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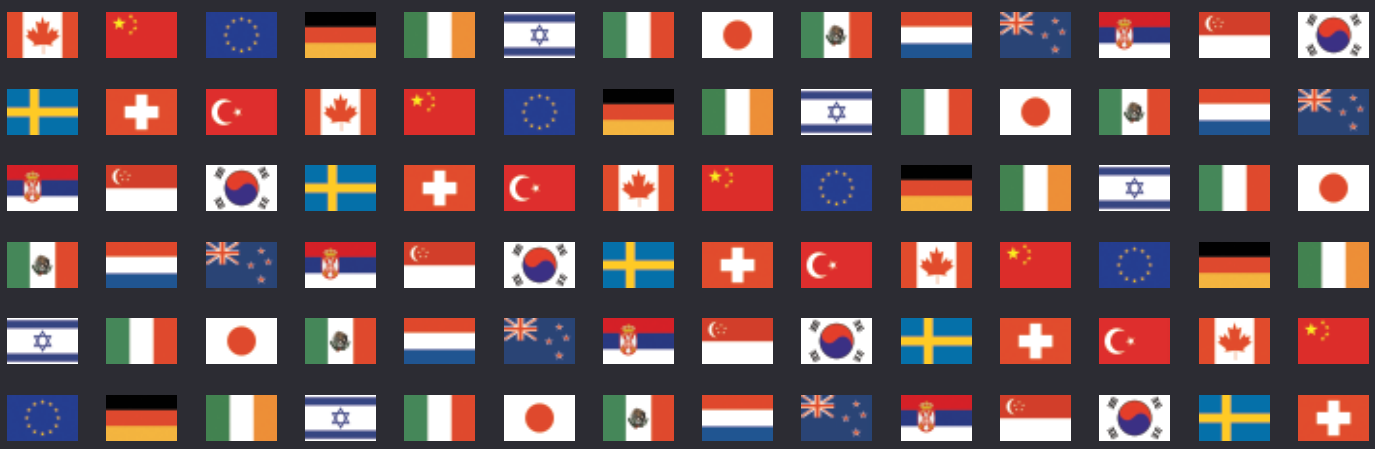
Contributing editor
Alexander Ehlers



LEXOLOGY
Getting The Deal Through

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Lexology Getting The Deal Through provides international expert analysis in key areas of law, practice and regulation for corporate counsel, cross-border legal practitioners, and company directors and officers.

Throughout this edition, and following the unique Lexology Getting The Deal Through format, the same key questions are answered by leading practitioners in each of the jurisdictions featured. Our coverage this year includes new chapters on Canada, China, the European Union, Israel, and South Korea.

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Every effort has been made to cover all matters of concern to readers. However, specific legal advice should always be sought from experienced local advisers.

Lexology Getting The Deal Through gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. We also extend special thanks to the contributing editor, Alexander Ehlers of Ehlers, Ehlers & Partner, for his continued assistance with this volume.

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For further information please contact editorial@gettingthedealthrough.com

Contents

India

Manisha Singh and Rajeev Kumar
LexOrbis

ORGANISATION AND FINANCING OF HEALTHCARE

Organisation

1 | How is healthcare in your jurisdiction organised?

India's public- and private-service healthcare system is mixed. In urban India, however, most private healthcare providers offer secondary and tertiary medical services. The Bhore Committee Report, also known as the Report on the Health Survey and Development Committee, was a milestone report for India, from which existing health policy and structures have developed.

Sub-centres

Sub-centres (SCs) are the farthest and first-hand point between the healthcare system and communities and consist of plains with 5,000 inhabitants, and hilly and tribal areas with 3,000 inhabitants. SCs are given interpersonal communication assignments to influence behaviour and provide services in the areas of maternal and child health, family care, education, immunisation, diarrhoea prevention and communicable disease control.

Primary health centres

Primary health centres (PHCs) are the primary point of contact in hilly or tribal areas of 20,000 inhabitants between a group of the village and the medical officer. State governments develop and retain PHCs in accordance with the Minimum Needs Programme (MNP) and Basic Minimum Services Programme (BMS). PHCs engage in healthcare practices, both preventive and curative.

Community health centres

The state governments, under the MNP or the BMS, establish and maintain community health centres (CHCs) in areas with a population of 120,000 and in hilly and tribal areas with a population of 80,000 that are difficult to reach. A CHC must include a surgeon, a doctor, a gynaecologist or obstetrician, a paediatrician and 21 medical staff. Each CHC consists of 30 beds, an operating room, an X-ray room, a working room and a laboratory. CHCs serve as referral centres for PHCs in the neighbourhood and offer obstetrical treatment and consultation with experts.

Financing

2 | How is the healthcare system financed in the outpatient and inpatient sectors?

Although free ambulatory and hospital care is provided by government facilities, many patients visit private hospitals because of population constraints. Health insurance is available but is restricted to public servants. Individuals must purchase their own health insurance. The National Health Protection Scheme for the economically weak sections was implemented by the government in 2018. This system makes secondary and tertiary cashless care available in private hospitals and clinics.

Basic structures

3 | What are the basic structures of the provision of care to patients in statutory and private care?

In India, 18 per cent of outpatient care and 44 per cent of inpatient care is covered by public healthcare. People from a poorer background are more likely than those of the middle- and upper-class backgrounds to use public healthcare. In addition, the assistance of a public health provider is more likely to be sought by women and senior citizens. The government's intention was to establish a public health system that would ensure that all people could be treated for diseases irrespective of their socioeconomic status or caste.

To provide access to medical services irrespective of financial status or rank, a system of general services was established. In each case there are significant differences between states' dependence on the public and private health sectors. The federal government focuses on healthcare for families and disease prevention, while state governments manage local hospitals and sanitation, which vary by state depending on community needs. The federal government shares responsibility with the states. Coordination between state and federal governments takes place for health issues involving a vast amount of funding. In comparison to the costs of private healthcare, public healthcare is much cheaper. The public healthcare system is relied upon by many citizens.

HEALTHCARE SERVICES

Authorisation

4 | What steps are necessary to authorise the provision of health services, and what law governs this?

There are two categories of hospitals in India: public and private. They may be general, specialised, or multi-specialty hospitals. The Clinical Establishment Act 2010 was passed and enforced by the central government for the purposes of establishing private hospitals in India. It requires a one-time registration. This act has been implemented by the state governments to manage the registration process for companies that wish to set up a hospital. It requires that the company is registered and meets all the requirements, including having a memorandum of association, being incorporated and having a capital structure. It also requires that securities and account information be verified. The Minister of Corporate Affairs assigns each director a Director Identification Number. Any manager who wants to join a company must register as a legal necessity (registration is only required once). Registration in accordance with the Companies Act 2013 is also necessary.

Structure

5 | Which types of legal entities can offer healthcare services?

In India, the types of organisations that provide healthcare are not restricted. The health ministry in India is responsible for controlling the health sector. The Directorate General of Health Services is a scientific data repository in the areas of health and medical education. To ensure the safety, effectiveness and consistency of medicines, cosmetics, diagnostics, and medical devices sold in the country, the Central Drugs Standard Control Organisation develops guidelines and standards. It also oversees the import and licensing of medicinal products and monitors market approval of new medicinal products and the requirement of clinical trials. By adding and removing drugs based on defined export and import criteria, and by market share pharmaceutical companies, the National Pharmaceutical Pricing Authority regularly updates the list of medicines under price control.

The National Medical Commission is the governing body for regulating medical education and accessing medical institutions. The Indian Drug Controller is a high-level pharmaceutical regulatory body regulating a variety of issues, including drug approval and regulations, clinical trials, new product launches, new licences to import drugs and implementation of new laws on drugs. The most important licence that a business owner needs to obtain is the Food Safety and Standards Authority of India licence. This licence regulates the sale of all food products in India, including special dietary foods, health supplements, organic foods, functional foods, and nutraceuticals.

The Ministry of Health and Family Welfare, the Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy, and the Central Drugs Standard Control Organisation and state authorities, among others, regulate healthcare in India.

Services of foreign companies

6 | What further steps are necessary for foreign companies to offer health services?

Companies formed in India, whether Indian or foreign, are registered under the Companies Act 2013. This Act facilitates international business in India. Two notable options for a foreign company seeking to start business in India are a joint venture or a wholly owned subsidiary. A foreign company may start operations in India, forming a co-venture with an Indian entity, or establish a wholly owned subsidiary in fields where 100 per cent foreign direct investment is available. It is not possible to accept foreign direct investment from certain industries such as real estate, lotteries, gambling, and atomic power.

The Companies Act 2013 regulates the formation, management, reorganisation and decommissioning of companies. The Competition Act 2002 controls combinations (merger control) and anticompetitive behaviour. The Income-tax Act regulates the dividends, capital gains, fusions, dividends, and sales of recession. The Indian Contract Act sets out the general principles governing the creation and implementation of contracts. The Foreign Exchange Management Act (FEMA), enacted in 1999, regulates foreign exchange and investment inflow and outflow into and out of India and sector-specific criteria. FEMA establishes market rules based on best practice according to the Securities and Exchange Board of India. The Securities Contracts (Regulation) Act 1956 regulates the listing and trading in Indian stock markets and regulates the listing agreements with the stock exchanges.

ADVERTISING

Legislation

7 | Which legislation governs advertising of medicinal products to healthcare professionals?

The legislation regulating pharmaceutical advertising in India is as follows.

- The Drug and Cosmetics Act 1940 (DCA) and its Rules of Procedure prohibit the promotion of prescription drugs (Schedule H, H1 and X drugs).
- The Drugs and Magic Remedies (Objectionable Advertisement) Act 1954 (DMRA) and its 1955 Rules prohibit any advertiser from using a medication to diagnose, cure, mitigate, provide therapy for or prevent a prescribed disease or disorder. The Consumer Protection Act 2019 (CPA), together with the DCA and the DMRA, prohibits false or misleading medicinal statements.
- The Cable TV Network Rules 1994 include an advertising code that prevents any TV network from broadcasting commercials for any product with a rare or magical property that is difficult to prove.
- The Advertising Standards Council of India Code (the ASCI Code) for Self-Regulation in Advertising prohibits advertising that could be in contravention of the DCA and the DMRA.

Pharmaceutical and healthcare professionals in India have their own codes of self-governance, and some of those codes are covered by drug publicity. For voluntary approval and self-regulation by the Indian pharmaceutical industry the government has issued the Uniform Code for Pharmaceutical Marketing Practices (UCPMP). In addition to the UCPMP, some pharmaceutical companies have their own internal codes. For example, the Organisation of Pharmaceutical Producers of India (OPPI) has its very own set of internal guidelines known as the OPPI Code 2019.

Rules and regulations of other healthcare groups, which are legally binding, are as follows.

- The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002 apply to modern medical practitioners in India.
- Dental professionals must follow the Revised Dentists (Code of Ethics) Regulations 2014.
- Several rules for pharmacists are provided for in the Pharmacy Practice Regulations 2015.
- The Homeopathic Practitioners (Professional Conduct, Etiquette and Code of Ethics) Regulations 1982 apply to homeopathic practitioners.
- Practitioners of Indian medicine (such as Ayurveda, Siddha, Unani and Tibb) are required to comply with the Practitioners of Indian Medicine (Standards of Professional Conduct, Etiquette and Code of Ethics) Regulations 1982.

The UCPMP is not legally enforced because it is not federal legislation. The UCPMP applies to the pharmaceutical industry. Since August 2020, all associations in the pharmaceutical industry have been directed by the National Pharmaceutical Pricing Authority (NPPA), India's drugs price regulator, to ensure that the UCPMP is complied with. A quarterly NPPA report should also be submitted by industry associations to the NPPA, which details complaints received from the industry association regarding the breach of the UCPMP by a member firm and measures taken to address the complaint.

Main principles

8 What are the main rules and principles applying to advertising of medicinal products aimed at healthcare professionals?

The significant legal provisions and guidelines for healthcare professionals are set out in the following: section 3 of the DMRA; sections 16–17 and 94–106 of the Drugs and Cosmetics Rules 1945; section 6.8 of the Indian Medical Council Rules 1957; and section 1 (General Points) of the ASCI Code.

Advertising of medical devices

9 Is the advertising of medical devices to healthcare professionals regulated as rigorously as advertising in the pharmaceuticals sector? What are the main differences?

Yes. The DMRA is India's primary law for medical devices and drug advertising and is valid for both public and medical advertisers. The UCPMP is a voluntary code of conduct to be applied by pharmaceutical companies and enforced by industry associations, which contains guidelines on marketing for health practitioners. In addition, the Indian Medical Council (Professions, Etiquette and Ethics) Regulations 2002 restrict the acceptance of donations, travel facilities, hospitality, and cash and monetary grants from manufacturers of pharmaceutical and medical devices.

DATA PROTECTION, PRIVACY AND DIGITISATION IN HEALTHCARE

Digitisation

10 What are the legal developments regarding digitisation in the healthcare sector and industrial networks or sales channels?

In September 2013, the Ministry of Health and Family Welfare (MoHFW) announced the Electronic Health Record (EHR) Standards for India (the EHR Standards). These standards were selected from the best electronic health record standards available, which are widely used across the globe, with a view to their suitability and application in India. The committee that recommended the guidelines is composed of experts, practitioners, government officials, technologists, and members of the industry. The standards notified were received from several technology and social commentators and not just professional entities, regulators, and stakeholders.

The EHR Standards were updated in 2016 in consultation with general stakeholders. As a result, health organisations and providers across the country were notified and asked to implement the latest EHR Standards. With standards such as the Systematized Nomenclature of Medicine Clinical Terms being made free in Canada, the MoHFW supported the adoption and appointment of an interim national resource centre to handle the standardisation of medical terminology that is widely accepted by IT communities in healthcare sectors worldwide.

Provision of digital health services

11 Which law regulates the provision of digital health services, and to what extent can such services be provided?

The Digital Information Security in Healthcare Act 2018 (DISHA) was launched by the MoHFW to regulate the safety of data in healthcare services. This Act aims to safeguard the privacy and confidentiality of data relating to electronic health, protection and standardisation.

Authorities

12 Which authorities are responsible for compliance with data protection and privacy, and what is the applicable legislation? Have the authorities issued specific guidance or rules for data protection and privacy in the healthcare sector?

To promote and implement e-health standards, enforce privacy and security policies for electronic health information and regulate storage and sharing of electronic health records through DISHA, the MoHFW aims to establish a national legislative body in the form of a national digital health authority.

Requirements

13 What basic requirements are placed on healthcare providers when it comes to data protection and privacy? Is there a regular need for qualified personnel?

It is the responsibility of the healthcare provider or agency to protect the privacy and safety of individuals' digital health information. The privacy and security of digital medical data shall be protected from unauthorised access, use or disclosure, and accidental and deliberate destruction by taking all physical, administrative, and technical action necessary when digital health data is collected, stored and transferred. The health establishment or information exchange must ensure that its employees follow routine training and supervision in compliance with security standards and procedures.

Common infringements

14 What are the most common data protection and privacy infringements committed by healthcare providers?

Healthcare providers are considered to have infringed digital health data if they violate the provisions found in Chapter II of the Personal Data Protection Bill 2019 when creating, acquiring, storing, distributing and disclosing digital health information. Furthermore, if a person handles digital health information in a dishonest, fraudulent, or negligent violates manner, infringes digital health information that is not anonymised and de-identified, or infringes healing data when a person fails to retain such data according to standard rules, then he or she will be held responsible for violating the digital health information.

The words 'dishonesty' and 'fraudulent' are defined in the Indian Penal Code 1860. Any person who is committing a serious violation of healthcare information will be sentenced to three to five years' imprisonment and fined not less than 500,000 Indian rupees. The fine imposed may, depending on the court's opinion, be paid as compensation to the person whose data has been violated.

COLLABORATION

Legislation

15 Which legislation governs the collaboration of the pharmaceutical industry with healthcare professionals? Do different rules apply regarding physicians in the outpatient and inpatient sectors?

The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002 (the MCI Regulations 2002) is the main legislation regulating the relationships of healthcare professionals with pharmaceutical companies. All physician–patient relationships, whether inpatient or outpatient, are covered by the MCI Regulations 2002. They set out the obligations of doctors to provide the best possible treatment for their patients. However, in the case of hospital therapy, doctors can be held responsible for any errors and can be charged, depending on

the degree of neglect and the level of patient care, under the Consumer Protection Act, through tort legislation or criminal proceedings.

Collaboration with healthcare professionals

16 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with healthcare professionals?

The main guidelines include section 6.8 and 6.8.1 of the Code of Conduct for pharmaceutical and allied industries, which states that medical practitioners shall comply with and abide by the legal limitations specified in section 1.9 of the MCI Regulations 2002.

Collaboration with patient organisations

17 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with patient organisations?

There is no legislation in India that applies to collaborations between pharmaceutical industries and patient organisations.

Common infringements

18 What are the most common infringements committed by pharmaceutical manufacturers regarding collaboration with healthcare professionals?

Violations of the MCI Regulations 2002 are the most common infringements by healthcare professionals, such as the provision of a healthcare professional for non-medical purposes, holding social events to promote an organised convention or conference and providing gifts or benefits to encourage a health professional to participate in a conference or meeting. In addition, a violation of digital health data in the form of modifying, destroying, deleting or otherwise influencing digital health data, whether knowingly, dishonestly, fraudulently or negligently, is punishable under the Indian Penal Code 1960.

Collaboration on medical devices

19 Is the collaboration of manufacturers of medical devices with healthcare professionals and patient organisations regulated as rigorously as collaboration in the pharmaceuticals sector? What are the main differences?

There are no specific guidelines in this area at present.

COMPETITION LAW

Authority enforcement

20 Are infringements of competition law by healthcare providers pursued by national authorities?

Yes, by the Competition Commission of India (CCI).

Private enforcement

21 Is follow-on private antitrust litigation against healthcare providers possible?

The CCI is the only organisation in India responsible for the enforcement of competition law. Consumers may take civil action, either at their own initiative or based on information from the CCI, to recover losses or harm caused by anticompetitive activities. The CCI examines and decides on anticompetitive behaviour. The Competition Appeal Tribunal will decide on the compensation claims resulting from the findings of the CCI pursuant to section 53N of the Competition Act 2002.

Anti-corruption and transparency

22 What are the main anti-corruption and transparency rules applicable to healthcare providers?

In India, corruption is governed by the Indian Penal Code 1860 and the Prevention of Corruption Act 1988, as amended (the PC Act). On 26 July 2018, the Indian parliament adopted new amendments to the PC Act, which allowed prosecution on the supply side, among other primary changes. The President approved the amendments. In addition to the investigating and prosecution authorities, the Comptroller and Auditor General and the Central Vigilance Commission have played a key role in public interest litigation.

PRICING AND REIMBURSEMENT

Price regulation

23 To what extent is the market price of a medicinal product or medical device governed by law or regulation?

The Drugs (Prices Control) Order (DPCO) of 1995 governs and regulates the pricing of pharmaceutical products. The National Pharmaceutical Pricing Authority (NPPA), an independent expert body, was formed on 29 August 1997 to address various issues, such as:

- updating the list of drugs under price controls on the basis of established criteria and guidelines;
- recognising and maintaining data on production, export, import and market share, corporate profitability for bulk medicines or formulations, etc;
- undertaking or sponsoring relevant pricing studies on drugs and pharmaceuticals;
- advising the government on revisions to drug policies; and
- recapitalising deficiencies and taking measures to remedy such shortages.

The prices of pharmaceutical products are determined by producers and are based on different factors (eg, production costs, market competition, company profitability). On 15 May 2013, the Department of Drugs published a DPCO modifying price controls and significantly increasing the number of drugs covered by price ceilings. In 1995 only 74 bulk medicines were regulated by the former DPCO and 348 medicines were price controlled by the new DPCO. A new class of drug was identified in 2013, covered by the patented medicines, pursuant to rule 123E of the Drugs and Cosmetics Act. However, the NPPA will interfere if retail prices of non-scheduled drugs (which it cannot fix the prices of) increase by 10 per cent or more per year. Manufacturers (not subject to direct price controls) of non-scheduled products are not obliged to comply with any NPPA pricing approvals. In addition, the government may not sell a non-scheduled drug at a price that exceeds the fixed or revised price of any non-scheduled bulk drug as it considers appropriate in the public interest.

Negotiations between manufacturers and providers

24 Must pharmaceutical and medical device manufacturers negotiate the prices of their products with public healthcare providers?

Price negotiations for patented medicinal products were considered for a long time. However, specialist committees and the Department of Pharmaceuticals do not seem to have developed any guidelines that would include a method for calculating the ceiling price of patented drugs in the non-scheduled category.

Reimbursement

25 | In which circumstances will the national health insurance system reimburse the cost of medicines?

The Indian national health system covers the costs of medicines for patients enrolled in the Central Government Health Scheme or Employees' State Insurance Scheme. Private insurance providers cover, at a minimum, a 24-hour hospital treatment charge as part of the conditions set out in their portfolios. Furthermore, the patient is reimbursed for up to 30 days before and up to 60 days after the hospitalisation. In addition, private insurers will not cover the cost of medicine used for the treatment of chronic conditions, such as high blood pressure, diabetes and other conditions requiring long-term treatment.

Price adjudication

26 | If applicable, what is the competent body for decisions regarding the pricing and reimbursability of medicinal products?

The NPPA was established on 29 August 1997 as an independent body of experts responsible for making decisions on the pricing and reimbursability of medicinal products.

Discount

27 | Are manufacturers or distributors of medicinal products statutorily obliged to give a discount to health insurance schemes or third parties?

No, medicinal product manufacturers and distributors do not have to give a discount to health insurance schemes or third parties. The NPPA determines the price of planned medicines, however.

UPDATE AND TRENDS

Key developments of the past year

28 | Is there any legislation expected in the near future that will have a major impact on the current legal environment for medicines or medical devices?

Of the six pillars underpinning the Finance Minister's budget proposals in her 2021 Budget speech, health and well-being was a key focus. Health experts have long waited for this and the Finance Minister reported that the government supports a systemic approach.

The Finance Minister also announced a new centrally financed system for the next six years, the PM AtmaNirbhar Swasth Bharat Yojana, which will cost 641 billion rupees. It will include the creation of comprehensive public health laboratories in all 11 districts of the states and 3,382 public health units. This will be a major challenge owing to the lack of infrastructure in under-served small towns and villages, as has been highlighted during the covid-19 pandemic. The National Centre for Disease Control (NCDC) will be improved, including its divisions and monitoring units. This is an essential step towards planning for possible pandemics and emergencies in the field of health, together with the creation of four regional national virology institutes.

In 2019, the Ministry of Health and Family Welfare abolished the Indian Medical Council Act 1956 (the IMC Act) and replaced it with the National Medical Commission Act 2019 (the NMC Act). The NMC Act is administered and implemented by the National Medical Commission (NMC), which replaced the Indian Medical Council on 25 September 2020. Its members are appointed by the central government. As the NMC Act has only recently been enforced, its effects are not yet known. The rules and regulations enacted under the IMC Act will continue to apply, unless the NMC provides new guidelines.

To provide formal training for postgraduate Ayurveda students in forms of surgery, the Central Council of Indian Medicine (CCIM) published a notification amending the Indian Medical Central Council Regulations 2016. The report provides Ayurveda postgraduate students with training in over 50 forms of operations, ranging from general surgery to eye and ear procedures.

Coronavirus

29 | What emergency legislation, relief programmes and other initiatives specific to your practice area has been implemented to address the pandemic? Have any existing government programmes, laws or regulations been amended to address these concerns? What best practices are advisable for clients?

No updates at this time.

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