The Life Sciences Law Review- India

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Introduction

India, the largest democracy in the world, has rightly been termed the 'pharmacy of the world'. The country's objective data speak for themselves. There are more than 4,655 pharmaceutical manufacturing plants, including the world's third-largest in terms of volume and 13th in terms of value, and it accounts for 20 per cent in terms of volume and 1.4 per cent in terms of value of the global pharmaceutical industry. In 2016–2017, the domestic pharmaceutical market stood at US$16.4 billion and pharmaceutical exports at US$16.8 billion, which is expected to grow to US$55 billion by 2020. According to data released by the Department of Industrial Policy and Promotion (DIPP), this sector attracted cumulative foreign direct investment (FDI) inflows worth US$15.57 billion between April 2000 and September 2017. In view of the growing market and demand, the government has, from time to time, had to upgrade its regulatory framework. The Guidelines on Similar Biologics for regulating the approval process for biosimilars were introduced in 2012 by the Ministry of Health and Family Welfare, and a draft Drugs and Cosmetics (Amendment) Bill 2015 was released so as to amend the Drugs and Cosmetics Act 1940. The objective of the said bill is to introduce provisions for clinical trials and regulation of medical devices.

The Regulatory Regime

Classification

India has a federal form of government and the regulatory framework is divided between national and state authorities. The Drugs and Cosmetics Act 1940 (DCA) and the Drugs and Cosmetic Rules 1945 (DCR) regulate the manufacture, sale, import, export and clinical research of drugs and cosmetics. The Central Drugs Standard Control Organization (CDSCO) under the Ministry of Health and Family Welfare regulates pharmaceutical products through the Drug Controller General of India (DCGI). The DCGI registers all imported drugs, new drugs and drugs in selected categories. It also has responsibility for clinical trials and quality standards. The state licensing authorities (SLAs), which are currently 35 in number, register all other products, accredit manufacturing plants and conduct the bulk of quality monitoring and inspections. In addition to the DCA and the DCR, the other pieces of legislation that regulate the approval mechanism of drugs, cosmetics and food include the Pharmacy Act 1948, the Drugs and Magic Remedies (Objectionable Advertisement) Act 1954 (the DMR Act), the Narcotic Drugs and Psychotropic Substances Act 1985, and the Drugs (Prices Control)

Order 1995 (under the Essential Commodities Act). Food-related substances other than those referred to above are covered by the Food Safety and Standards Act 2006. With the increasing market for biologics expected to touch US$250 billion by 2020, the CDSCO issued in 2012 the Guidelines on Similar Biologics, which laid down the regulatory pathway for a biologic claiming to be similar to an already authorised reference biologic. The DCA and DCR apply to the following categories: (1) 'cosmetics', which means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance, and includes any article intended for use as a component of a cosmetic; (2) 'drugs', which means all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on the human body for the purpose of repelling insects, such as mosquitoes; (3) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects that cause disease in human beings or animals; and (4) 'devices' intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals.

Non-clinical studies

Pre-clinical trials on animal models are regulated by the protocols outlined in Schedule Y of the DCA. Prior to conducting animal studies, statutory approvals from an institutional biosafety committee and an institutional animal ethics committee must be submitted. The studies should ideally be conducted pursuant to good laboratory practices (GLPs). Standard operating procedures should be followed for all tasks related to these studies. Further, a Committee for the Purpose of Control and Supervision of Experiments on Animals has been constituted under the Prevention of Cruelty to Animals Act 1960 to ensure that animals are not subjected to pain or suffering before, during or after the performance of experiments. An amendment to the Breeding of and Experiments on Animals (Control and Supervision) Rule 1998 was made in 2001 and 2006 to regulate animal experimentation. The government prohibited animal testing for cosmetics2 and made further amendments to prohibit the import of cosmetics tested on animals.

Clinical trials

In India, clinical trials are regulated through various mechanisms, including the Drugs and Cosmetics Act 1940 and Rules 1945, Schedule Y regulations for conducting clinical research issued by the CDSCO, and guidelines for interpreting the regulations, such as the Indian Council of Medical Research guidelines and the Indian Good Clinical Practice (GCP) Guidelines. While not legally binding, these guidelines for conducting clinical trials have been accepted by the industry in India. The prerequisites for conducting clinical trials in India are permission from the DCGI, ethics committee approval and mandatory registration of the trials. The Clinical Trials Registry – India was

set up by the National Institute of Medical Statistics to compulsorily register clinical trials. The ethics committee is required to review and accord its approval to the clinical trial (CT) protocol. The ethics committee will not approve any clinical trial protocol without it being registered with the licensing authority. In addition to having a clinical protocol registered with the licensing authority, the trial site will also have to be registered. It is mandatory for clinical trials to be conducted in compliance with the approved protocol requirements of Schedule Y of the GCP guidelines. A three-tier process was put in place in 2014 for reviewing and evaluating CT applications: first by the Subject Expert Committees (SECs) (formerly New Drug Advisory Committees (NDACs)) or the Investigational New Drugs (IND) committee, next by the Technical Committee, and thereafter the Apex Committee will review the recommendations of the SEC or IND committee. A Supreme Court order in 2013 stayed approximately 157 clinical trials in India and directed that no trials for new drugs should be permitted unless the consent of the subject is recorded through an audiovisual medium. The Supreme Court also emphasised the need for a balanced approach and laid down three principles for approving trials, namely assessment of risk versus benefit to patients, the need for innovation with regard to existing therapeutic options, and the unmet medical needs in the country Through a series of amendments to the DCR, the government introduced provisions relating to free medical management and financial compensation for clinical trial subjects, specifying the prerequisites for obtaining licensing authority permission to conduct clinical trials with human subjects, creating a system for the pre-screening of ethics committee registration applications, creating procedures for analysing the reports of serious adverse events occurring during clinical trials, and procedures for payment of compensation in cases of trial-related injury or death. On 15 December 2014, the government inserted a new rule, Rule 122 DAB, providing a compensation formula to determine clinical compensation in cases concerning a serious adverse event of death during a clinical trial. Pursuant to the provisions of the amendment, an independent expert committee has to be constituted to examine the report of a serious adverse event of death and give its recommendation to the licensing authority within the prescribed period. The DCGI shall decide the quantum of compensation to be paid by the sponsor or representative, as the case may be.

Named-patient and compassionate use procedures

There is no provision under the DCA and DCR that provides for compassionate use of medicines and medical devices. However, Rule 34(a) of the DCR permits the importation of small quantities of new drugs for the purpose of treatment of patients suffering from life-threatening diseases or diseases causing serious permanent disability, or such diseases requiring therapies of unmet medical needs. Rule 36 further provides for imports of small quantities of drugs for personal use. Further, Rule 122A of the DCR authorises the licensing authorities to waive local clinical trials in the public interest and grant permission for the importation of new drugs based on clinical trials done in other countries. There has also been an increase in the off-label use of drugs by medical practitioners. Currently, there is no guideline that regulates off-label use. However, if any company is advertising or selling a drug for an indication that has not been approved, they can be liable for an action under the DMR

Act.

Pre-market clearance

For commercial distribution and sale of any medicine and drug, approval from the licensing authorities is necessary. Under Rule 122E of the DCR 1945, a new drug includes (1) a drug, be it chemical or biotechnological, that has not been used in the country to any significant extent and that – except during local clinical trials – has not been recognised in the country as effective and safe for the proposed claims; (2) a drug already approved by the licensing authority for certain claims but that is now proposed to be marketed with modified or new claims, namely indications, dosage, form (including sustained release dosage form) and route of administration; or (3) a fixed-dose combination (FDC) of two or more drugs, individually approved earlier for certain claims, which are now proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in an already marketed combination is proposed to be changed, with certain claims, namely indications, dosage, form and route of administration. The Central Licensing Authority (CLA) is responsible for approving new drugs. A new drug continues to be considered as a new drug for a period of four years from the date of its first approval or its inclusion in the Indian Pharmacopoeia, whichever is earlier. Once a drug ceases to be a new drug, manufacturing approvals can be obtained from the state regulatory authorities. The form prescribed for seeking approval of a new drug is Form 44. For the importation of a new drug, permissions have to be obtained from the licensing authority on Form 44 accompanied by a fee of 50,000 rupees. The rules further provide for a reduced official fee in the event that the same applicant applies for approval of the same drug in a modified dosage form or a new claim alone. Besides having to submit forms and paying the prescribed fee while seeking an import licence, the importer has to submit data, including those released from local clinical trials carried out in accordance with the guidelines prescribed by the Act. After the licensing authority is satisfied, permission is granted to import the raw material or finished formulation on Forms 45 and 45A. In view of the definition of a 'drug' including certain medical devices and drugs, a similar approval procedure prescribed for chemical or biotechnological drugs will also apply to medical devices. In India, approval of medical devices has been quite unregulated. The CDSCO has introduced guidelines applicable to medical devices and has appointed the Central Licensing Approval Authority to oversee the approval of such medical devices. In practice, regulated medical devices that are imported can be legally sold in India after submission of the technical dossier to the Central Licensing Approval Authority. The bill of 2015 is an attempt by central government to regulate the medical device approval process. This follows the incorporation, in August 2014, of the amendment of the DCR provisions regarding the manner of labelling, and the qualification of competent persons to manufacture and test medical devices. Schedule Y of the DCR prescribes the approval process of generic drugs and the biosimilar guidelines for the approval of similar biologics. Appendix 1A of Schedule Y provides 5 The Drugs and Cosmetics Rules 1945 were amended vide GSR 690(E) dated 25 September 2014. © 2022 Law Business Research Ltd India 150 an outline of the nature of data that has to be submitted to the licensing authority to import and manufacture a new

drug already approved in the country and includes submission of bioavailability (BA) or bioequivalence (BE) and comparative studies in accordance with the BA and BE guidelines.

Regulatory incentives

In India, there are no regulatory incentives and therefore patent term extensions, patent linkage, data protection or data exclusivity for the originator's products are not provided. By conducting BE studies, the second applicant can obtain regulatory approval of the innovator's product. In the Bayer v. CIPLA case, the Supreme Court of India clearly held that India neither provides nor recognises patent linkage. However, the Delhi High Court in Bristol Myers Squibb v. Hetero Drugs made the following observation with regard to patent linkage: 'It is expected that the Drug Controller General of India while performing statutory functions will not allow any party to infringe any laws and if the drug for which approval has been sought by the defendants is in breach of the patent of the plaintiffs, the approval ought not to be granted to the defendant.' There is no procedure in India for expedited approval. However, in the public interest, the DCGI can expedite the approval process for important products. Recently, in the public interest, the DCGI agreed to a fast-track approval for a licence for Sovaldi, a drug for the treatment of hepatitis. Further, India does not have any legislation akin to the US Orphan Drug Act.

Post-approval controls

Schedule Y of the DCR 1945 prescribes post-approval controls (PSUR), which require marketing authorisation holders to submit a report every six months for the first two years after drug approval is granted. For the subsequent two years, the PSUR report must be submitted annually. Post-market surveillance includes procedures for the distribution of records, complaint handling, adverse incident reporting, product recall and taking of corrective measures. Schedule Y also requires the applicant to inform the licensing authority if the marketing of the new drug is delayed after having obtained marketing approval. In the event that the applicant and manufacturer fail to launch the product in the market within a period of six months from obtaining a licence from the CDSCO, the licence would be treated as cancelled.6 Also in 2010, the CDSCO launched the Pharmacovigilance Programme of India (PvPI) with a view to safeguarding the safety of the Indian population by monitoring drug safety and reducing the risks associated with the use of medicines. PvPI was initiated with the All India Institute of Medical Science as the National Coordinating Centre for monitoring adverse drug reactions (ADRs); 22 ADR monitoring centres were also set up – the number of these was increased to 90 in 2012–2013.

Manufacturing controls

In the case of imported drugs, the licensing authority, the DCGI, approves the manufacturing site, following inspection, and grants a Registration Certificate. The SLA is authorised to grant manufacturing licences following inspection of the premises. The manufacturer is required to

maintain the quality standard as specified in the ICH Q6A guidelines and follow the good manufacturing practice (GMP) prescribed by Schedule M to the DCR. The second schedule to the DCA also provides the standards that have to be complied with by drugs manufactured and marketed in India.

Advertising and promotion

The DMR Act, inter alia, regulates the advertising of drugs for treatment of diseases specified in the Schedule. Section 2(a) of the DMR Act states that advertisements include any notice, circular, label, wrapper and other documents and any announcement made orally or by any means of producing a transmitting light, sound or smoke. However, the Act has certain provisions wherein the advertising of drugs can be carried out subject to certain conditions laid down by Section 14, which includes any signboard or notice displayed by a registered medical practitioner on his or her premises, indicating that treatment of any disease, disorder or condition specified in Section 3 of the Schedule and the rules are undertaken in those premises. Schedule J of the DCR also regulates the advertising and marketing of drugs to some extent.

Distributors and wholesalers

The state licensing authorities provide wholesale and retail licences for distribution and sale of products.

Classification of products

The classification of drug products under the DCR has been based on their intended use. Broadly, there are two categories of products: prescription-only drugs and non-prescription drugs. Schedules H, H1 and X deal with prescription drugs, whereas Schedule G drugs are considered non-prescription drugs. Additionally, Schedules C and C1 cover drugs derived from biological origin and other related special products, Schedule X covers some narcotic drugs and Schedule F is for vaccines, serums, and the like. New drugs can also be categorised on the basis of their approval status.

Imports and exports

Obtaining approvals for the importation of drugs into India consists of three main phases: (1) new drug approval (not necessarily for new drugs only); (2) an import drug registration certificate; and (3) an import licence. Insofar as the export of drugs are concerned, the Pharmaceuticals Export Promotion Council of India is an authorised agency set up under the provisions of the Foreign Trade Policy by the Ministry of Commerce and Industry in 2004. The Ministry of Foreign Trade has provided some guidelines for the export of special chemical organism materials and equipment and technology items. The CDSCO has published a guidance document on the government submission form for the issuance of no-objection certificates (NOCs) for the export of unapproved or approved

new products or banned drugs. To obtain a NOC, the applicant has to provide a valid export order and identify the premises where the drug is manufactured.

Controlled substances

The DCA includes several provisions for regulating the manufacture, sale and import of controlled substances listed in Schedule X. Essentially, Schedule X drugs cannot be sold without prescription. They have to be stored under lock and key in a cupboard or drawer reserved solely for the storage of these substances, and comply with special packaging and labelling requirements. Further, controlled substances have to be labelled with the symbol 'Rx' in red with a special warning. Besides the DCA and DCR, India also enacted the Narcotic Drugs and Psychotropic Substances Act (the NDPS Act) in 1985 to achieve a dual objective of limited use of narcotic drugs and psychotropic substances for medical and scientific purposes as well as preventing abuse of the same. The NDPS Act was framed to comply with three international conventions to which India is a signatory, namely the Single Convention on Narcotic Drugs 1961, the Convention on Psychotropic Substances 1971 and the UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988, as well as Article 47 of the Constitution of India.

Enforcement

Section 27 of the DCA sets out the penalties for the manufacturer for the sale of drugs in contravention of the provisions of the Act. The DCA provides for punishment under the Indian Penal Code in the event that a drug is deemed to be adulterated or spurious and likely to cause death or such harm as amounts to grievous hurt; such offences are punishable with imprisonment and fine. In addition to imprisonment and a fine, the DCA under Section 31 provides for confiscation of goods. Prosecution under the DCA and DCR can be instituted only by an inspector or any gazette officer of the central government or a state government authorised in writing on behalf of the central government or the state government by general or special order, or by a person aggrieved or by a recognised consumer association. Special designated courts have been put in place for the trial of offences under the DCA.

Emergency and pandemic situation

Considering the serious nature of the covid-19 pandemic and emergency situation, there is an urgent need of vaccine to be available for patients suffering from the covid-19 virus. Currently, three new vaccine candidates are at different stage of development and approval in India.

- A vaccine developed by Serum Institute of India Private Limited (SIIPL) and AstraZeneca, COVISHIELD, has been granted permission for restricted emergency use in adult individuals above the age of 18 years. AstraZeneca had received Emergency Use Authorisation for the vaccine in UK subject to various conditions and restrictions. The safety and immunogenicity data from the

ongoing Phase II/III clinical trial of the COVISHIELD vaccine in India was found to be comparable with the phase II/III clinical trials conducted by AstraZeneca in UK, Brazil and South Africa.

- COVAXIN, Bharat Biotech's vaccine for covid-19, is an inactivated whole virion, coronavirus vaccine having potential to target mutated coronavirus strains. The data generated in Phase I and II clinical trials demonstrated a strong immune response (both antibody as well as T cell) and in vitro viral neutralisation. The ongoing phase III clinical trial on 25,800 Indian subjects has demonstrated safety as of the date of writing. COVAXIN has been granted permission for restricted use in emergency situations in the public interest as an abundant precaution, in clinical trial mode, to have more options for vaccinations, especially in case of infection by mutant strains.
- Cadila Healthcare Limited completed the Phase I/II clinical trial of Novel Corona Virus 2019-nCoV vaccine. The CDSCO has given permission for conducting Phase III clinical trials in India.

Pricing and Reimbursement

The health insurance system in India includes voluntary private health insurance and government health insurance schemes, such as the Central Government Health Scheme (CGHS), Rashtriya Swasthya Bima Yojana, the National Rural Health Mission and the Employees' State Insurance (ESI) Scheme. The health insurance system in India covers approximately 3 per cent to 5 per cent of the population. The national health system covers the cost of medicines for patients registered under the CGHS or ESI schemes. Private insurance companies 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. However, private insurance companies in India generally do not reimburse the cost of medicines that are used for treating chronic diseases, such as blood pressure and diabetes, that require regular medication for prolonged periods of time. In 1997, the government set up the National Pharmaceutical Pricing Authority (NPPA) as an independent body of experts to deal, inter alia, with issues relating to price fixing and revision, updating the list of drugs included or excluded from price control, and so on. The pricing of pharmaceutical products is regulated and falls under the Drug Prices Control Order (DPCO) 1995. In 1970, all drugs were controlled, but this control has gradually been reduced (to 347 drugs in 1978, to 163 drugs in 1987 and finally to 73 drugs in 1994). 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 to 348 medicines. The new DPCO includes provisions for regulating the price of new drugs, including patented medicines. On 29 May 2014, the NPPA issued guidelines for monitoring the inter-brand price difference of non-scheduled formulations and scheduled formulations in the public interest in several therapeutic areas, such as tuberculosis, malaria, diabetes, cardiovascular diseases, HIV/ AIDS and asthma. As a consequence, in July 2014, the NPPA brought 108 non-scheduled drugs under price control, including patented drugs. The Indian Pharmaceutical Alliance challenged the NPPA guidelines, which were later withdrawn by the government. Having said this, with a view to promoting indigenous research and development, the National Pharmaceutical Policy 2002 provided a few exemptions in the pricing of new drugs developed through indigenous research and

development, drugs produced by an indigenous process and new-drug delivery systems developed through indigenous research and development. These drugs are eligible for exemption from price control for a period of 15 years from the date of the commencement of their commercial production in the country or until the expiry of the patent in India.

Administrative and Judicial Remedies

As stated in Section II.x, civil and criminal actions can be initiated for a violation of the provisions of the DCA and DCR and penalties include imprisonment and fines under the Indian Penal Code. Additionally, medicinal product liability can arise under the Consumer Protection Act. Class actions are permitted under the Consumer Protection Act. Consumer associations or consumers having a common interest can make a complaint. Insofar as administrative actions are concerned, by and large they are related to suspension, cancellation or refusal to grant marketing or manufacturing approvals or licences. Any person who is aggrieved by the order passed by the licensing authority may, within 30 days of the receipt of the order, appeal to the central government or state government and the central or state government may, after such enquiry as it considers necessary and after giving the appellant an opportunity for making a representation in the matter, make such orders in relation thereto as it thinks fit.

Financial Relationships with Prescribers and Payers

There is no specific legislation dealing with interactions with payers, but there are various provisions dealing with the proper conduct of their procurement processes relating to bribery and kickbacks. In general, no health practitioner may manufacture, sell, advertise or promote any medicine or medical device to the public or keep a pharmacy and, equally, may not advocate the preferential use or prescription of any medicine or medical device that would not be clinically appropriate. The Organisation of Pharmaceutical Producers of India (OPPI) Code of Pharmaceutical Practices 2012 clearly provides that member companies shall not provide to a medical practitioner any cash or monetary grant for individual purposes in an individual capacity under any pretext, or provide any gift to a medical practitioner. The Uniform Code of Pharmaceutical Marketing Practices (UCPMP) is a comprehensive code on marketing practices for pharmaceutical companies. The UCPMP states that no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to persons qualified to prescribe or supply by a pharmaceutical company; gifts for the personal benefit of healthcare professionals (such as tickets to entertainment events) are also not to be offered or provided. The OPPI has urged the Department of Petroleum to make the UCPMP a statutory code. The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002,7 as amended in 2009, also bring in regulation for medical practitioners and state the following:

- A physician must not give, solicit, or receive, or offer to give, solicit or receive any gift, gratuity, commission or bonus in consideration of or in return for the referring, recommending or procuring of any patient for medical, surgical or other treatment.

- A physician must not, directly or indirectly, participate in or be a party to an act of division, transference, assignment, subordination, rebating, splitting or refunding of any fee for medical, surgical or other treatment.
- A medical practitioner must not receive any gift from any pharmaceutical or allied healthcare industry and their sales people or representatives.

Recently, the Medical Council of India issued a re-notification requiring medical practitioners to prescribe drugs with generic names. The term 'generic name' is not to be confused with off-patent drugs, and means to prescribe the drug by its chemical salt.

Special Liability or Compensation Systems

The Ethical Guidelines for Biomedical Research on Human Participants, prepared by the Indian Council of Medical Research in 2006, has been accepted as the standard by institutional ethics committees for regulating research on human beings. The sponsor, whether a pharmaceutical company, a government or an institution, should agree, before the research begins, in the a priori agreement to provide compensation for any physical or psychological injury to which participants are entitled, or agree to provide insurance coverage for an unforeseen injury whenever possible. Further special compensation mechanisms and formulas have been introduced by Ministry of Health notifications to pin down the liabilities of sponsors or contract research organisations in cases of clinical trial-related injury or death.8 Further, the manufacturer or investigator is liable to provide free medical management for as long as is required.9 The CDSCO has also issued a formula to be used as guidance in determining the amount of compensation that a clinical trial sponsor must pay in the event of clinical trial-related injury.

Transactional and Competition Issues

The past few years have seen several collaborative agreements between pharmaceutical companies: the Sun Pharma-Merck's marketing and distribution agreement for Januvia and Janumet; Bayer Zydus Pharma, the joint venture agreement between Bayer and Zydus Cadila; Matrix Laboratory's acquisition by Mylan Inc; and last but not least the Sun-Ranbaxy agreement are all examples of the recent trends. The large number of transactions between pharmaceutical companies and their impact on excessive pricing, availability of drugs and abuse of dominant position led the Competition Commission of India (CCI) to intervene in some such transactions. To regulate the transactions between two or more companies, the CCI has increasingly used Sections 3, 4 and 5 of the Competition Act 2002. The first case to be scrutinised by the CCI was the merger of Sun Pharma and Ranbaxy. The CCI granted approval of that merger. Section 140 of the Indian Patents Act also provides a list of conditions that are considered as being 'restrictive or prohibitive' in any contract for or in relation to the sale or lease of patented articles made by the patented process.

Current Developments

The CDSCO took several initiatives in the year 2014, which included the introduction of e-governance at CDSCO and the Drugs and Cosmetics (Amendment) Bill 2013 for clinical trials and medical devices based on the recommendations of the Prof Ranjit Roy Chaudhury Expert Committee. The CDSCO also issued 14 orders in July 2014 to ensure that data generated in clinical trials is authentic, while the rights of human subjects participating in the trial are well protected. The DCGI now requires submission of data for safety and efficacy for FDCs to the CLA after the DCGI learned of the SLA granting licences for FDCs without due approvals. To further strengthen the regulatory process, the government rolled out reforms for 2015. This began with the Drugs and Cosmetics (Amendment) Bill 2015, including the revision of GMP for drugs as well as medical devices. Radical steps need to be taken to ensure that the applicant for approval provides complete patent details for the application on Form 44, and an intimation to this effect should be given to the innovator, particularly when the DCGI proposes relying on those studies to grant approvals. Notification should also be given to the owner of the original data, in the event that the DCGI relies on the innovator's data to grant approvals to subsequent approvals irrespective of whether a patent exists or not. Furthermore, to further streamline the functioning of SLAs, a centralised mechanism should be introduced whereby the state authorities, before granting manufacturing approvals, notify the CLA; this is also notified to the public through the official website. Finally, for the first time, the intellectual property policy of India has been documented and codified into a focused document with a view to creating an innovation ecosystem to improve the innovation index in India (which has been extremely low).

KEY CONTACT



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