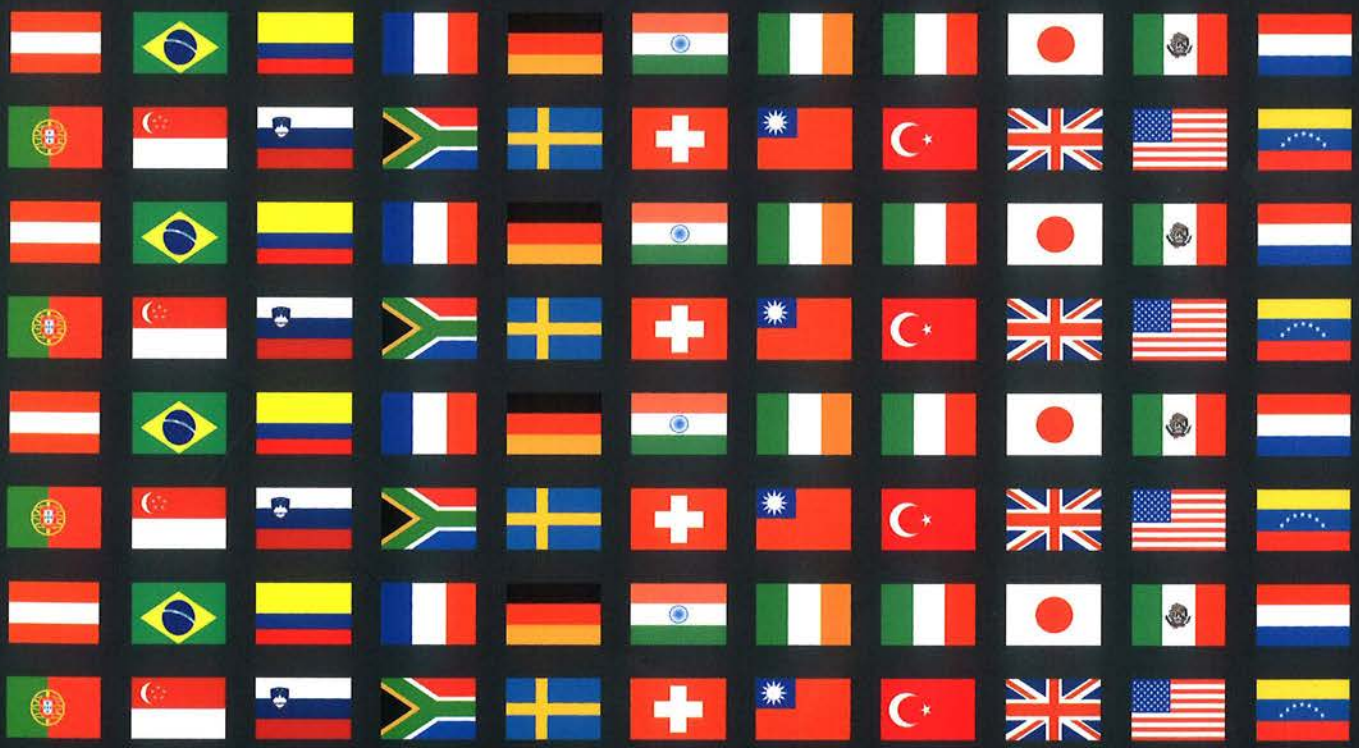
Life Sciences

Contributing editor
Alexander Ehlers



2018

GETTING THE DEAL THROUGH

India

Archana Shanker and Devinder Singh Rawat
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Organisation and financing of healthcare

1 How is healthcare in your jurisdiction organised?

Healthcare is a state responsibility according to the Constitution of India (article 42, 'Provision for just and humane conditions of work and maternity relief' and article 47, 'Duty of the State to raise the level of nutrition and the standard of living and to improve public health').

Each state has its own healthcare delivery system in which both public and private (for-profit as well as non-profit) parties operate. While states are responsible for the functioning of their respective healthcare systems, certain responsibilities also fall to the central government, namely aspects of policymaking, planning, guiding, assisting, evaluating and coordinating the work of the various provincial health authorities, and providing funding to implement national programmes. The organisational structure of the healthcare system is as follows:

- at the national level, the organisation consists of the Union Ministry of Health and Family Welfare (MoHFW);
- at the state level, the organisation is under the state department of health and family welfare of each state. Each state department is headed by a minister and has a secretariat under the charge of the Secretary or Commissioner (Health and Family Welfare) belonging to the cadre of the Indian Administrative Service;
- at the regional level, each regional and zonal setup covers three to five districts and acts under authority delegated by the State Directorate of Health Services;
- the district-level structure of health services is a middle-level management organisation that provides a link between the state and the regional structures on one side, and the peripheral-level structures (such as primary health centres and sub centres) on the other;
- at the sub-divisional (administrative division) level, healthcare services are rendered through the office of the Assistant District Health and Family Welfare Officer; and
- at the community level, one community health centre has been established for every 80,000 to 1.2 million members of the population, and the centres provide basic specialty services in general medicine, paediatrics, surgery, obstetrics and gynaecology.

National health policy, 2017

The Draft National Health Policy, 2017 has been introduced in guiding the approach for addressing the health sector. The primary aim of the National Health Policy, 2017 is to prioritise the role of the government in shaping healthcare systems and includes:

- investments in health;
- organisation of healthcare services;
- prevention of diseases and promotion of good health through cross-sectoral actions, access to technologies;
- developing human resources;
- encouraging medical pluralism;
- building a knowledge base;
- developing better financial protection strategies; and
- strengthening regulation and health assurance.

The key principles of the National Health Policy, 2017 are:

- professionalism, integrity and ethics: the policy aim to maintain highest professional standards, integration and ethics in healthcare delivery supported by a regulatory environment;
- equity, affordability and universality: reducing inequality so that healthcare services are provided to all and minimising disparity on account of gender, poverty, caste, disability, other form of social inclusion and geographical barriers;
- patient-centered and quality of care: evolve and disseminate standards to ensure quality of healthcare;
- accountability: assign financial and performance accountability, transparency in decision-making and elimination of corruption in the healthcare system;
- inclusive partnerships: partnership with academic institution, not for profit agencies and the healthcare industry;
- pluralism;
- decentralisation; and
- dynamism and adaptiveness:

The pricniples of National Health Policy, 2017 are:

- ensuring adequate investment: the policy proposes to increase the healthcare expenditure from 1.5 per cent of the GDP to 2.5 per cent of the GDP by 2025 in a time-bound manner.
- preventive and promotive health: the policy envisages complementing the international 'Health in All' approach with Health for All in India. The policy empowered public health cadre to address social determinants of health effectively, by enforcing regulatory provisions. The policy identifies coordinated action on seven priority areas for improving the environment for health:
  - the 'Swachh Bharat Abhiyan' campaign to clean up streets;
  - balanced, healthy diets and regular exercise;
  - addressing tobacco, alcohol and substance abuse;
  - *Yatri Suraksha* – preventing deaths due to rail and road traffic accidents;
  - *Nirbhaya Nari* – action against gender violence;
  - reducing stress and improving safety in the workplace; and
  - reducing indoor and outdoor air pollution.

The National Health Policy, 2017 proposes seven key policy shifts in organising healthcare services that includes:

- primary care – from selective care to assured comprehensive care with linkages to referral hospitals;
- secondary and tertiary care – from an input-oriented to an output-based strategic purchasing;
- public hospitals – from user fees and cost recovery to assured free drugs, diagnostic and emergency services to all;
- infrastructure and human resource development – from normative approach to a targeted approach to reach under-serviced areas;
- urban health – from token interventions to on-scale assured interventions, to organise primary healthcare delivery and referral support for urban poor. Collaboration with other sectors to address wider determinants of urban health is advocated; and
- national health programmes – integration with health systems for programme effectiveness and in turn contributing to strengthening of health systems for efficiency; and
- AYUSH services – from stand-alone to a three-dimensional mainstreaming.

Legal framework

The Draft National Health Policy recommends distribution of responsibility and accountability between the Centre and the states in meeting the objectives of the Health Care System.

The policy also set up the basic background and assesses the development of economics and health systems so as to include a Health Rights bill making health a fundamental right. Thus, to make healthcare a justiciable right is to imply that its denial is an offence. Questions that need to be addressed are manifold, namely:

- When healthcare is a state subject, is it desirable or useful to make a central law?
- Whether such a law should mainly focus on the enforcement of public health standards on water, sanitation, food safety, air pollution etc, or whether it should focus on health rights – access to healthcare and quality of healthcare?

A Draft Policy has recently been announced. However, significant progress have been made to achieve the objectives and its complete implementation will have a positive effect on overall management and the delivery of healthcare services in India.

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

Inpatient (hospitalisation) financing consists of the following:

- patient's out-of-pocket expenses;
- health insurance (held by 3 per cent of the population, and made up of 50 per cent social insurance, 23 per cent private insurance and 17 per cent community health insurance);
- government funding for the Central Government Health Scheme (CGHS) and Employees' State Insurance (ESI) scheme; and
- the public-funded scheme, which consists of the National Health Insurance Programme (RSBY) and the National Rural Health Mission (NRHM).

Outpatient financing consists of the following:

- patient's out-of-pocket expenses (70 per cent);
- health insurance (there is very minimal funding by insurance);
- government funding for the CGHS and ESI scheme; and
- the public-funded schemes (ie, the RSBY and the NRHM).

Compliance – pharmaceutical manufacturers

3 Which legislation governs advertising of medicinal products to the general public and healthcare professionals?

Pharmaceutical advertising is governed by the following legislation:

- the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, which controls the advertisement of drugs in certain cases (including misleading advertisement);
- the Drugs and Cosmetics Rules, 1945, which regulate the labelling and branding of pharmaceutical products, cosmetics and homeopathic medicines in India;
- the Medical Council of India (MCI) (Professional Conduct, Etiquette and Ethics) Regulations, 2002 (MCI Regulations), which relate to ethical conduct that may affect the relationship of medical practitioners with the pharmaceutical industry;
- the Marketing Code, which is a voluntary code for the Indian pharmaceutical industry that was introduced on 2 June 2011 by the Department of Pharmaceuticals under the Ministry of Chemicals and Fertilisers, and which relates to the promotion of pharmaceutical products and the interaction of pharmaceutical companies with healthcare professionals; and
- the OPPI Code of Pharmaceutical Marketing Practices (the OPPI Code). OPPI is a non-governmental scientific organisation that is an active Indian member of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). The OPPI Code provides guidelines for pharmaceutical marketing that are based on the IFPMA Code of Pharmaceutical Marketing Practices. Although not mandatory, the OPPI Code provides useful guiding principles that may be followed to ensure better marketing of pharmaceutical products.

4 What are the main rules and principles applying to advertising aimed at healthcare professionals?

The main rules and principles that apply to advertising aimed at healthcare professionals are as follows:

- section 3 of the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954;
- sections 16 and 17 and Rules 94 to 106 of the Drugs and Cosmetics Rules, 1945;
- section 6.8 of the MCI Code;
- section 1 (general points) of the Marketing Code; and
- section 5 of the OPPI Code, which provides the requirements regarding information content in pharmaceutical advertising.

5 What are the main rules and principles applying to advertising aimed at the general public?

There is no legislation that regulates direct marketing of medicinal products to the general public. The direct marketing of prescription drugs (Rx) defined under schedules H and X of the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954, is prohibited in India. However, over-the-counter (OTC) medicinal products can be advertised by pharmaceutical companies. There is no statutory binding legislation that prevents advertisement of drugs that are not defined under Schedule H or X. Although the phrase 'over-the-counter' has no legal recognition in India, all drugs that are not included in the list of 'prescription drugs' are considered to be non-prescription (or OTC) drugs. Various OTC drugs are advertised in India, including digestives, antacids, anti-flatulents, cold drugs and analgesic balms, vitamins, tonics and health supplements, medicated skin treatments, analgesic and cold tablets, antiseptic creams and glucose powders.

The OPPI Code of Ethics for the Advertisement of OTC drugs in India provides guidelines for responsible advertising promoting the sale of medicines that may be purchased by the public without prescription and for which therapeutic claims are made. These voluntary guidelines provide good faith principles that advertisements of non-prescription systemic analgesics and painkillers shall carry a 'use only as directed' warning. This must be clearly visible, audible or legible (as appropriate, depending upon the advertising medium). In the case of an advertisement for vitamin preparations and tonics, such advert shall not infer that such products are a substitute for good nutrition or can replace a balanced diet.

The Pharmacy Council of India notified the regulation, namely Pharmacy Practice Regulation 2015, in the Official Gazette on 15 January 2015. Under the Pharmacy Practice Regulation, the definition of 'prescription' has been defined under section 2(j).

'Prescription' means a written or electronic direction from a registered medical practitioner or other properly licensed practitioners such as dentist, veterinarian, etc, to a pharmacist to compound and dispense a specific type and quantity of preparation or prefabricated drug to a patient.

Prescription is defined as written or electronic direction from a registered medical practitioner, which means the prescription can be written or in an electronic form.

There are abundant online portals that offer the service of delivering Schedule H and Schedule X medicines to the patient or consumer against the prescription uploaded on their server. The elaborated definitions of 'prescription' as provided are an alternate means to deliver Schedule H and Schedule X medicines to the patients or user.

However, there is a restriction on the advertisement of Schedule H and Schedule X medicines. The portals are allowed to deliver Schedule H and Schedule X medicines as per the requirement. Therefore, restrictions on the advertising of Schedule H and Schedule X on the internet still persist.

6 What are the most common infringements committed by manufacturers with regard to the advertising rules?

The most common infringement committed in relation to adhering to the advertisement standards defined under the OPPI Code and the Marketing Code are advertisements that are incomplete: that is, advertisements not listing the date of production of the advertisement, and advertisements not listing the marketer's name and address, in both first and reminder advertisements.

7 Under what circumstances is the provision of information regarding off-label use to healthcare professionals allowed?

The Drug Controller General of India (DCGI) has not approved any off-label use of drugs. Consequently, off-label use of a drug is illegal in India, and health professionals are obliged to obey the Professional Conduct, Etiquette and Ethics Regulations 2002 of the MCI. Accordingly, they are required not to evade legal restrictions such as those found under the Drugs and Cosmetics Act (Chapter 1.9).

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

The MCI Regulations form the primary legislation that governs connections between healthcare professionals and pharmaceutical companies, as well as their relationship to patients.

The MCI Regulations apply to doctor-patient relationships regardless of whether patients are inpatients or outpatients; they lay down the duty of doctors to give their patients the best possible treatment available. However, in the case of inpatient treatment, doctors may be held liable for any errors, and can be prosecuted under the Consumer Protection Act, tort law or through criminal proceedings depending upon the degree of negligence and the standard of care provided by a doctor to a patient.

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

The main rules in this regard are as follows:

- section 6.8 of the code of conduct for doctors and professional associations of doctors in their relationship with the pharmaceutical and allied health-sector industry; and
- section 6.8.1 of the above code: in dealing with the pharmaceutical and allied health-sector industry, medical practitioners shall follow and adhere to the legal restrictions as defined in section 1.9 of the MCI Professional Conduct, Etiquette and Ethics Regulations 2002.

10 What are the most common infringements committed by manufacturers with regard to collaboration with healthcare professionals?

The most common infringements committed by manufacturers with regards to their interactions with healthcare professionals are violations of the ethical code of conduct laid out by the MCI Regulations, including offering a healthcare professional luxury trips and parties to secure his or her participation in an organised convention or conference; and giving gifts or incentives to encourage a healthcare professional to promote the manufacturer's medicinal products.

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

In India, there is no regulation that corresponds to the European Federation of Pharmaceutical Industries and Associations Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations.

12 Are manufacturers' infringements of competition law pursued by national authorities?

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

13 Is follow-on private antitrust litigation against manufacturers possible?

The CCI is the primary authority in charge of the enforcement of competition law in India. The CCI can start investigations either on its own initiative or based on information received, and consumers can institute legal proceedings to recover losses or damages caused by anticompetitive practices. The CCI will scrutinise the anticompetitive practice and issue its finding.

The Appellate Tribunal, COMPAC, under section 53N of the Competition Act 2002, can adjudicate on claims for compensation that may arise from the findings of the CCI.

14 What are the main mandatory anti-corruption and transparency rules applicable to pharmaceutical manufacturers?

See getting www.gettingthedealthrough.com.

Compliance - medical device manufacturers

15 Is the advertising of medical devices and the collaboration of manufacturers of medical devices with healthcare professionals and patient organisations regulated as rigorously as advertising and collaboration in the pharmaceuticals sector?

Yes.

Pharmaceuticals regulation

16 Which legislation sets out the regulatory framework for granting marketing authorisations and placing medicines on the market?

The Drugs and Cosmetics Act 1940, regulates the import, manufacture, distribution and sale of drugs and cosmetics in India.

17 Which authorities may grant marketing authorisation in your jurisdiction?

The Central Drug Standard and Control Organisation (CDSCO) is the national regulatory authority in India that evaluates the safety, efficacy and quality of drugs. The CDSCO is headed by the DCGI, which is an apex regulatory body under the MoHFW and is responsible for the approval of new drugs. The DCGI is advised by the Drug Technical Advisory Board and the Drug Consultative Committee. Licensing and classification of medical devices are handled by the Central Licensing Approval Authority (CLAA). The CLAA is also responsible for setting and enforcing safety standards; it appoints notified bodies to oversee and assess conformity, conduct post-market surveillance, and issue warnings and recall drugs in the event that there are any adverse effects. The CDSCO establishes safety, efficacy and quality standards for pharmaceuticals and medical devices. It publishes and updates the Indian Pharmacopeia, which is a list of regulated pharmaceuticals and devices.

The CDSCO is divided into several zonal offices that conduct pre and post-licensing inspections, post-market surveillance and issue recalls when necessary. In addition to its regulatory functions, the CDSCO offers technical guidance, trains regulatory officials and analysts and monitors adverse events. The CDSCO works with the World Health Organization (WHO) to promote good manufacturing practice and international regulatory harmony.

18 What are the relevant procedures?

The regulatory approval process in India can be divided into two categories based on the definition of a drug: an approval process for a new drug and an approval process for a drug that has ceased to be a new drug. Approval for the manufacture and import of drugs is governed by the Drugs and Cosmetics Act of 1940 and Rule 1945. All applications for approval for 'new drugs' have to be obtained from the CDSCO. Once a drug ceases to be a 'new drug', the applicant can seek permission for a manufacturing licence from any of the more than 27 competent state regulatory authorities. The applicant is required to submit data as per Appendix I of Schedule Y, which is similar to the data required for any new chemical entity. All of the data from any Phase I to Phase III clinical trials are required for such new drug. However, if the drug is approved in other countries, the applicant is required to submit data based on the Indian population alone (ie, only from the Phase III trial).

19 Will licences become invalid if medicinal products are not marketed within a certain time? Are there any exceptions?

Under Rule 28 of the Drug and Cosmetics Act 1940 and the 1945 Rules, import licences are granted for three years. The applicant is required to seek a fresh import licence after the expiry of the existing licence, and such application should be made three months prior to the expiration of the existing import licence period. Marketing authorisations cease if a medicine is not put on the market within three years of its authorisation; as such, in the event that an importer or manufacturer fails to market a drug within three years, a fresh licence will be required.

20 Which medicines may be marketed without authorisation?

Manufacturing licences for drugs that cease to be new drugs, as per the definition of 'new drug' according to Rule 122E of the Drug and Cosmetics Act, can be obtained directly from the state regulatory authority.

21 Are any kinds of named patient programmes in place? If so, what are the requirements for pre-launch access?

Directive 2001/83/EC states that an unlicensed drug may be made available in response to a bona fide unsolicited order by healthcare professionals for use by their individual patient under their direct personal responsibility. Rule 123 of the Drugs and Cosmetics Act, 1940 and the 1945 Rules are directed to exemptions, and state that the drugs specified in Schedule K can be made available to the patients under certain circumstances.

Drugs can be supplied by a registered medical practitioner to his or her own patient, as can any drug specified in Schedule C supplied by a registered medical practitioner at the request of another such practitioner if it is specially prepared with reference to the patient's condition and for the use of such individual patient.

Pricing and reimbursement of medicinal products

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

The pricing of pharmaceutical products is regulated and falls under the Drug Prices Control Order (DPCO) 1995. In India, successive DPCOs have reflected a declining trend in the control basket. In 1970, all drugs were controlled, but such control has gradually been reduced (to 347 drugs in 1978, to 163 drugs in 1987 and finally to 73 drugs in 1994). The government set up the National Pharmaceutical Pricing Authority (NPPA) on 29 August 1997 (www.nppaindia.nic.in) as an independent body of experts that deals with the following matters:

- price fixing and revision, and other related matters such as updating the list of drugs included or excluded from price controlling on the basis of the established criteria and guidelines;
- monitoring the prices of uncontrolled drugs and formulations and overseeing the implementation of the provisions of the DPCO;
- monitoring the availability of drugs, identifying shortages and taking remedial steps to address such shortage;
- collecting and maintaining data on production, exports and imports, market share of individual companies, profitability of companies, etc, for bulk drugs and formulations;
- undertaking or sponsoring relevant studies in respect of pricing of drugs and pharmaceuticals;
- advising the government on revisions to the drug policy, as well as assisting the government in parliamentary matters relating to drug pricing; and
- monitoring and analysing price movements of non-scheduled medicines on a monthly basis. The prices of these formulations are fixed and determined by the manufacturers themselves depending on various factors (cost of production, market competition, the company's profitability, etc).

On 15 May 2013, the Department of Pharmaceuticals issued a DPCO that altered the price regulations and substantially increased the number of medicines covered by the price cap umbrella. The earlier DPCO of 1995 regulated only 74 bulk drugs, whereas the current DPCO will regulate the price of as many as 348 medicines. The new DPCO includes provisions for regulating the price of new drugs. A new drug class has been defined under Rule 122E of the Drugs and Cosmetics Act, and can include patented medicines as well.

In *KS Gopinath* (2003), the Supreme Court directed the government to ensure that 'essential and life-saving drugs do not fall out of price control'. The DPCO 1995 controls the price both for bulk drugs and formulations that are scheduled drugs.

The DPCO 1995 does not regulate or fix the price of non-scheduled drugs; however, in cases where there is an annual increase of the retail price of 10 per cent or more, the NPPA can intervene. Manufacturers of non-scheduled drugs (eg, drugs not under direct price control) are not required to adhere to any price approvals issued by the NPPA regarding such drugs. However, in order for the NPPA to monitor the price of such drugs and take corrective measures where warranted, it is a requirement that manufacturers must inform the NPPA of the price of their drugs within 30 days of the commencement of any price increase. Further, in the case of non-scheduled drugs, the government may, as it deems necessary in the public interest, fix or revise the price of any non-scheduled bulk drug, and the manufacturer or importer of such bulk drug shall not sell said drug at a price that exceeds the fixed or revised price.

23 Must pharmaceutical manufacturers negotiate the prices of their products with the public healthcare providers?

Price negotiations for patented drugs have been on the agenda for some time. However, to date no guidelines appear to have been formulated by any specialised committee or by the Department of Pharmaceuticals to provide a formula for deriving the 'ceiling price' of patented drugs in the non-scheduled category.

In March 2013, the Department of Pharmaceuticals issued a draft policy on the pricing of patented drugs. A summary of the recommendations in this report are as follows:

- the government should expand the coverage of the healthcare and insurance scheme (at least for prescription medicines) to all citizens not covered under any other insurance or reimbursement scheme;
- there is no need to link price negotiations of a patented medicine with its marketing approval;
- a committee headed by the chair of the NPPA should be established for deciding the price of patented medicines;
- the reference prices of the patented medicines to be used for price negotiations in India will be the procurement prices of those medicines in the United Kingdom, Canada, France, Australia and New Zealand;
- there will be three categories of patented drugs as follows:
  - a brand new class of drugs that have no therapeutic equivalence in India: for such medicines, the originator company will submit the government procurement price list to the committee. The committee will take the per capita gross national income (with purchasing power parity) of the country of the originator company. The ratio of the per capita income of that particular country to the per capita income of India will be calculated. The price of the medicine in India will be worked out by dividing the price of the medicine in the originator country by this ratio, and the lowest price will be used for negotiations for further reductions;
  - drugs that have therapeutic equivalence in addition to improved therapeutic equivalence over existing drugs (improved efficacy) in India: the committee would use the reference pricing as explained above, but would ensure that the cost of treatment does not increase with respect to the cost of treatment with existing equivalent medicines; and
  - drugs that have comparable therapeutic efficacies to existing drugs should be given differential treatment while fixing prices; and
- for medicines introduced for the first time in India: the pricing committee for patented drugs will fix the price of new medicines taking various factors into consideration, such as the cost involved, risk factors and any other relevant factors.

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

India's national health system covers the cost of medicines for patients registered under the CGHS or ESI schemes. The medicines are distributed at the hospital or dispensary level. However, if a medicine is not available at a distribution centre, the cost of such medicine is reimbursed.

Private insurance companies will reimburse expenses incurred for the treatment of diseases and conditions that are listed in their portfolios and for which a patient is hospitalised for at least 24 hours. In addition, medicines that are required by a patient for up to 30 days prior to hospitalisation and up to 60 days post-hospitalisation are reimbursed. However, medicines subsequently required by the patient must be purchased as an out-of-pocket expense. Further, private insurers do not reimburse the cost of medicines that are used for treating chronic diseases, such as blood pressure, diabetes, etc, which require regular medication for prolonged periods of time.

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

As mentioned in question 22, the NPPA was set up on 29 August 1997 as an independent body of experts that is responsible for decisions regarding the pricing and reimbursability of medicinal products.

26 Are manufacturers or distributors of medicinal products statutorily obliged to give a discount?

No. Manufacturers and distributors of medicinal products are not statutorily obliged to give a discount on pricing. However, the NPPA plays an important role in fixing the price of scheduled drugs.

Medicine quality and access to information

27 What rules are in place to counter the counterfeiting and illegal distribution of medicines?

Counterfeit medicines are medicines that are deliberately and fraudulently mislabelled with respect to their identity or source. Counterfeiting can apply to both branded and generic products, and counterfeit products include:

- products with the wrong ingredients or without active ingredients;
- products that are missing key ingredients;
- products with insufficient active ingredients;
- products that are improperly labelled, stored or handled; and
- products with fake packaging.

The term 'counterfeit medicine' is not defined in the Drug and Cosmetics Act, 1940. However, the terms 'misbranded drug', 'adulterated drug' and 'spurious drug' are defined under sections 17, 17A and 17B respectively of the Drugs and Cosmetics Act as types of 'counterfeit medicine'.

28 What recent measures have been taken to facilitate the general public's access to information about prescription-only medicines?

The WHO Country Office for India, in collaboration with the Karnataka State Pharmacy Council, has established five drug information centres (in Haryana (Sirsa), Chhattisgarh (Raipur), Rajasthan (Jaipur), Assam (Dibrugarh) and Goa (Panaji)) to provide organised drug information to both healthcare professionals and consumers. Most drug information centres are attached to pharmacy colleges or hospitals where clinical pharmacy programmes are in place; a few are not attached to health facilities, but are often associated with state pharmacy councils. Drug information centres routinely respond to inquiries regarding:

- appropriate therapy for specific patients;
- adverse reactions to drugs;
- efficacy of drugs;
- drug interactions;
- intravenous additive incompatibilities;
- biopharmaceutic and pharmacokinetic parameters of drugs;
- dosing in cases of renal failure;
- appropriate therapy for a disease state;
- identification of foreign drugs;
- information on investigational agents; and
- information on new drugs.

In addition, a reliable resource of information on medicines is the National Formulary of India (NFI). Although the NFI serves primarily as a guidance document for medical practitioners, pharmacists, nurses, medical and pharmacy students, and other healthcare professionals, it is also accessible to the general public. The first, second and third editions of the NFI were published by the MoHFW in 1960, 1966 and 1979 respectively. In the past three decades, there has been a massive expansion in the range of new drugs available and their formulations. To address the necessity of publishing an updated version of the NFI, the MoHFW, through Notification F.No.X.11035/2/06-DFQC, dated 8 May 2008, has assigned this responsibility to the Indian Pharmacopoeia Commission (IPC). As a result, an updated NFI will be published by the IPC on behalf of the MoHFW.

29 Outline major developments to the regime relating to safety monitoring of medicines.

The Pharmacovigilance Programme of India (PvPI) was launched with the broad objective of safeguarding the health of the 1.27 billion people that form India's population. Adverse drug reactions (ADRs) are reported from all over the country to the National Coordination Centre (NCC) for the PvPI (NCC-PvPI), which also collaborates with the global ADR monitoring centre (which is based in Sweden and run by the WHO and Uppsala Monitoring Centre) to contribute to the global ADRs database. NCC-PvPI monitors ADRs in the Indian population and helps the CDSCO in making decisions regarding the safe use of medicines.

The CDSCO, which is under the aegis of the MoHFW, initiated the PvPI in July 2010, and the All India Institute of Medical Sciences (AIIMS) is the NCC for monitoring ADRs in India to safeguard the public's health. (AIIMS is one of 22 ADR monitoring centres that were set up under the PvPI). To ensure a more effective implementation of the programme, the NCC was moved from AIIMS to the IPC in April 2011.

The PvPI's mission is to safeguard public health by ensuring that the benefits of using medicines outweigh the risks associated with their use. Since considerable social and economic consequences arise from ADRs and a positive cost:benefit ratio of implementing appropriate risk management exists, there is a need to engage both healthcare professionals and the public at large in a well-structured programme to build synergies for monitoring ADRs in the country.

The PvPI collates and analyses data, and uses the inferences to recommend informed regulatory interventions, as well as communicating risks to healthcare professionals and the public. The broadened scope of pharmacovigilance regarding patient safety includes the detection of medicines of substandard quality as well as prescribing, dispensing and administration errors. Counterfeiting, antimicrobial resistance and the need for real-time surveillance of mass vaccinations are further pharmacovigilance challenges that need to be addressed.

Archana Shanker **archana@anandandanand.com**
Devinder Singh Rawat **devinder@anandandanand.com**

First Channel Building
Plot No. 17 A, Sector 16 A
Noida 201301 (UP)
India

Tel: +91 120 405 9300
Fax: +91 120 424 3056 / 058
www.anandandanand.com