissions” must have the power to: (1) investigate data processing activities and monitor application of the Directive; and (2) intervene in the processing and to order the blocking, erasure, or destruction of data as well as to ban its processing. They must also be authorized to hear and resolve complaints from data subjects and must issue regular public reports on their activities (Article 28).

Transfers of Data Outside the EU. Most importantly from the U.S. perspective, the Directive requires that Member States enact laws prohibiting the transfer of personal data to countries outside the European Union that fail to ensure an “adequate level of [privacy] protection” (Article 25). Where the level of protection is deemed inadequate, Member States are required to take measures to prevent any transfer of data to the third country. Member States and their Data Protection Commissions must inform each other when they believe that a third country does not ensure an adequate level of protection.

Source: http://www.export.gov/safeharbor/sh_overview.html
http://www.export.gov/safeharbor/sh_workbook.html

Appendix B

Recognition of professional qualifications in the EU³⁰

General system for the recognition of professional qualifications

The Directive distinguishes five levels of professional qualifications which encompass the general system of evaluation of qualifications. These are as follows:

- attestation of competence which corresponds to general primary or secondary education, attesting that the holder has acquired general knowledge, or an attestation of competence issued by a competent authority in the home Member State on the basis of a training course not forming part of a certificate or diploma, or of three years professional experience;
- certificate which corresponds to training at secondary level, of a technical or professional nature or general in character, supplemented by a professional course;
- diploma certifying successful completion of training at post-secondary level of a duration of at least one year, or professional training which is comparable in terms of responsibilities and functions;
- diploma certifying successful completion of training at higher or university level of a duration of at least three years and less than four years;
- Diploma certifying successful completion of training at higher or university level of duration of at least four years.

On an exceptional basis, other types of training can be treated under one of the five levels.

Minimum training conditions for the medical profession Sector specific conditions are laid down for various professions, including health professionals. These conditions are as follows:

- **Doctor:** basic medical training precedes specialist medical training or the training of general practitioners.
- **Basic medical training:** admission to basic medical training shall be contingent upon possession of a diploma or certificate providing access to universities or equivalent institutes which provide higher education and shall comprise a total of at least six years of study or 5 500 hours of theoretical and practical training provided by, or under the supervision of, a university.
- **Specialist medical training:** admission to specialist medical training shall be contingent upon completion of six years of study in basic medical training and comprise full-time theoretical and practical training at a university or other recognized centre for a minimum duration which is not less than the duration specified in the Directive (such as, for example, 5 years for the specialization in general surgery).
- **Training of general practitioners:** admission to general medical training shall be contingent upon completion of six years of study in basic medical

³⁰ The discussion is based on the following sources: Eur-Lex Directives 2005/36/EC, 93/16/EEC, Healthcare Professionals Crossing Borders Agreement (2005), Polak, G., (2007), Gerlinger, T., and R. Schmucker (2007).

training and comprise full-time practical training in an approved hospital, for a minimum duration of two years for any training of general practitioners leading to the award of evidence of formal qualifications issued before 1 January 2006, and of three years for certificates of training issued after that date.

- **Nurses responsible for general care:** admission to training for nurses responsible for general care shall be contingent upon completion of general education of 10 years, as attested by a diploma or other recognized certificate, shall comprise at least three years of study or 4 600 hours of theoretical and clinical training on a full-time basis, and shall include at least the program described in the Directive.
- **Dental practitioners:** admission to training as a dental practitioner presupposes possession of a diploma or certificate giving access, for the studies in question, to universities or higher institutes of an equivalent level, and shall comprise a total of at least five years of full-time theoretical and practical study, comprising at least the program described in the Directive.
- **Veterinary surgeons:** admission to veterinary training shall be contingent upon possession of a diploma or certificate entitling the holder to enter, for the studies in question, university establishments or institutes of higher education of an equivalent level, and shall comprise a total of at least five years of full-time theoretical and practical study at a university or other recognized higher institute, covering at least the study program referred to in the Directive.
- **Midwives:** access to training as a midwife shall be contingent upon the following routes:- completion of at least the first ten years of general school education. In this case, it entails specific full-time training as a midwife comprising at least three years of theoretical and practical study covering at least the program described in the Directive;
 - possession of evidence of formal qualifications as a nurse responsible for general care. In this case, it entails in total at least a specific full-time training as a midwife of 18 months' duration, covering the study program described in the Directive.
- **Pharmacist:** admission to a course of training as a pharmacist shall be contingent upon possession of a diploma or certificate giving access, for the studies in question, to universities or higher institutes of an equivalent level, and shall include training of at least five years' duration, including at least four years of full-time theoretical and practical training at a university and a six-month traineeship in a pharmacy which is open to the public or in a hospital.

Appendix C

Barriers to India's Telemedicine Exports to the EU

(a) Data Protection, privacy, and information security issues

EU regulations do not permit data on EU patients to be sent outside the EU region for cross-border reporting and diagnosis on the grounds of data security and confidentiality, unless there is a legal basis for the transfer. Legal basis may be provided if the European Commission issues an official “adequacy finding” for a country which determines that the country offers an adequate level of data protection on the basis of its national laws. The European Commission has, however, issued only a very small number of adequacy determinations for countries such as Canada, Argentina, and Switzerland. India is not included in this list. While there are other legal bases for international data transfers where a country has not received an adequacy finding (e.g., prior consent, execution of standard EU-approved contractual clauses, binding corporate rules subject to the approval of EU Data Protection Authorities), these regulations impose additional costs and complexity to outsourcing transactions undertaken by Indian telemedicine providers,

There are also stringent national-level legislations on data and information security and data privacy relating to disclosure and use of Protected Health Information. There are associated administrative, physical, technical, and organizational costs of compliance. For instance, there is need to adopt information security standards along the lines of the British Standard for Information Security management, BS-7799 and to get certified. Compliance with EU data protection laws is also complicated by the lack of harmonization among Member States as even basic concepts of the General Directive, such as the definition of personal data differ across countries, creating problems of interpretation and compliance.

Indian providers note that the restriction on outsourcing patient data on the grounds of data protection has no basis since data security depends on having electronic security and necessary IT protocols, as is the case with other IT-enabled services where work in finance, HR, etc. is outsourced to India and delivered by Indian IT and BPO companies. It has nothing to do with the geographic territory where the work is done. Given the high level of IT security systems and protocols in place in India's IT industry, restrictions on outsourcing of data on data security grounds are not justified. Though the UK's BS7799 security protocol is slightly more stringent than the US' Health Insurance Portability and Accountability Act (HIPAA), Indian companies already adhere to the HIPAA and BS7799 data security protocols. Indian telemedicine providers have been validated by overseas establishments in the US and even the National Healthcare Group of Singapore for data security compliance and some have tie-ups with MNCs. Servers and systems are robust enough for compliance with the EU's data confidentiality norms. Companies doing such work have ISO, BS7799, and HIPAA compliance. They have physical, administrative and technical checks to control data leakage. It is always possible for the client to audit the company on a regular and random basis to certify the level of data security and compliance.

Respondents noted that there is little cause for concern as providers have to sign all the clauses laid down by the client. If one signs an agreement with an EU client, the

client country and EU clauses would have to be agreed to when taking on this work. There is a set of legislation on patient data protection and anonymization of data through coding, etc. in the EU, which need to be followed. Patient confidentiality is also not a problem as the data tends to be coded, anonymized, and morphed. Moreover, the data is secure as it resides in the clients' servers and only the work is done remotely. But there is little awareness in the EU about existing standards of security in Indian companies. Although TCS has done software development work for the NHS database, with much of this development being done in India, the NHS is not willing to outsource the same information to India for reporting purposes. Unless the EU restriction on sending patient data to non-member countries is relaxed, India's potential in telemedicine cannot be tapped in the EU region.

The issue of data protection has been raised in the Joint Economic and Trade Committee (JETCO) meetings between India and the UK, but with no progress. However, many respondents feel that these restrictions will eventually be relaxed by the EU. The NHS has supposedly verbally committed to outsourcing to India and third countries outside the EU within two years. In anticipation of these changes, some Indian telemedicine providers are adopting strategies to prepare for this opportunity. The most promising markets are seen to be the UK and the Scandinavian countries of Denmark, the Netherlands, and Sweden. Some Indian companies are establishing a commercial presence and partnerships to enter the EU market. They are incorporating subsidiaries in EU member countries or obtaining subcontracted work to local offices based in the EU.³¹ However, none of the respondents felt that making use of an overseas commercial presence to service the telemedicine market in the EU is scalable as this would not enable Indian providers to leverage their cost advantage. Scaling up the business could only occur if the work was directly outsourced to India and hence the restrictions on international data transfer are a critical barrier in the telemedicine area.

(b) Recognition and accreditation issues

In order to provide telemedicine, the establishment needs to be accredited by the relevant authorities in the client country. Accreditation of the establishment also requires the recognition and board certification of the company's technical manpower by the relevant authorities in the client country.

In Europe, each country has specific regulations for certification of radiologists. Indian telemedicine providers are following the strategy of getting their professionals empaneled and registered in the client country. Some keep the registration and certification of their staff ready so that they can take advantage of the opportunities created as soon as the EU decides to outsource beyond the region.

The main concern of Indian telemedicine establishments is the cumbersome certification process. In the UK, Indian radiologists can report from within the EU

³¹ There is thus a link between Mode 1 and Mode 3, with the latter enabling the former, but even if an Indian telemedicine providers were to establish a commercial presence in an EU country, it would not be permitted to do direct telemedicine delivery from India. Any outsourcing work would have to be done through this commercial establishment based within the EU for doing such business with EU countries. The commitments made by the EU in health services in Mode 1 are largely unbound and this linkage is thus not inscribed.

territory, provided they register with the UK's General Medical Council (GMC). In order to be able to service a contract in the UK, one needs physicians who are registered in the UK. Indian radiologists have to certify as Fellows of the Royal College of Radiology, following which they can register with the GMC. It is necessary to pass the exam given by the Royal College of Radiologists to demonstrate competence. As four years of residency are required in the UK for board certification while in India there are only three years of residency, the remaining one year of research and training has to be made up through certification. There has been some relaxation of the regulations with the GMC accepting senior residency or Associate or Junior Professorship in lieu of the remaining one year of training to qualify for certification.

Following this, the registration application has to be filed with the GMC. The GMC requires documentation of all training, 5-10 reference letters from the applicant's colleagues, a log of all training and procedures done since the person started working (which is often not possible), 360-degree appraisal, including from patients, ward boys, peers, seniors, and referral checks involving a 25-page format. These have to be submitted in prescribed formats. There is excessive detailing of filing specifications, the CV, and sub-items of information such as clinical experience, teaching, administration, research, and college activities. It can take 3-4 months to gather the documentation and another 2-3 months to address the queries raised by the GMC. There is a final requirement for the applicant to go in person and identify himself/herself to get registered and considerable paperwork for security clearance. It was further noted that there is implicit discrimination in the GMC registration process between EU member country professionals, such as those from Eastern Europe, and others such as from India.

These details of the certification and registration process were provided by an Indian company based on its experience in deploying staff to its UK-based delivery center. The company had to apply to the UK board for radiology, the Postgraduate Medical Education and Training Board (PMETB), then get its cases referred to the Royal College of Cardiology for certification, and subsequently get registered with the British GMC. According to Manipal's experience with this project, the time to get the person certified and registered and over to the local delivery center in the UK was around one year, while the contract duration was shorter than a year.³² In addition, it cost £15,000 for certification and £300-400 for GMC registration. There is a defined filing procedure with an application fee of £1500 per person, which is not refundable. In addition, there is the cost involved for the visa, the physical appearance, and the costs for the process of filing and contracting a vendor to help with the filing, paperwork, and queries. Only after the GMC registration is over can the Indian radiologist work in the UK. However, companies are willing to undergo this process of certification and registration as it helps prepare them for future outsourcing from the market and establishes them as credible providers from their home country. There

³² The company has sent its staff on a rotational basis for a period of stay that is less than 183 days in a fiscal year, in order to get treatment as a non-resident and thus avoid taxation. So, its deployed personnel stay for 6 months in any year. Invoicing is required for the doctor who is sent there and is treated as a non-resident. This person is recruited by Manipal Health Services and is sent on deputation to the UK while Manipal continues to pay him here and invoice its UK-based delivery centre. Thus, the company makes use of its local presence in the UK to take advantage of the tax regulations for non-residents.

are also potential spin-offs in other areas such as medical value travel, education, and research.

There is also the issue of overall accreditation of the telemedicine establishment in India. Some of the current providers doing business with the US are internationally accredited, by the Joint Commission International (JCI) in the US or by the Ministry of Health in Singapore. Some of the established telemedicine providers have had to undergo a rigorous process of evaluation and subsequently received blanket accreditation along with regular audits from their client countries. The companies interviewed felt that EU countries are likely to have very stringent accreditation processes as well if and when they outsource telemedicine work to non-member countries. It was not clear whether EU countries would accept the type of certification provided by the JCI or the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) or whether separate certification would be required in individual EU countries and how onerous the requirements might be. But it was also evident that the established providers preferred a rigorous accreditation process which would audit their internal systems, data security measures, etc. over a blanket restriction on outsourcing without any evaluation, citing their accreditation experience with the Government of Singapore as a model to be emulated. They also felt prepared for such an evaluation process given their investments in IT, infrastructure, personnel, and physical and administrative systems and processes.

The regulations in one specific area of telemedicine, namely, teleradiology services, illustrate the stringent and cumbersome legislation in the EU. Selected eligibility and operational requirements for teleradiology companies and teleradiologists are provided below. Note: * indicates requirements that are most pertinent to Indian providers.

*Eligibility and operational requirements for teleradiology companies*³³

Teleradiology companies which provide reporting of medical images of EU citizens:

- Should be registered with the Healthcare Commission or equivalent in each EU Member State where their patients reside, and be subject to its regulations/standards.*
- Only fully qualified specialist clinical radiologists should provide the teleradiology service. They must be properly accredited and registered within the European Community. They should be formally registered in the country in which the teleradiology services are being provided, and should also be registered and subject to quality and revalidation requirements of the EU Member State for which they wish to provide teleradiology services.*
- Teleradiology Providers should ensure that teleradiologists reporting imaging of patients in a particular Member State comply with the regulation revalidation annual appraisal and other national Clinical Governance Regulations of that Member State.*
- Teleradiology Providers should ensure security and privacy of transmitted patient data comply with EU and National Directives*
- Teleradiology providers should have adequate medico-legal and insurance

³³ Ibid.

cover.*

- The reporting radiologist must have a proper knowledge of the national language of the source country. This is enshrined in the qualifications directive and should be monitored by the national or regional authorities.*

*Eligibility and operational requirements for teleradiologists*³⁴

A teleradiologist who reports on medical images of EU patients should:

- Be registered with the Medical Regulatory Body of each EU Member State where his/her patients reside.*
- Should be on the Radiology Specialist Register of the Medical Regulatory Body of each Member State where his/her patients reside.*
- Should have individual insurance/indemnity cover for each of the Member States where his/her patients reside.*
- Must have a proper knowledge of the language(s) of each Member State where his/her patients reside, as required by the EU Qualifications Directive 2005.*
- Should have a “Certificate of Current Professional Status” when applying for registration with a Medical Regulatory Body.
- If providing teleradiology services for patients in another EU Member State, teleradiologists should be subject to the same regulatory requirements as local radiologists. Such specific national medical regulatory arrangements may include revalidation, recertification, relicensure, annual appraisal.*
- Teleradiologists should be subject to the regulations applied to locum doctors by the Medical Regulatory Body in each Member State where his/her patients reside.

(c) Contractual issues

At present, Indian provider companies purchase malpractice policies in the client country market and buy separate malpractice policies for each contract. As malpractice environments and the limits of coverage vary across countries, this poses practical difficulties for Indian telemedicine establishments. It is not clear how this would be tackled in the case of EU countries where state insurance trusts play an important role and liability regulations may be more stringent.

Breach of contract and jurisdictional issues are also likely to pose difficulties in entering into contracts with EU countries, given the problems with the Indian legal framework. To give comfort to the client, all contracts need to be settled in overseas courts in case of a breach, which would impose additional costs on the provider. Due to legal concerns regarding liability, indemnity, and non-disclosure, service level agreements can take 8-16 months to be established in the case of US clients, and this is also likely to be the case with EU clients.

For every investigation, the patient’s consent is required. The process of obtaining patient consent is both cumbersome as well as prohibitive. This could pose challenges in getting more business in the EU.

³⁴ Fitzgerald, R., “Regulation of Teleradiologists and Teleradiology Providers in the EU”, Royal College of Radiologists, UK

(d) Perceptions, attitudes, and stakeholder resistance

Due to problems with perceptions about India as well as low levels of acceptability and exposure to such technology among EU patients, there could be resistance to telemedicine in the EU.³⁵ An added challenge is the relatively lower flexibility in the EU compared to the US, where the former is more state-driven in its approach to healthcare while the latter is more institution-driven and thus more amenable to new technologies and approaches to healthcare delivery. Coupled with this are linguistic, cultural, and social barriers. For example, reports need to be interpreted in the client country's language and accurate translation is required. A locally-certified radiologist and translator is required in the client country or persons of EU origin based in India have been used to do the translation work.

EU governments are also sensitive to privatizing such services. Although government procurement of such services could involve further outsourcing to private players with possible sub-contracting to private providers in other countries, this is not likely to take off very fast in the near future. There is also resistance from the professional lobby in those countries to telemedicine for fear of displacement.³⁶

³⁵ It is worth noting that the UK government itself has had problems with patient record management and lost the detailed records of some 20 million people recently.

³⁶ The example of the US was given where earlier Indian providers were doing teleradiology for the Massachusetts General Hospital but due to lobbying by the American Association of Radiologists, such work was restricted to US Board Certified Radiologists and legislation passed restricting even the preliminary reading from being done by non-US certified radiologists.

Appendix D

Barriers to Clinical Trials and Research Outsourcing

(a) Standards and Accreditation

Some Indian companies already conduct clinical trials for European pharmaceutical companies. They need to get accredited by the client by proving conformity with the client country's accreditation norms and standards for conducting clinical trials. This includes meeting their guidelines on Good Clinical Practice (GCP), Good Manufacturing Practice (GMP), and Good Tissue Practice (GTP). GCP is mandatory for anyone involved in clinical trials and the CRO's competence and adherence to this standard is validated by the sponsor company. Since the clinical trials are not done at one center but involve several hospitals and different ethics committees, the work has to be coordinated according to GCP guidelines and client specifications. This involves proper documentation by the CRO and demonstration of competence to be principal investigators for the clinical trials work and investments in periodic training.

Each country has its own GCP standards but they are mostly in line with the guidelines of the International Conference on Harmonisation (ICH). As the EU, the US, and Japan are members of the ICH, their standards and accreditation for clinical trials largely conform to the ICH guidelines on GCP. India has also taken steps to align its own GCP guidelines to international regulations. The 2006 and 2007 guidelines by the Indian Council for Medical Research (ICMR) and the Department of Biotechnology (DBT) are very much in line with the international guidelines on GCP, GMP, and GTP. Hence, showing conformity with global practices and standards is not a major problem for Indian CROs.

Laboratories that are engaged in clinical research need to get certification from the client country's authorities. Some Indian CROs have obtained certification from the College of American Pathologists (CAP); this US standard for accrediting labs is recognized internationally and enables the Indian CRO to undertake global clinical trials from India. Other Indian CROs have affiliated themselves with overseas labs to get certification for conducting global clinical trials. Clinigene, a CRO, is affiliated with a Belgian lab called Esoterix (which is a part of the Lab Corporation Company based in the US); the affiliation gives the company international certification. One company has got its toxicology lab accredited by the Dutch GLP authorities. Depending on the clinical research and trials segment, additional accreditations may be required. For instance, in the area of stem cell research, accreditation is required from the Foundation for Accreditation for Cellular Therapy (FACT). To conduct Phase II-IV clinical trials, certain accreditation exams have to be taken to prove competence. These are compulsory requirements for any CRO.

The accreditation process involves adherence to certain norms with regard to physical infrastructure, operating procedures, qualification and training of personnel, proper documentation, and demonstration of staff competence for the work undertaken. Preparedness for the annual audit is important. Most respondents felt that many Indian CROs are in a position to get such accreditation from overseas, including EU country authorities.

(b) Norms for clinical trials

The importance of adherence to global and national standards in the conduct of clinical research and trials for EU countries is evident from the following summary of regulations for the UK.³⁷

Medicines for Human Use (Clinical Trials) Regulations 2004 (the Regulations) regulate clinical trials in the UK since they came into force on May 1, 2004. The EU Directive requires "competent authorities" of the Member States to perform certain functions in relation to clinical trials. The UK competent authority responsible for those functions is the "licensing authority", which acts through the Medicines and Healthcare products Regulatory Agency (MHRA).

- Pharmacology studies in healthy human volunteers (Phase 1 studies) require authorization from the MHRA where previously they only needed the favorable opinion of an ethics committee.
- Investigational medicinal products (IMPs) must be manufactured to good manufacturing practice (GMP) standards and the manufacturer must have a manufacturing licence.
- Each trial must have an identified sponsor who takes responsibility for its initiation, management and conduct. The Regulations allow a group to collaborate to take on these responsibilities.
- Establish an ethics committee system on a statutory basis.
- Require all clinical trials to be conducted in accordance with the principles of good clinical practice (GCP).
- Provide additional protection for minors and physically or mentally incapacitated adults who are candidates for clinical trials.
- Require sponsors to provide trial medicines free of charge to patients if they are not covered by a prescription charge.
- Provide for inspection by the MHRA for GCP and GMP to help ensure those standards are maintained.
- Provide for enforcement of these new provisions.

The two main international norms required of companies undertaking clinical trials are good clinical practice and good manufacturing practice. As stated in the UK regulations:

- The requirement to conduct all clinical trials in accordance with the internationally recognized principles of Good Clinical Practice (GCP), will help to ensure that all UK trials are conducted to the appropriate high standard and that risks to patient volunteers are minimized.
- The requirement to manufacture investigational medicinal products to Good Manufacturing Practice (GMP) standards will help ensure that trial participants are not exposed to poor quality or badly prepared medicines.

Inspections by the Medicines and Healthcare products Regulatory Agency (MHRA)

³⁷ Discussion based on the following sources: Bakhle, D., (2003), FICCI (2005), Julka, P.K., (2007), Lubbock, M., and Depuydt, A., (2007), Eur-Lex Directive 2001/20/EC, Timmermans, K., (2007).

to check that the principles and standards of GCP and GMP are being followed will improve the overall quality of UK clinical trials and help identify non-compliance. If misconduct persists or inspectors suspect fraud, the regulations provide powers of enforcement.

There are provisions to protect adults through requirements of informed consent and transparency in the undertaking of clinical trials and various other conditions to prevent exploitation of any kind of patient. There are also pharma-covigilance arrangements whereby investigators and trial sponsors together must record serious unexpected adverse reactions thought to be caused by the trial medicine and report them to the MHRA. Assessors at the MHRA can identify safety signals from these reports indicating when trial participants are at increased risk and the trial should be modified or stopped.

(c) Data protection

Data protection remains a key concern, although Indian companies are already in the clinical data management business given their IT strength, and some pharmaceutical MNCs have set up subsidiaries in India and tied up with IT companies like TCS to do clinical data management.

Most of the data protection concerns are not legitimate. To ensure data security, the client company performs a detailed audit of the data protection system in a CRO, such as the design of facilities, how data is sent across floors, and background checks on personnel. The research company signs the EU directive and the client country clauses as part of the contract. Thus, any violations are subject to penalties and disputes are to be tried in the client country's courts or in some neutral territory, not in India. Moreover, there are IT security protocols in place for data management, which conform to UK or US standards. Data exclusivity is also signed by a CRO since the sponsor or mother company owns all data and analysis, publications, and scientific claims; even CROs that are subsidiaries of biotech or pharma companies sign data exclusivity agreements to prevent conflict of interest between the parent and client company.

(d) Manpower mobility

Clinical trials outsourcing needs to be supported by policies that facilitate the mobility of technical manpower from both sides. The EU is restrictive about issuing technical visas, usually giving short duration, single-entry visas. As CROs often need to send technical manpower to the client country, this can pose a barrier.

Appendix E

Barriers to Medical Value Travel Exports

(a) Regulations affecting insurance portability

A key requirement for medical value travel from the EU to take off in India is insurance portability, i.e., state insurance trusts or private insurance companies need to accept the treatment provided by Indian doctors and healthcare establishments for reimbursement.

The best known restriction is that the flight time between the UK and the country where the medical care is received cannot exceed 3 hours; this prevents NHS patients from seeking medical care in India. Since removing this restriction would help the NHS address its own capacity shortages, this issue has been discussed in forums such as the bilateral Indo-UK initiative under JETCO (Joint Economic and Trade Committee), but there has been no progress.

Another impediment is the fact that the majority of healthcare in the EU is public. The bulk of the population is covered by public health insurance trusts and a minority of around 20 per cent is covered by private insurance. The voluntary health insurance segment is small as is the out-of-pocket paying/non-insured population, given the generous state health insurance schemes. Thus, for medical value travel to expand from the EU, public health insurance providers would need to recognize healthcare provided in India as equivalent to what is provided there under the public health system, for reimbursement purposes. This creates problems because national health systems would need to publicly accept their failure to meet the health requirements of their people and would also pose the challenge of officially ensuring equivalence between the quality and standards of the health systems and getting this politically and socially accepted among the public (which would be subject to problems of perception about India). A proposal was mooted for a pilot program with the NHS on medical value travel for selected treatments and providers, but it did not take off.

There has been some discussion about private insurance portability to India, but no progress. Under JETCO, there were talks of tie-ups between reputed Indian hospitals and insurance companies in the UK for specific groups who could be covered for treatment in India. Wockhardt and Apollo have been trying for tie-ups with health insurance companies like BUPA and Standard Life Insurance, which are interested in India's health insurance market. BUPA sought tie-ups with Indian hospitals for reimbursement of specified amounts and for selected institutions and procedures, but this private initiative did not take off. If this tie-up were to materialize, it would be possible to get reimbursement from the NHS to BUPA International as a third party. However, overseas insurance companies have voiced concerns over the quality of the treatment delivered in India and whether treatment in India is justified.

Indian hospitals are also interested in tying up with multinationals, including companies in the EU, to cover their employees for medical treatment in India for specified procedures and operations. While such corporate tie-ups are possible, the unions of those companies have objected. The benefits of medical value travel to private insurance companies in the EU need to be better highlighted. There has been

insufficient marketing of the gains to private insurance companies, especially for preventive and maintenance surgeries, and this lack of awareness impedes tie-ups between insurance companies and private hospitals in India.

With regard to alternative medicine, while India is seen as a potential destination, there are problems of reimbursement as these treatments and therapies are not recognized for lack of scientific evidence and registration. There are also regulations on the sale of alternative medicines in the EU that restrict sales to specified conditions; further, the medicines may need to be registered, which complicates reimbursement for such treatment in India.

(b) Growing competition

The EU is becoming more sensitive to the issue of greater choice for patients and there are discussions among EU governments to facilitate cross-border mobility of their patients and reimbursement for approved treatment in other member countries. India will be at a disadvantage compared to its competitors in Eastern Europe, which would benefit from the understanding among EU member countries regarding recognition of qualifications, insurance portability, e-health interoperability, and movement of persons.³⁸

(c) Perception and other issues

One of the biggest challenges in expanding medical tourism from the EU is the perception that India has poor hygiene and infrastructure. Added to this are problems of cultural and linguistic differences, and the difficulties involved in travel and stay. There is also sensitivity to publicly accepting India as a treatment destination. For instance, a recent article notes that although the Indian Health Minister had proposed lifting the three-hour flying time limit and the UK Department of Health has still not decided on the issue, the UK public is opposed to the idea of flying all the way to India for treatment at taxpayer's expense; the NHS is seen as a symbol of national pride and accepting treatment in India would be akin to accepting the failure of their public health system. A spokesperson for the UK Department of Health has said, "The government is very clear that the NHS will not pay for health tourism...the proposal to fly NHS patients there for treatment is not being considered."³⁹ Such sensitivities are a critical barrier to medical value travel exports from India to the EU.

³⁸ The EU is, however, facing problems in cross-border movement of patients and their reimbursements and several cases have been filed in European courts. Thus, the difficulties in enabling cross-border movement of patients to non-member countries like India and reimbursement are likely to be immense.

³⁹ Business Standard, March 4, 2008, p.16.

Appendix F

Barriers to Back Office Services Exports from India to the EU

(a) Accreditation issues

Certification is required in segments such as medical coding and analysis, where medical coders need to be certified by the concerned regulatory bodies in client countries. In the US it is the American Association of Professional Coders; one needs to get certification from this body and also undertake continuing credits to maintain certification status. The EU does not have a similar certifying body. Thus, certification by US authorities would need to be acceptable to the EU (which according to respondents should be possible given the very stringent requirements for medical coding certification in the US).

(b) Limited scope of the EU market

Given the dominance of the public health insurance trusts in the EU, unless there is political acceptance of outsourcing back-office work there may not be as much scope in the EU as in the US. Coding work would have to be offered to the EU for data analysis and diagnostic purposes rather than reimbursement purposes given the more limited market for health insurance back-office services in the EU.

(c) Data privacy and restrictions on international data transfer

The EU directives concerning international data transfer and requirements of compliance and empanelment by EU Data Protection Authorities will limit the scope for India's medical back-office support services. There will also be the issues of compliance with country-specific data security norms, such as BS7799. The main problem is lack of awareness in the EU about systems in India: Indian companies follow strict IT security norms, Indian companies handling outsourced work are BS7799 and HIPAA compliant and are open to audits of their IT security protocols by clients, and the data do not cross borders with only the work being done remotely.

Appendix G.

Constraints on Collaboration between India and the EU

Although there are opportunities in the area of staffing and temporary movement of personnel, this is constrained by political and social sensitivities and immigration barriers for non-EU medical personnel relative to EU nationals. The recent experience in the UK with the treatment of Indian doctors receiving training in that country is a case in point.⁴⁰ Another constraint is that Indian medical qualifications are not recognized by EU member countries (just as the Medical Council of India does not recognize the medical qualifications of EU countries). As pointed out by one company, lack of recognition requires Indian healthcare providers to get their doctors registered and certified in the UK at a cost of around £12,000-18,000 per doctor. In the design and production of medical devices or testing of medical equipment, the constraints are mainly regulatory or implementation-related shortcomings in India. These are in the form of ethical regulations, liability and compensation-related concerns, and lack of internationally accepted standards for registration of medical devices and technologies in India.

⁴⁰ This refers to the recent experience in late 2007 and early 2008 where Indian doctors holding visas under the Highly Skilled Migrant Program in the UK were rendered jobless when the British government decided to give preference to European doctors in the National Health Service.

Appendix H

Domestic Constraints on India's Healthcare Services Exports to the EU

(1) Accreditation and standards

The absence of mutual recognition of Indian medical qualifications is an important constraint for Indian healthcare providers. Indian medical personnel are required to undergo cumbersome and expensive certification and registration processes. Lack of mutual recognition also prevents Indian companies from drawing upon the overseas pool of medical manpower, such as radiologists, to exploit opportunities in markets like the UK.

The root of this problem is the lack of standardization in medical training in India, across states and across medical colleges and training institutions, which is a constraint to receiving recognition from overseas medical authorities. There is considerable variation in internal standards of training, syllabi, etc. which makes it difficult for Indian medical training institutions to get certified and globally recognized. In some areas like paramedics, there is no regulatory body to set standards and nursing training is also highly variable.

This problem of divergent standards is pertinent to healthcare establishments and segments such as clinical trials and research. The lack of international accreditation by Indian healthcare establishments such as hospitals constrains India's scope for medical tourism exports. The Quality Council of India has introduced the NABH accreditation but this is not yet accepted internationally by the International Society for Quality in Health Care Inc (ISQuA) as being akin to the Joint Commission International (JCI) or Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) type of accreditation (the arguments here are on similar lines as for lab certification and international recognition of Indian standards in the case of clinical trials). Likewise, in the clinical trials and research business, very few Indian labs are internationally accredited and most Indian institutions do not yet meet the guidelines of the International Conference on Harmonization – WHO Good Clinical Practice (ICH-GCP). The Quality Council of India has introduced the National Accreditation Board for Laboratories (NABL) but it is not internationally recognized. If an Indian CRO has not got its labs internationally accredited, it may need to send its samples to Singapore for analyses and cannot do the work from India.

Although some Indian hospitals have obtained international accreditation, such as JCI certification, the process is expensive and time-consuming. While it is easy for Indian hospitals to get accredited on the clinical side, hospitals (especially the older ones) face problems with infrastructure because they have to comply with established norms for building design, space utilization, energy efficiency, safety systems, etc. that impose additional capital and land procurement costs for setting up new hospitals. It is difficult for Indian hospitals to get high ratings even if they are internationally accredited. Since one international certification may involve crores of rupees, large-scale international certification may not be possible in the near future. The lack of international accreditation by Indian hospitals, however, makes it difficult to tap the medical value travel market in developed countries and to get insurance portability.

More generally, there have been deficiencies in setting standards for clinical establishments and implementation has remained ineffective, further compounded by the multiplicity in the types of clinical establishments. At the Central level, some aspects of healthcare services have been regulated through legislation, such as management of medical waste, setting up blood banks, and pre-natal diagnostic tests, but there is an absence of an overall statutory framework for the licensing healthcare establishments such as hospitals, nursing homes and clinics, and laying down the minimum standards. While some private medical establishments rank with quality institutions in the industrialized countries, due to the lack of regulation of clinical establishments many including those in the private sector are of poor standard and lack elementary facilities.

Accreditation is also relevant in the area of alternative treatments and therapies which constrains insurance portability for those seeking such treatment. The main problem is the lack of standardization in alternative medicines and therapies, with reputed providers coexisting with fly-by-night operators. Regarding reimbursement, the authorities in the EU may not recognize the different streams and the associated drugs (due to the existence of generics, for instance). There is no scientific clearance system and although regulations exist for such treatments, these have not been followed by many providers as many alternative medicine providers are not willing to register themselves.

(2) India's legal and regulatory framework

There are a variety of inadequacies in India's legal and regulatory framework. One important constraint relates to guidelines for clinical trials approvals in India. Shortcomings still persist although in the past few years clinical trials regulations have improved,⁴¹ with restrictions on certain kinds of trials (repeat Phase-I trials) being lifted (though restrictions on Phase-I first in human trials for molecules discovered abroad continue for valid reasons) and greater clarity in the guidelines for testing and registration of pharmaceutical products.⁴²

The approval process is slow and bureaucratic. CROs have to obtain multiple

⁴¹ Today, there is a lot more clarity in the approval process. Category A approval is easy to get and takes about 6 weeks, if the study is done in Europe, Japan and the US and the same protocol has to be followed in India. Category B approval is required where the work has not been done earlier. This needs more documentation and may take 3-6 months. There are approvals required for getting blood samples out of the country for the import of drugs, etc. A CRO has more approval processes as it is not into drug discovery and must demonstrate competence.

⁴² In India, one cannot do a Phase I trial for first into man in the case of new chemicals that are developed overseas. First in human trials (which are done on healthy volunteers) were earlier restricted completely. They are now permitted if the test is done by a pharmaceutical company that is into drug discovery but they are not permitted for contract research organizations. The reasons for curbs on such trials relate to concerns about India being used as a dumping ground for untested molecules and Indians being used as guinea pigs for trying out new drugs. All other phases, namely, Phases 2-4, are completely allowed, though with some time lag to allow for data about the safety and other features of the drug to be tested. The outcomes of the drugs are done on 100 healthy volunteers. There is a restriction on blood samples being taken out of India and the approval process for doing so is cumbersome. But this restriction was seen as being justified to prevent the exploitation of genetic material from India. Bioequivalence studies are freely permitted and regulations on approvals from the DCGI may be relaxed if the molecule has already been permitted for more than a defined period in the Indian market, with only ethics committee approval being required in such cases.

clearances before they can undertake clinical trials. Approvals are needed from the Ministry of Environment's Environment Committee, the Drug Controller General of India (DCGI), and the Ministry of Commerce. For import and export of live tissue and drugs for testing purposes, clearance is needed from the Ministry of Commerce and the balance of these samples has to be returned. The lack of well-defined guidelines on sourcing and ethics results in approval problems. The clearances may take several weeks or months, which makes it difficult to get business given that pharmaceutical companies want a quick turnaround. Compared to Eastern European countries, the review time is longer in India.

The ethics approval process is also very cumbersome in India as the CRO needs to be approved by multiple ethics committees, one in each hospital where they try out the drug. Even if only three patients in a hospital are involved, they need approval from the hospital's ethics committee. The process is time-consuming and costs around Rs. 25,000 per approval.

There are also shortcomings due to the absence of legislation in certain areas such as the movement of drugs within India from one point to another or the lack of procedural controls on the use of medical devices. While registration is compulsory for clinical trials, there is poor enforcement of this requirement. The lack of central laboratory accreditation that is recognized internationally (such as the CAP) is also perceived as a problem for the Indian clinical trials industry.

Bioequivalence studies from India face credibility problems because the guidelines for biotechnology products with regard to testing and registration are not clear in contrast to those for pharmaceutical products. Moreover, regulatory clearances are particularly slow in this area. Given that biotech products constitute around half of the clinical trials market in the UK, the lack of clear guidelines could constrain India from tapping business in this segment within the EU. It was also pointed out that since sequencing is important in trials, the lack of clarity in some areas affects opportunities in others.

Thus, while the overall environment for clinical trials has improved in recent years, Indian companies face problems due to long review times and lack of clarity on the approval process, which creates difficulties in telling the client when the trials can be started.

Another issue is the legal framework and the jurisdiction where disputes are to be resolved. India does not have a credible and efficient legal framework and clients lack confidence in the enforcement of contract provisions in case of a violation. Thus far, CROs have insisted on dispute resolution on neutral territory and have signed mutual agreements on resolution issues.

India's legislation on clinical trials is modeled on the US FDA regulations, since the US accounts for half of India's clinical trials business, but not with EU legislation. For example, EU legislation requires a pharmaceutical person to issue drugs but this is not part of Indian legislation. Thus there are gaps between India's clinical trials legislation and that of EU countries.⁴³

⁴³ It was pointed out that India's main competition comes from Eastern Europe and South Africa. Their

Companies that outsource clinical trials to Indian CROs have concerns about ethics procedures and adherence to approval procedures on ethics by CROs in India. Although the ethics committees in hospitals are largely structured along international guidelines, outsourcing companies in Europe are concerned that Indian CROs may violate ethics and bypass approval procedures.

(3) Data protection

The one area of legitimate concern is the possible breach of data confidentiality after submission of the data to the regulatory body in India. Client companies are concerned that this data could be copied or passed on to third parties. There is also a requirement that some data, such as that on toxicology, should remain undisclosed and should not be made available to generic companies. India is not seen as being strict in enforcing such data exclusivity and lacks guidelines in this area. There is concern that strict firewalls are not in place which could permit leakage of such data.

(4) Insurance

The lack of insurance portability, public or private, constrains India's medical tourism exports to the EU. Insurance portability has been affected by the lack of recognition of Indian medical qualifications. The lack of mutual recognition of medical qualifications becomes a constraint on getting Indian healthcare delivery accepted for reimbursement by state or private insurance providers in those countries.

Apart from accreditation issues, other factors also have a bearing on insurance portability. One such issue is the concern over malpractice liability, dispute resolution systems, and jurisdiction. There is concern, for instance, that if the patient faces a problem, there may be difficulties in getting compensation and in litigating malpractice and negligence cases. As one legal expert in the UK pointed out, EU patients would be reasonably sure of getting a fair deal if there were a case of medical negligence following treatment in the EU; they would be assured of due compensation that would be linked to European costs and wages. However, if there were a malpractice case following treatment in India, there would be concerns about due compensation given India's slow legal system, the lack of a transparent and effective legal framework to deal with such cases, and the likely lower level of compensation. There would also be concerns about where the arbitration is done. Thus, a combination of factors pertaining to standards and accreditation, dispute resolution mechanisms and the legal framework act as a constraint on insurance portability from the public or private sector in the EU and inhibit medical travel from that region to India.

There are also constraints in the insurance area due to the absence of insurance in emerging areas such as clinical trials in India. Clinical trials insurance is not required by the Indian government and is also not available in India. However, many client companies insist that CROs get insurance to cover any adverse effects of the drugs that are tested. CROs, the pharma companies and the patients need to be protected by

legislation is aligned with those of the main clinical trial client markets in Europe and their approval processes are faster than ours.

getting clinical trials insurance. CROs get such insurance abroad at very high cost. As this is an emerging concept, there is still lack of clarity on claim settlement and what should be covered if there are adverse effects due to the drug as opposed to the trial conditions as opposed to the doctor's negligence.

(5) Other issues

The respondents noted constraints in specific areas. On the taxation front, a respondent from a CRO noted that consultants who are brought over from the client company country to monitor the trials and outcomes are subject to VAT and service tax on their services. These taxes add 22.5 per cent to the fees of the consultant and are deducted at source; the additional charge is passed on to the CRO, making them less competitive. Since such monitoring is done for work that is export-oriented, such services should not be subject to these taxes.

Another problem cited was that Indian authorities do not give multiple-entry visas to such consultants, who may have to be brought over several times in a year if the clinical trials are carried out over an extended period. There is also a long lead time in getting the visa application processed and the visa issued. This creates complications as often the consultants are given very little notice and the trials have to be done quickly.⁴⁴

There are also regulatory problems and delays in bringing certain medical devices into the country. This affects export opportunities in areas such as medical device testing, research and production outsourcing, and medical value travel.

⁴⁴ There are two purposes for monitoring. One is to check that the CRO is following the protocols for testing. The other purpose is to give the right to market the drug. The pharma companies may have monitors on their payrolls or may hire them as independent consultants to verify if the trials have been done well and to rectify anything if needed. This gives rise to visa issues. A certain number of monitoring visits are required depending on the nature of the clinical trial.

