Pharmaceutical regulatory law

Regulatory framework and authorities

What is the applicable regulatory framework for the authorisation, pricing and marketing of pharmaceutical products, including generic drugs?

The legislative framework for the marketing, authorisation and pricing of pharmaceutical products in India (including generic drugs) consists of:

- the Drugs and Cosmetics Act 1940 (DCA), the Drugs and Cosmetics Rules 1945 (DCA Rules) and the Drugs (Control) Act 1950, which regulate the manufacture and distribution of pharmaceutical products;
- the Drugs (Price Control) Order 2013 (DPCO), framed under the Essential Commodities Act 1955, which regulates the pricing of certain essential medicines listed therein;
- the Pharmacy Act 1948 and the Pharmacy Practice Regulations 2015 (the Pharmacy Regulations), which prescribe conditions and qualifications, upon satisfaction of which a person can be authorised to handle or dispense medicines;
- the Medicinal and Toilet Preparations Act 1955, which levies an excise duty on medicinal preparations that contain alcohol, narcotic drugs or narcotics; and
- the Drugs and Magic Remedies (Objectionable Advertisements) Act 1954, which controls the advertisement of drugs in India.

Regulatory authorities

Which authorities are entrusted with enforcing these rules?

A dual regulatory control system exists. The central regulator for pharmaceutical products is Central Drugs Standard Control Organisation (CDSCO), which undertakes approval of new drugs, clinical trials, standard setting, import licensing and licensing for the manufacture of certain categories of drugs. However, drug regulatory authorities at the state level assume responsibility for issuing licences for manufacture, distribution and sale of drugs, and monitoring these activities.

Pricing

Are drug prices subject to regulatory control?

Drug prices in India are subject to the regulatory control of the National Pharmaceutical Pricing Authority (NPPA), which is the governing authority under the DPCO. Among other things, the NPPA is entrusted

with the task of fixing and revising prices of controlled drugs and formulations; enforcing of the DPCO; and monitoring prices of both controlled and decontrolled drugs in the country.

Notably, price controls are applicable to 'scheduled formulations' (ie, drugs mentioned in Schedule I of the DPCO, which can be found at http://www.nppaindia.nic.in/wp-content/uploads/2018/12/DPCO2013_03082016.pdf). Once a drug has been notified as a scheduled formulation, the NPPA may only revise (ie, increase or decrease) the ceiling retail prices as per the wholesale price index. These scheduled formulations also include drugs from the National List of Essential Medicines 2015, which, as its name suggests, contains an exhaustive list of vital drugs that are subject to regulatory control. The Ministry of Health and Family Welfare (MOHFW) determines the drugs that are to be included within the National List of Essential Medicines (NLEM) by way of a consultation process. The consultation process takes place every few years (usually three years) and is based on the revisions and additions to the Model List of Essential Medicines published by the World Health Organization every two years.

'Non-scheduled formulations', namely, formulations that are not mentioned in Schedule I of the DPCO, are not under a price control. However, under the DPCO, the retail prices of these formulations can only be increased by a maximum of 10 per cent year on year.

Lastly, the Government of India (GoI) may also, in the case of extraordinary circumstances and in the public interest, fix the ceiling price or retail price of any drug, whether scheduled or non-scheduled, or of a new drug for such period as it may deem fit.

Distribution

Is the distribution of pharmaceutical products subject to a specific framework or legislation? Do the rules differ depending on the distribution channel?

The legislative framework for the distribution of pharmaceutical products consists of:

- the DCA and the DCA Rules, which regulate the import, manufacture, distribution and sale of drugs in India. As per the DCA rules, a licence is required to 'sell, stock, exhibit or offer for sale or distribute drugs'. An application must be made to the appropriate authority designated by the state government, which may issue a retail, restricted or a wholesale licence (a Sale and Distribution Licence);

- the Narcotic Drugs and Psychotropic Substances Act 1985, which regulates the purposes for which, and quantity and price at which, certain drugs may be sold;
- the Pharmacy Act and the Pharmacy Regulations, which prescribe conditions and qualifications upon the satisfaction of which a person can be authorised to handle or dispense medicines. A pharmacy is also required to satisfy the conditions under Schedule N of the DCA Rules to be eligible for a Sale and Distribution Licence; and
- the Draft Guidelines on Good Distribution Practices for pharmaceutical products-Reg, 2018 (the Draft Guidelines) were introduced by the CDCSO for consideration and comments of the stakeholders. The Draft Guidelines have been proposed to be applicable to all persons and outlets involved in any aspect of the storage and distribution of pharmaceutical products, throughout the entire supply chain, between the manufacturer and the patient.

The legislative framework described above makes no distinction in the treatment of the multiple distribution channels. In addition to this, MOHFW has released the draft Drugs and Cosmetics (Amendment) Rules 2018. These draft rules relate to streamlining the regulation of sale of drugs through online portals or ‘e-pharmacies’.

Intersection with competition law

Which aspects of the regulatory framework are most directly relevant to the application of competition law to the pharmaceutical sector?

Competition rules and the pharmaceutical sector-specific laws on marketing, authorisation and pricing of pharmaceutical products must be read in conjunction with each other. More specifically, the following aspects of the regulatory framework listed in question 1 are most relevant to the application of competition law in the pharmaceutical sector:

- the DPCO empowers the GoI to set ceiling prices for certain scheduled formulations on the basis of which manufacturers may set maximum retail prices, after accounting for local taxes. For new drugs, manufacturers may set maximum retail prices on the basis of retail prices determined by the government and local taxes;
- the Essential Commodities Act, which empowers the government to regulate the production, supply and distribution of essential commodities, including pharmaceutical products; and

- the Pharmacy Act, which prescribes the conditions and qualifications upon the satisfaction of which a person may be authorised to handle or dispense medicines.

The Competition Commission of India (CCI), as per its advocacy mandate in October 2018, issued a policy note titled 'Making Markets Work for Affordable Healthcare' (the Healthcare Policy Note; https://www.cci.gov.in/node/4184) covering the role of intermediaries in drug price build-up; quality perceptions behind proliferation of branded generics; vertical arrangements in healthcare services and lack of transparency and regulation of the pharmaceutical sector and competition.

Competition legislation and regulation

Legislation and enforcement authorities

What are the main competition law provisions and which authorities are responsible for enforcing them?

The Competition Act 2002 (CA02) and its allied regulations constitute the framework for competition law in India. The CA02 is primarily enforced by the CCI. The orders of the CCI can be appealed to the National Company Law Appellate Tribunal (NCLAT). A further appeal lies to the Supreme Court of India (the Supreme Court).

The main CA02 provisions governing the pharmaceutical sector are as follows:

- anticompetitive horizontal agreements and anticompetitive vertical restraints (section 3 of the CA02);
- abuse of dominant position (section 4 of the CA02); and
- combinations (sections 5 and 6 of the CA02).

The CCI has also issued its Healthcare Policy Note, focusing on issues leading to anticompetitive concerns in the healthcare and the pharmaceutical sector in India.

Public enforcement and remedies

What actions can competition authorities take to tackle anticompetitive conduct or agreements in the pharmaceutical sector and what remedies can they impose?

The CCI can direct enterprises to cease and desist from their involvement in anticompetitive agreements or conduct. The CCI can also impose monetary penalties for anticompetitive conduct that can extend to up to 10 per cent of a company's average (relevant) turnover for the

preceding three financial years. In the case of cartels, the fine can be up to three times the profit made for each year for which the cartel was in existence. Additionally, the CCI may impose fines on individuals responsible for anticompetitive conduct.

In relation to the penal powers of the CCI, the Supreme Court in Excel Crop Care Limited v Competition Commission of India and Another (2017 (8) SCC 47) has now limited the scope of turnover to only 'relevant turnover' (ie, at the time of determining the quantum of penalty in the case of a multi-product company, the CCI may only consider the turnover of the 'infringing' product or service, as opposed to the total turnover of the enterprise found guilty of contravening the provisions of the CA02).

Further, with respect in relation to individual penalties, the CCI, in M/s Arora Medical Hall, Ferozepur v Chemists & Druggists Association, Ferozepur (Case No. 60 of 2012), imposed a penalty of an amount equal to 10 per cent of the average income of the preceding three years on an individual office bearer of the Chemists and Druggists Association, Ferozepur, for entering into an agreement to limit supply of drugs and medicines. This set a trend, and the CCI has adopted equally stringent approaches in subsequent cases, such as Rohit Medical Stores v Macleods Pharmaceutical Limited and Ors (Case No. 78 of 2012), where the CCI imposed a penalty equal to 10 per cent of the average income of the preceding three years on an office bearer of the Himachal Pradesh Society of Chemists and Druggists Alliance (HPSCDA) for his active involvement in anticompetitive practices carried out by the HPSCDA

The CCI is also empowered to modify anticompetitive agreements (whether horizontal or vertical or agreements entered into by a dominant enterprise), order the division of a dominant enterprise or pass any other order it may deem fit. Where an enterprise found to be in contravention of the CA02 is a member of a group and the CCI finds other members of such group to also be responsible for or have contributed to such contravention, it may pass orders against such members of the group as well. 'Group' is defined as 'two or more enterprises, which directly or indirectly are in a position to exercise 50 per cent or more of the voting rights in the other enterprise; appoint 50 per cent of the members of the board of directors in the other enterprise; or control the management and affairs of the other enterprise'.

Private enforcement and remedies

Can remedies be sought through private enforcement by a party that claims to have suffered harm from anticompetitive conduct or agreements implemented by pharmaceutical companies? What

form would such remedies typically take and how can they be obtained?

The NCLAT is empowered to allow compensation from any enterprise, for any loss or damage that is shown to have been suffered, as a result of any contravention of the provisions of Chapter II of the CA02 (anticompetitive agreements and abuse of dominant position and merger control). Claims for compensation may be filed by the central government, state government, local authority or any enterprise or person.

The claim may arise from the final findings of the CCI or NCLAT (in an appeal against the findings of the CCI). Compensation may also be sought for contravention of orders of the CCI or NCLAT. There have been few cases in which compensation applications have been filed, with none relating to the pharmaceutical sector. In the decision of Adidas India Marketing v Nike India & Ors (CA No. 45/2007), the erstwhile Competition Appellate Tribunal (COMPAT), the predecessor to the NCLAT, held that the power of the COMPAT to award compensation is restricted to cases where loss or damage has been caused as a result of monopolistic or restrictive or unfair trade practice; the COMPAT has no jurisdiction where damage is claimed for a mere breach of contract. In this case, the COMPAT also imposed a fine on the applicant for filing a frivolous compensation claim.

Sector inquiries

Can the antitrust authority conduct sector-wide inquiries? If so, have such inquiries ever been conducted into the pharmaceutical sector and, if so, what was the main outcome?

The CCI, as per its advocacy mandate, commissions market reports and conducts sectoral studies from time to time to determine whether industry practices contravene the CA02. In July 2010, the CCI commissioned a study entitled ‘Competition Law and Indian Pharmaceutical Industry’. The study, conducted by the Centre for Trade and Development in New Delhi, concluded that although there was exponential growth in the industry, there was limited price competition among retailers. In 2013, the CCI initiated another study on the domestic pharmaceutical industry to look into issues relating to the patents regime, pricing, the process of manufacture and the terms and conditions for the sale of drugs through chemists and druggists in India. The outcome of the study is still awaited.

In February 2014, the CCI issued a press release in which it noted that it had passed several orders identifying the following practices in the

pharmaceutical sector as being anticompetitive and in contravention of the provisions of the CA02:

- the issuance of a no objection certificate by trade associations as a precondition for appointing stockists;
- compulsory payments of product information service charges to the trade associations for release of new drugs or formulations;
- the fixation of trade margins for sale of drugs or formulations by the trade associations; and
- calls for boycotts by trade associations.

As such, the press release drew the attention of associations of chemists, druggists, stockists, wholesalers and manufacturers to bring any violations of the CCI order to the CCI's notice.

The CCI, in its 17 years of enforcement of the CA02, has received over 50 cases pertaining to the pharmaceutical and healthcare sector. While deciding these cases, the CCI has observed that information asymmetry in this sector restricts consumer choice and as such felt the need for a closer examination of this sector. Pursuant to this, the CCI has taken lot of initiatives in this sector, culminating in a workshop on 'Competition Issues in Pharmaceutical and Healthcare Sector in India'. The issues identified and recommendations suggested by the relevant stakeholders in this workshop have been documented in healthcare policy note.

The CCI has also invited entities to carry out a study on the pharmaceutical and healthcare industry in India to look into public and private hospitals, insurance companies, pharmaceutical firms and their associations, and doctors and their associations, to understand if there were any anticompetitive practices prevalent in these industries. The Healthcare Policy Note, issued in October 2018 by the CCI, covers role of intermediaries in drug price build-up; quality perceptions behind proliferation of branded generics; vertical arrangements in healthcare services and lack of transparency and regulation of pharmaceutical sector and competition.

Health authority involvement

To what extent do health authorities or regulatory bodies play a role in the application of competition law to the pharmaceutical sector? How do these authorities interact with the relevant competition authority?

The CA02 empowers the CCI to make a reference to other statutory authorities on issues emanating from legislations whose implementation

is entrusted to separate authorities established under various laws, such as sectoral regulators. Similarly, statutory authorities may also refer issues that may be related to competition law to the CCI, should such a need arise. We are not aware of any such reference in the pharmaceutical sector. However, while analysing a pre-merger notification concerning television channel broadcasting (including through Cable TV services and Direct-2-Home services), the CCI sought the opinion of the Telecom Regulatory Authority of India and the Ministry of Information and Broadcasting.

NGO involvement

To what extent do non-government groups play a role in the application of competition law to the pharmaceutical sector?

Non-government groups can play a role in the application of competition laws in two ways: they may give information to the CCI regarding anticompetitive conduct, on the basis of which an investigation may be initiated. They may also be asked for their views as third parties during an ongoing investigation. There have been instances of investigations being initiated by the CCI on the basis of information provided by trade or consumer associations.

Review of mergers

Thresholds and triggers

What are the relevant thresholds for the review of mergers in the pharmaceutical sector?

The CA02 has not prescribed sector-specific merger review thresholds. The assets and turnover value-based notification thresholds specified under the CA02 are applicable across all sectors. (Notification thresholds are available on www.cci.gov.in/sites/default/files/quick_link_document/Revised%20thresholds.pdf).

Is the acquisition of one or more patents or licences subject to merger notification? If so, when would that be the case?

The CA02 requires the mandatory notification of acquisitions of shares, voting rights, assets or control, when the relevant jurisdictional thresholds are satisfied and the transaction does not benefit from any exemption.

Intellectual property rights (IPRs), including patents, have also been held as being assets. The CCI has also considered exclusive licences as assets. Accordingly, the acquisition of one or more patents or licences (only when exclusive) may be subject to merger reporting requirements.

Market definition

How are the product and geographic markets typically defined in the pharmaceutical sector?

The CCI has typically accepted relevant product markets, which have been defined using the EphMRA anatomical therapeutic chemical (ATC) classification for pharmaceutical products. Markets have been defined at both ATC3 (therapeutic) and ATC4 (chemical/molecular) levels.

The CCI's decisional practice reveals the adoption of differing approaches given the complexity of each case. In Procter and Gamble Company/Merck Consumer Health Holding Germany GmbH (C-2018/06/579) and Sanofi/Boehringer Ingelheim International GmbH (C-2016/07/413) the CCI assessed overlaps at both ATC3 and ATC4 levels. However, in Sun Pharmaceutical Industries Limited/Ranbaxy Laboratories Limited (C-2015/05/170) (Sun/Ranbaxy), the CCI analysed overlaps only at the molecular level, in other words 'medicines and formulations based on the same API'.

Geographic markets are typically defined as pan-India.

Sector-specific considerations

Are the sector-specific features of the pharmaceutical industry taken into account when mergers between two pharmaceutical companies are being reviewed?

The CCI has indeed taken certain sector-specific features of the pharmaceutical industry into consideration while reviewing transactions in the pharmaceutical space. A pertinent example is the pervasive level of government regulation in the sector, especially with respect to prices. The CCI, in Sun/Ranbaxy, assessed a total of 51 molecules for potential competition concerns, out of which it determined that seven were likely to result in an appreciable adverse effect on competition (AAEC). However, no AAEC was determined with respect to four of the formulations, even though they had relatively high combined market shares owing to the fact that they were covered in the NLEM and were subject to price control.

Addressing competition concerns

Can merging parties put forward arguments based on the strengthening of the local or regional research and development activities or efficiency-based arguments to address antitrust concerns?

The CA02 prescribes several factors that the CCI must consider when determining if any conduct or agreement results in an AAEC. These factors include the following:

- the creation of barriers to new entrants in the market;
- the driving of existing competitors out of the market; and
- foreclosure of competition by hindering entry into the market; and
- accrual of benefits to consumers;
- improvements in production or distribution of goods or provision of services; or
- promotion of technical, scientific and economic development by means of production or distribution of goods or provision of services.

Accordingly, while analysing the effect of a merger, the CCI is bound to consider positive factors such as benefits to consumers, promotion of technical development and increased efficiency in production or distribution of goods.

Horizontal mergers

Under which circumstances will a horizontal merger of companies currently active in the same product and geographical markets be considered problematic?

The CA02 and its allied regulations do not specify any thresholds for overlap that may automatically be considered problematic. The relevant test is whether the overlap between the merging parties is likely to cause an AAEC in India. The CCI has typically used high combined market shares in the relevant markets as a primary indicator of whether a horizontal merger is likely to cause an AAEC. Also included in this assessment are factors such as presence of strong competitors, barriers to entry in the market (such as the presence of patented products) and (especially for pharmaceutical mergers) the level of governmental regulation.

To take an example, in Sun/Ranbaxy, the CCI determined overlaps between Sun Pharmaceutical Industries Limited (Sun Pharma) and Ranbaxy Laboratories Limited (Ranbaxy) at the ATC4 (molecular) level. Of the 51 overlapping or competing formulations, the CCI deemed seven as being problematic. The parties had high combined market shares (up to even 90-95 per cent) in the market for these seven formulations. Sun/Ranbaxy thus became the first transaction for which the CCI ordered divestments in certain products.

Product overlap

When is an overlap with respect to products that are being developed likely to be problematic? How is potential competition assessed?

The CCI requires information on pipeline products and services to be disclosed in respect of transactions that involve high market shares to be able to examine whether there is likely to be a concern. Specifically, the Combination Regulations clarify that where the combined market share of the parties in horizontal overlap markets exceeds 15 per cent, or 25 per cent in vertically linked markets, it is preferable for parties to notify the proposed combination in the more detailed Form II. At the time of providing information in Form II, parties are required to disclose whether any of the parties have 'pipeline products or services' (ie, products or services likely to be introduced in the market in the near future). If so, parties are then required to provide an estimate of projected sales and market shares over the course of the following three to five years.

The CCI typically assesses such pipeline products to determine whether the transaction in question would have an AAEC in the relevant markets for such pipeline products. In Sun/Ranbaxy, the CCI assessed two pipeline products of Ranbaxy in the therapeutic category for 'oral anti-diabetics', which overlapped with certain formulations sold by Sun Pharma in India. As part of its assessment, the CCI considered whether the transaction would stall the release of these pipeline products by Ranbaxy. However, given the likelihood of new entry into the market for such products in India, the CCI did not conclude that this led to any AAEC in India.

Remedies

Which remedies will typically be required to resolve any issues that have been identified?

Post its assessment of a notified transaction, the CCI may approve it unconditionally, disapprove it or approve it subject to certain modifications. The CCI has, in the past, directed both behavioural as well as structural modifications aimed at mitigating the competitive effects of the transaction. In Sun/Ranbaxy, which was the first instance of a detailed Phase II investigation in India, the CCI ordered Sun Pharma and Ranbaxy to divest seven brands and appointed PricewaterhouseCoopers to supervise the divestment process. The purchase of the divested assets by Emcure Pharmaceuticals was approved by the CCI in March 2015.

Further, the CCI has, on at least three occasions, modified the terms of long-term non-compete clauses entered into by the parties to transactions in the pharmaceutical space. The duration of these non-

compete obligations was reduced to three to four years to ensure that they did not unreasonably hinder entry into the market.

Anticompetitive agreements

Assessment framework

What is the general framework for assessing whether an agreement or concerted practice can be considered anticompetitive?

Under the CA02, any agreement in respect of production, supply, distribution, storage, acquisition or control of goods, or provision of services that causes or is likely to cause an AAEC within India shall be void. Specifically, horizontal agreements that fix prices, limit or control production or supply of goods or services, share markets or sources of production, or result in bid-rigging are presumed to be anticompetitive. This presumption is rebuttable, though it is quite difficult to do so. Efficiency-enhancing joint ventures are not subject to the presumptive rule that is otherwise applicable to horizontal anticompetitive agreements.

Vertical restraints, including tie-in arrangements, refusal to deal, resale price maintenance (RPM) arrangements, exclusive supply and exclusive distribution agreements, are prohibited only if they cause or are likely to cause an AAEC in India. The CCI considers the following factors while determining whether an agreement causes or is likely to cause an AAEC:

- creation of barriers to entry;
- market foreclosure;
- removal of competitors;
- benefit to consumers;
- improvement in production or distribution of goods or services; and
- promotion of technical, scientific and economic development.

The above provisions relating to anticompetitive agreements do not apply to reasonable and necessary conditions or restrictions imposed for the protection of IPRs that have been registered under identified IPRs in India. Moreover, agreements exclusively relating to the export of goods or services are also exempt from the scope of anticompetitive agreements.

Technology licensing agreements

To what extent are technology licensing agreements considered anticompetitive?

Technology licensing agreements may be considered anticompetitive if they cause or are likely to cause an AAEC in India.

Restrictive terms in technology licensing arrangements are likely to be examined as vertical restraints under the CA02. Absent market power, restrictions in technology licence agreements are less likely to raise concerns. When the licensor enjoys significant market power, the restrictions it imposes in licensing agreements, regardless of whether the underlying technology is protected by IPRs, may be susceptible to scrutiny by the CCI. For instance, any attempt by a licensor to determine or influence the pricing decision (for the licensed IP) of the IP licensee may be scrutinised as a potentially anticompetitive RPM.

Licensors may also impose territorial or customer-specific restrictions as part of a licensing arrangement (ie, by forbidding the sale of the licensed product to a set of customers or territory). Such territorial or customer specific restriction may be scrutinised as potentially anticompetitive 'exclusive distribution' or an anticompetitive 'refusal to deal'. A licensor may also restrict licensees from dealing with any competing licensor, a restriction that may be examined as a potentially anticompetitive 'exclusive supply' arrangement. Any attempt by the licensor to make the grant of the IP licence conditional on the IP licensee purchasing the IP licensor's other products, services or licences would be treated as a potentially anticompetitive tie-in arrangement.

Unlike in the US and the EU, where refusal to deal is usually examined as unilateral conduct, in India, a refusal to grant a licence altogether or imposition of unreasonably restrictive licensing terms may be examined as a potentially anticompetitive vertical restraint. For instance, in Shamsher Kataria v Honda Siel (Case No. 3 of 2011) (Autoparts case), the CCI viewed certain automobile companies' refusal to license their diagnostic (software) tools and repair manuals to independent repairers and workshops as an anticompetitive (vertical) refusal to deal.

Importantly, the CA02 provides a limited carve-out allowing owners of IP duly registered under an identified IP statute in India, including restrictions accompanying their licensing arrangements, which are both reasonable and necessary to prevent the infringement of their existing IP rights. In the Autoparts case, the automobile companies under investigation were unable to benefit from this limited exception as many were unable to adequately demonstrate either that their IP was registered in India, or that the restrictions in question were both reasonable and necessary for protecting their IP rights (presuming they were validly registered).

Finally, restrictive conditions or the imposition of unfair royalty rates in technology agreements, where the licensor has sufficient market power to be held ‘dominant’, may be scrutinised as an abuse of dominance under section 4 of the CA02. The limited carve-out for IP holders under the CA02 is not available for such unilateral conduct.

Co-promotion and co-marketing agreements

To what extent are co-promotion and co-marketing agreements considered anticompetitive?

Co-promotion and co-marketing agreements may raise both vertical and horizontal anticompetitive concerns. A vertical relationship is created when the owner of the patented drug (owner) grants another entity (partner) the right to distribute, sell or market the product by way of the co-marketing agreement. If such an agreement incorporates vertical restraints contemplated in section 3(4) of the CA02 (such as tie-in arrangement or RPM), the same set of concerns as discussed in question 21 would arise.

Co-marketing or co-promotion arrangements also create a horizontal relationship between the contracting parties, since the owner typically retains the right to manufacture, distribute, sell and market its product while it grants similar rights to manufacture, distribute, sell and market to the counter-party. In such a case, the owner and the partner become competitors in the downstream market for manufacture, sale, distribution and marketing, as the case may be. Accordingly, any provision in the agreements that results in directly or indirectly fixing prices, limiting production or supply, market allocation or sources of production or any form of bid-rigging, will be presumed to be anticompetitive. For instance, a non-compete clause in a co-marketing agreement that restricts the partner from selling any other pharmaceutical product that is similar to the subject of the co-marketing arrangement is likely to be viewed as an agreement (between entities engaged in the same level of trade) to limit the supply of the product in the market, and will be presumed to cause an AAEC under the CA02. Similarly, a non-compete clause that essentially precludes the partner from selling the subject products to a particular kind of customer (eg, hospital dispensaries) or certain markets (certain regions within India), is likely to be viewed as a horizontal arrangement to allocate markets, and will be presumed to result in an AAEC under the CA02. While the CCI is yet to reach a finding on horizontal anticompetitive concerns arising out of co-promotion or co-marketing agreements, the parties to such agreements will have the opportunity to present counter evidence to rebut the presumption of AAEC usually associated with anticompetitive horizontal agreements.

It has been reported that the CCI is currently investigating Novartis, Abbott, Emcure and USV for possible collusion in the sale of Vildagliptin (an anti-diabetic drug). It has been alleged that Novartis, the patent holder and drug manufacturer, has engaged in price-fixing through co-marketing arrangements with Abbott, Emcure and USV. Abbott had challenged CCI's prima facie order before the Delhi High Court, stating that the document submitted by NPPA was inaccurate and that the email submitted purportedly by one of Abbott's employee was forged. The Delhi High Court did not find merit in the contentions and dismissed the writ petition. However, no other orders in the matter have been passed by the CCI and it is difficult to ascertain the status of this investigation.

Other agreements

What other forms of agreement with a competitor are likely to be an issue? How can these issues be resolved?

As indicated in question 22, agreements between actual or potential competitors, including buyer-seller agreements (between entities that otherwise compete), that directly or indirectly result in fixing prices, limiting supplies and allocating markets (by division of geographic areas or customer base) are prohibited on the basis of the presumption that they cause an AAEC in India. Implementing firewalls to prevent the exchange of confidential and sensitive business information (that would make it difficult to fix prices or coordinate supplies) may mitigate, but not eliminate, the risk of scrutiny by the CCI for potential anticompetitive conduct.

Apart from the types of co-marketing agreements identified in question 20, agreements in the nature of 'pay-for-delay' or reverse settlement agreements (where patent-holding pharmaceutical companies enter into private agreements with generic companies to delay the entry of generics for a consideration) are likely to raise concerns under the CA02. It is likely that the CCI will see a pay-for-delay arrangement as an anticompetitive agreement between competitors to restrict the supply of goods in the market. However, the CCI will also likely examine the application of the limited IP carve-out under section 3(5) of the CA02 to such agreements. Even while the patent holder may have entered into a 'pay-for-delay' agreement with a generic company during the term of the patent (which, under the Indian Patents Act, 1970, gives exclusive rights to the patentee for, inter alia, making, using and selling the patented drug), the possibility that the CCI will consider the pay-for-delay arrangement a reasonable and necessary condition for protecting IP rights under section 3 of the CA02, appears to be low.

Similarly, the CCI may also examine settlement agreements between patent-holding pharmaceutical companies and generic companies to settle patent infringement proceedings. Agreements to settle such patent infringement litigation may be viewed as anticompetitive agreements to limit or restrict the supply of products under section 3 of the CA02 if they have been entered into either with the objective of, or result in, the delay or thwarting of the entry of a potential competitor in the market. Such delay or restriction on the entry of a competitor would effectively extend the benefit of the patent protection beyond the statutory lifespan of the patent and hence not benefits from the limited carve-out provided under section 3(5) of the CA02.

In these cases, much like in the US and EU, the CCI is likely to focus on whether the purpose of these agreements or settlements is to delay the entry of a generic drug in the market, which would otherwise have competed with, and been available at, a fraction of the cost of the patented drug. In this respect, in August 2014, it was reported that the CCI is likely to review a patent deal between Hoffmann-La Roche and Cipla in respect of lung cancer drug, Erlotinib, as well as one between Merck Sharp and Dohme Corp (MSD) and India's Glenmark Pharmaceuticals Ltd on the antidiabetic drug, Sitagliptin. The same report also mentioned that the CCI would investigate the market impact of ex parte injunctions secured by Novartis AG and MSD against a dozen local drug makers, blocking them from launching copies of diabetes drugs Vildagliptin and Sitagliptin. However, apart from investigation into an alleged cartel arrangement between Novartis and its co-marketing partners, Emcure, USV and Abbott, in respect of a diabetes drug, there has since been no further report or order from the CCI on these issues.

Issues with vertical agreements

Which aspects of vertical agreements are most likely to raise antitrust concerns?

Vertical restraints are not, per se, anticompetitive, unless they cause or are likely to cause an AAEC in India. The CA02 identifies an inclusive set of vertical agreements such as tie-in arrangements, refusal to deal, RPM arrangements, exclusive supply and exclusive distribution agreements, which would be anticompetitive if they cause or are likely to cause an AAEC in India.

Patent dispute settlements

To what extent can the settlement of a patent dispute expose the parties concerned to liability for an antitrust violation?

As indicated in question 23, antitrust issues arising out of the settlement of patent disputes have yet to be considered by the CCI. However, settlements of patent infringement litigation between parties may be reviewed by the CCI to examine whether the object or effect of the agreement is to delay or thwart the entry of a potential competitor in the market, to the detriment of consumers.

Joint communications and lobbying

To what extent can joint communications or lobbying actions be anticompetitive?

Joint communications or lobbying actions by way of a trade association or otherwise, to the extent that they relate to industry-wide issues such as government policies, taxes etc and not individual conduct, are unlikely to raise anticompetitive concerns. However, communications or actions that would facilitate any form of collusive practice (eg, on prices, territory of sales and introduction of new products) are likely to be examined under the provision on cartels.

Specifically, in the context of the pharmaceutical industry, in a large number of cases involving various chemists' and druggists' associations, the CCI found the obligation imposed by trade associations on pharmaceutical companies to pay mandatory product information service charges at the time of launching any new products to be anticompetitive to the extent they result in output restrictions and price-fixing (Varca Druggists case (MRTP 127/2009/DGIR), Sandhya Drug Agency case (Case No. 41 of 2011)).

Similarly, the following have been identified as anticompetitive conduct to the extent that they were found to limit supplies in the market and have the effect of determining prices:

- requiring new stockists to obtain a no objection certificate from the association before being eligible to be appointed to a pharmaceutical company (Belgaum Chemists & Druggists (Case No. C-175/09/ DGIR/27/28-MRTP), Santuka Associates (Case No. 20 of 2011), and Vedanta Bio Sciences, Vadodara v Chemists and Druggists Association of Baroda (Case No. C-87/09/DGIR);
- fixing industry-wide minimum trade margins (Peeveear Medical Agencies (Case No. 30 of 2011); and
- giving instructions to boycott pharmaceutical companies or stockists for non-compliance with the associations' norms (In re: Bengal Chemists & Druggists Association (Suo Moto Case No. 2 of 2012), Arora Medical Hall (Case No. 60 of 2012)).

However, in All India Tyre Dealers' Federation v Tyre Manufacturers Association (MRTP case: RTPE No. 20 of 2008), the CCI held that trade associations may adopt measures that are necessary to protect the interests of its members, as long as they are not in contravention of the CA02. The CCI found that the discussion around low prices, increase in input costs, petition for levy of anti-dumping duties, blacklisting importers and export realisation, among the members of the tyre manufacturers association, fell within the realm of legitimate lobbying conduct, as they were not undertaken with the aim of determining the individual conduct of any of its members.

Public communications

To what extent may public communications constitute an infringement?

Public communications that are aimed at or facilitate collusion, for example, of prices or production quantity, are likely to be examined under the provision dealing with cartels. For instance, announcements by an enterprise indicating a possible increase in its price, followed by other players in the market, may indicate collusion and invite scrutiny. The CCI, though, will have to prove that the public announcement of prices indeed led to an agreement among all competitors to fix prices. However, public announcements, joint press statements or press releases setting out common and legitimate industry concerns (eg, in respect of a government policy) are unlikely to be considered anticompetitive.

Exchange of information

Are anticompetitive exchanges of information more likely to occur in the pharmaceutical sector given the increased transparency imposed by measures such as disclosure of relationships with HCPs, clinical trials, etc?

The current Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002 prohibit any form of relationship between pharmaceutical enterprises and HCPs. However, in practice, the interaction between pharmaceutical companies, device manufacturers, or their agents and HCPs has always been opaque. It would therefore, be difficult to determine the likelihood of anticompetitive information exchanges between pharmaceutical companies and HCPs.

Recently, the GoI required all clinical trials to be compulsorily registered with the Clinical Trial Registry India. However, it is unclear whether disclosure in relation to clinical trials would facilitate any information exchange between pharmaceutical companies. In addition to these regulations and rules, there are several other regulations that require

pharmaceutical companies to disclose confidential information to third parties.

Such information exchange would not in itself constitute a contravention under the CA02. The CCI held in In Re: Alleged Cartelization in Flashlights Market in India (Suo Motu Case No. 1 of 2017) that the mere exchange of information between competitors did not constitute enough evidence to conclude that the parties were acting in a concerted manner contrary to the provisions of the CA02. Rather, such evidence has to be considered in conjunction with other evidence (such as contemporaneous increases in prices) to establish a contravention.

Notably, the CA02 does not expressly exempt conduct undertaken in compliance with any other regulation (other than the relevant exemption for IPRs). Therefore, if the information exchange between pharmaceutical companies mandated by other regulations results in any collusive conduct, the enterprises may still be liable under the provisions of the CA02.

Anticompetitive unilateral conduct

Abuse of dominance

In what circumstances is conduct considered to be anticompetitive if carried out by a firm with monopoly or market power?

The CA02 lists certain conduct, which, if practised by a firm in a dominant position, shall be considered an abuse of dominant position. This includes the following:

- imposing unfair or discriminatory conditions or prices on sale of goods;
- limiting or restricting production of goods, or technical or scientific development;
- denying market access;
- making the conclusion of contracts subject to the acceptance of obligations that have no connection with the subject matter of the contract; or
- using its dominant position in one relevant market to enter into or protect another.

De minimis thresholds

Is there any de minimis threshold for a conduct to be found abusive?

Under the CA02, once it is determined that the enterprise is dominant, there is no de minimis threshold for abusive conduct. Given the CCI's propensity to define the markets narrowly, the conduct in question may be found abusive even if the market size is very small or the number of customers being affected is insignificant.

For instance, in House of Diagnostics LLP v Esaote SpA (Case No. 9 of 2016), the CCI defined the relevant market as the market for 'dedicated standing/tilting MRI machines in India', distinguishing this market from regular MRI machines on account of its unique tilting system. Esaote, being the only manufacturer of dedicated tilting MRI machines, was found to have a 100 per cent market share, and thus a dominant enterprise - in spite of the fact that Esaote had sold very few machines in India. Esaote's alleged conduct (refusal to perform contractual obligations and unilaterally changing the essential terms of the contract) was examined only in respect of the informant (and no other consumers) and one supply order. On this basis alone, the CCI reached a finding that Esaote had abused its dominant position in the identified relevant market and imposed a penalty of 0.9 million rupees.

Similarly, in the Autoparts case, the CCI defined the relevant market as the market for sale of spare parts in respect of each original equipment manufacturer's (OEM) brand. The CCI found each OEM to be dominant in the supply of spare parts pertaining to their brand, and concluded that each enterprise had abused its dominant position in that relevant market by, inter alia, charging excessive prices for spare parts and denying market access to multi-brand workshops and independent repairers.

Market definition

Do antitrust authorities approach market definition in the context of unilateral conduct in the same way as in mergers? If not, what are the main differences and what justifies them?

The CA02 makes no distinction in its approach towards market definition in the context of unilateral conduct and mergers. It states that the relevant market must be determined with reference to the relevant product market and the relevant geographic market. To this extent, CA02 lists out certain factors that must be considered by the CCI while determining the relevant product market and the relevant geographic market such as the following:

- relevant product market:
    - physical characteristics or end-use of goods;
    - price of goods or services;

    - consumer preferences;
    - exclusion of in-house production;
    - existence of specialised producers; and
    - classification of industrial products; and
- relevant geographic market:
    - regulatory trade barriers;
    - local specification requirements;
    - national procurement policies;
    - adequate distribution facilities;
    - transport costs;
    - language;
    - consumer preferences; and
    - need for secure or regular supplies or rapid after-sales services.

Notably, the decisional practice of the CCI thus far, leans in favour of relatively narrow market definitions. For instance, in Belaire Owners Association v DLF (Case No. 19 of 2010), the CCI defined the relevant market in the narrowest possible way as the market for 'services of developer/builder in respect of high-end residential accommodation in Gurgaon'. Similarly, in Kapoor Glass v Schott India Pvt Ltd (Case No. 22 of 2010), the CCI defined the relevant market as only consisting of 'neutral USP-1 borosilicate glass tubes'. In Sun Pharma/Ranbaxy, the CCI defined the relevant market at the narrowest ATC4 level for each formulation.

Establishing dominance

When is a party likely to be considered dominant or jointly dominant? Can a patent owner be dominant simply on account of the patent that it owns?

An enterprise is considered dominant if it enjoys a position of strength that allows it to act independently of competitive forces in the market; or can affect the relevant market, competitors or consumers in its favour. The CA02 lists certain factors that the CCI must consider while assessing whether a firm is in a dominant position, including:

- market share of the enterprise;

- size and resources of the enterprise;
- size and importance of the competitors;
- economic power of the enterprise, including commercial advantages over competitors;
- vertical integration of the enterprises or sale or service network of such enterprises;
- dependence of consumers on the enterprise;
- monopoly or dominant position whether acquired as a result of any statute or by virtue of being a government company or a public sector undertaking or otherwise;
- entry barriers, including barriers such as regulatory barriers, financial risk, high capital cost of entry, marketing entry barriers, technical entry barriers, economies of scale, high cost of substitutable goods or service for consumers;
- countervailing buying power;
- market structure and size of market;
- social obligations and social costs;
- relative advantage, by way of the contribution to the economic development, by the enterprise enjoying a dominant position having or likely to have an AAEC; and
- any other factor the CCI may consider relevant for the inquiry.

The CCI has often considered high market shares as a proxy for dominance (Belaire Owners Association v DLF (Case No. 19 of 2010)). However, in National Stock Exchange v Competition Commission of India & MCX (Appeal No. 15 of 2011), the COMPAT concluded that the National Stock Exchange's (NSE) market position in the currency derivative (CD) segment could not be determined by its market share in isolation, in other words, in the CD segment alone. The COMPAT held that one had to take into account a whole host of factors, including size and resources of the enterprise, extent of vertical integration and economic power of the enterprise. The COMPAT concluded that, given the enormous economic strength of the NSE, its high market share in other segments of the market for trading and its ability to leverage its market power in other segments to protect its CD market position, it could be said to be dominant in the CD market. Notably, the COMPAT held the NSE to be dominant in the CD market even though the NSE's

market share in this market had drastically fallen over the past few years owing to the operations of the other enterprises present in the market.

Lastly, the CA02 does not recognise the concept of joint dominance. In In Re: Mr Arjun and Viacom 18 & Ors (Case No. 57 of 2017), the CCI dismissed allegations of joint dominance against a group of digital cinema equipment suppliers because section 4 of the CA02 did not allow more that one enterprise to hold a dominant position within a given relevant market.

IP rights

To what extent can an application for the grant or enforcement of a patent or any other IP right (SPC, etc) expose the patent owner to liability for an antitrust violation?

The CA02 does not prohibit or identify the mere application for the grant of a patent or the initiation of enforcement actions as anticompetitive. In practice, the CCI has opened the door for antitrust claims against IP holders' enforcement actions, including by way of injunctions.

Notably, and as indicated in question 21, the CA02 provides a limited carve-out for patent holders from antitrust liability in respect of anticompetitive agreements to the extent that the patentees conduct is necessary for the protection of its patents under the Patents Act. However, the same conduct may expose the patent holder to antitrust liability if it is found to be in a dominant position.

For instance, in the context of enforcing copyright and designs, in Bull Machines Pvt Ltd v JCB India (Case No. 105 of 2013), Bull Machines alleged that JCB had initiated bad faith litigation claiming infringement of its copyright and designs against it, and by doing so, had abused its dominant position in the market for backhoe loaders in India. The CCI, in its preliminary order, found merit in the argument and ordered an investigation, noting that 'predation through judicial processes presents an increasingly [sic] threat to competition, particularly due to its low antitrust visibility'. By ordering an investigation into the actions of JCB, the CCI demonstrated that vexatious infringement suits might be capable of being construed as an abuse of dominant position.

More recently, however, the CCI appears to have adopted a more cautionary approach while considering the use of court proceedings to enforce legitimate IPRs as abusive. For instance, while directing an investigation in Biocon Limited & Mylan Pharmaceuticals Private Limited v F Hoffmann-La Roche AG & Ors (Case No. 68 of 2016) (Biocon v Roche), the CCI, in its preliminary order, noted that recourse to legal proceedings is a right of every party and, as a general principle, cannot

be viewed as being sham litigation except under exceptional circumstances. In sum, the CCI is likely to test whether the actions of an IP holder, including by way of an application for the grant or enforcement of a patent, are genuine or merely the means to foreclose competition.

When would life-cycle management strategies expose a patent owner to antitrust liability?

The application of competition law to intellectual property is still at a relatively nascent stage in India. Complaints filed with the CCI involving the implementation (or non-implementation) of FRAND disputes or vexatious litigation following infringement claims are being challenged on jurisdictional issues (ie, whether the CCI, as an antitrust regulator, has requisite jurisdiction to determine these issues when sector-specific regulators exist). That said, the CCI is unlikely to intervene if the restriction or strategy in question is within the scope of the legitimate exercise of the patent right (as under the relevant IP statute). Moreover, where the strategy in question is both reasonable and necessary to protect such right, it is likely to pass muster under the CA02. In Shri Anand Prakash Agarwal v Dakshin Haryana Bijli Vitran Nigam (Case No. 1 of 2016), the CCI recognised that objective commercial justifications were an effective defence against allegations of abuse of dominant position.

For instance, a common strategy implemented by pharmaceutical companies to increase the life of their patents is ‘product hopping’. This involves discontinuing a patented drug towards the end of its patent term and introducing a reformulated ‘second generation’ drug, which may or may not offer distinct improvements over the first-generation drug. Under the CA02, while the introduction of a new product is not per se anticompetitive, while examining whether this strategy is a legitimate use of its patent rights from a competition perspective, the CCI is likely to examine the overall conduct of the patent holder in launching a new product (whether and how often this practice is adopted) and the effect on the ultimate consumer and the market.

Other life-cycle management strategies, such as creating a ‘patent cluster’, are likely to be scrutinised more closely by the CCI. Patent clusters involve the coming together of multiple companies to create new products by tying the product-creation process with existing patents. While the cluster arguably reduces research and development costs for each of the contributor patentees, it equally has the effect of precluding companies outside the cluster from using patents within the cluster, subject to the terms of exclusivity. To the extent that this collaboration is between competing pharmaceutical entities, the CCI may examine

whether the ultimate object of the collaboration is to exclude other players or determine prices. The CCI may also examine whether and to what extent these arrangements create ultimate consumer benefits (eg, the launch of new products that may not have been possible absent such collaboration).

Communications

Can communications or recommendations aimed at the public, HCPs or health authorities trigger antitrust liability?

Communications or recommendations by pharmaceutical companies or trade associations may be considered anticompetitive if they result in the denial of market access or limit production or supply. For instance, in Biocon v Roche, the CCI initiated an investigation against Roche for abusing its dominant position by making representations to various state health authorities and drug controllers against Biocon's products. In its prima facie order, the CCI equated such representations to 'abusive denigration' that could result in denial of market access for Biocon's products. Similarly, in In Re: InPhase Power Technologies Pvt Ltd v ABB India Limited (Case No. 12 of 2016), a letter sent by ABB to customers claiming to be the true owner of certain intellectual property was alleged to have result in denial of market access for InPhase. The case is currently under investigation.

Authorised generics

Can a patent owner market or license its drug as an authorised generic, or allow a third party to do so, before the expiry of the patent protection on the drug concerned, to gain a head start on the competition?

The CCI is yet to deal with cases involving 'product switching' (ie, when patent holders either market a generic version of their drug or authorise a third party to do so, towards the end of their patent protection). However, as in other cases involving the interplay between IP and antitrust, the CCI will be required to balance the legitimate rights of patent holders to take steps to protect and use their IP, including possibly by engaging in product switching with the likely restriction on new market entry.

Examining cases of product switching from an antitrust lens is likely to be more complex. During the term of its registered patent, an IP holder has the legitimate right to exclude others from making use of its underlying patent used in the drug. During this exclusivity period, a patent holder is free to decide how best to use its patent. Licensing its drug as an authorised generic before the expiry of its patent term would fall squarely within the scope of its rights. However, where the CCI

believes that such product switching is being employed with a view to deny market access to other generic manufacturing companies (the patent holder uses its legitimate first-mover advantage to market a generic drug as a cheaper alternative to its more expensive patent well in advance to gain a stronghold in the generic market for the same drug, by the time its patent expires), the CCI may consider whether this conduct may be viewed as an anticompetitive market-leveraging conduct, where the patentee uses its dominant position in the patented market to gain entry, and market share, in the alternate market for generic versions of that drug. Such anticompetitive leveraging may fall foul of section 4 of the CA02, which addresses abuse of dominance conduct.

While abuse of dominance provisions under the CA02 do not specifically require an 'effects' test, the CCI may equally consider whether the benefits of introducing a generic drug before the expiry of the patent (greater availability at cheaper price during the term of the patent) outweighs any potential market denial that such conduct may otherwise entail. Where such pre-term licensing is an outcome of collusive conduct (between the patentee and a generic manufacturer) to pre-empt the entry of an otherwise strong generic manufacturer, the risk of antitrust infringement would increase.

Restrictions on off-label use

Can actions taken by a patent owner to limit off-label use trigger antitrust liability?

Actions by a patent holder against off-label drug use are yet to be considered by the CCI. However, as discussed in question 34, the CCI will apply a similar filter (that of balancing the rights of the IP holder with the effect such conditions have on competition in the market) to determine whether such conduct would fall foul of the CA02.

Where there is sufficient evidence to demonstrate that steps taken by the patent holder to limit off-label drugs are legitimate (eg, to limit potential product liability law suits or potential hazardous or unknown effects of alternate uses that may damage the patent holder's reputation), the CCI is unlikely to consider such action as being problematic under the CA02. In fact, such restrictive conditions may benefit from the safe-harbour provisions under the CA02 that allow IP holders to impose such restrictive conditions as are reasonable and necessary to protect its patent rights.

However, where such restrictions on off-label use have been employed without any legitimate or reasonable basis, and only with a view to deny market access to possible competitors or downstream players (eg, to

preserve such benefit for itself), it is possible for the CCI to scrutinise this conduct as being anticompetitive.

Pricing

When does pricing conduct raise antitrust risks? Can high prices be abusive?

Pricing conduct under the CA02 may be examined as follows:

- anticompetitive horizontal agreements (ie, collusive price-fixing conduct under section 3(3) of the CA02);
- anticompetitive vertical restraints (ie, RPM under section 3(4) of the CA02); and
- abuse of dominant position (ie, unfair or predatory pricing under section 4 of the CA02).

If two or more competitors or potential competitors enter into an agreement to directly or indirectly fix prices or margins, it is presumed to result in an AAEC and is prohibited under the CA02. This would include any agreement to fix bid or tender prices or sales prices of drugs that are the subject of a co-marketing agreement. For instance, as mentioned in question 20, the CCI has initiated investigations against Novartis, Abbott, Emcure and USV for allegedly engaging in bid-rigging and price-fixing for the prices and supply of oral anti-diabetic drugs containing the active pharmaceutical ingredient, Vildagliptin. Similarly, the CCI found the practice of determining trade margin percentages for resale by the trade associations for chemists and druggists qualifies as an anticompetitive horizontal agreement under section 3(3) of the CA02.

The imposition of a condition by a seller to sell goods on the condition that the buyer will resell goods at a fixed price and not below it is construed as an anticompetitive RPM agreement. For RPM agreements to be treated as anticompetitive, the CCI will need to determine whether the condition results in an AAEC in the relevant market. The CCI has held in the past that, where a party has sufficient market power in the relevant market, the chances of an RPM causing an AAEC increases. More recently, in Fx Enterprise Solutions v Hyundai Motors (Case No. 36 of 2014), the CCI found Hyundai to have entered into an anticompetitive RPM agreement. The CCI found that by fixing a maximum retail price and permissible discount to be given by dealers, Hyundai was effectively setting a minimum resale price. This, along with a monitoring mechanism by way of a penalty scheme for errant dealers, contravened section 3(4)(e) of the CA02, as it stifled intra-brand competition. The imposition of unfair or discriminatory prices, including a predatory price, by a

dominant enterprise is a type of abuse of dominant position under section 4 of the CA02. For instance, in a sub judice matter before the CCI, the investigative wing of the CCI found a dominant super specialty hospital to have made excessive profits to the tune of more than 500 per cent on disposable syringes. On this basis, the investigation report concluded that the hospital had abused its dominant position. However, the inquiry is still pending as the CCI has widened the scope of investigation and has asked investigative wing to consider all aftermarket healthcare products and services and not just disposable syringes. Similarly, as indicated in question 28, in the Autoparts case, after finding that each OEM was dominant in the supply of spare parts for its own brand, the CCI held that each OEM had abused its dominant position by charging excessive prices for its spare parts.

Sector-specific issues

To what extent can the specific features of the pharmaceutical sector provide an objective justification for conduct that would otherwise infringe antitrust rules?

The pharmaceutical industry is driven by innovation and significant investment in the form of research and development activities. IPR protection for proprietary products helps in fostering innovation and attracting investment in research and development. The CA02 recognises the need for balancing the rights of IPR holders and hence provides the limited safe harbour to IP holders for imposing restrictions that are reasonable and necessary to protect rights granted under the IP.

Update and trends

Current trends and developments

40Are there in your jurisdiction any emerging trends or hot topics regarding antitrust regulation and enforcement in the pharmaceutical sector?

Emerging trends and hot topics40 Are there in your jurisdiction any emerging trends or hot topics regarding antitrust regulation and enforcement in the pharmaceutical sector?
The CCI recently released its Healthcare Policy Note identifying fundamental causes for the prevalence of anticompetitive practices in the healthcare and the pharmaceutical sector in India. More specifically, the CCI has noted that considerable ‘information asymmetry’ coupled with high trade margins are responsible for high drug prices in the pharmaceutical sector in India. The CCI has further acknowledged that generic drugs ensure robust competition; however, it is imperative to

have a legal mechanism in place that ensures that substandard or spurious drugs do not reach the Indian markets.

In addition, the CCI has also focused on the existing trend of vertical arrangements in the healthcare and pharmaceutical sector. More specifically, the CCI has pointed out anticompetitive practices of the hospitals where hospitals compulsorily tie healthcare services with either consumables such as medicines, syringes, etc, available at their partnered pharmacies, or diagnostics services being provided by their partnered services provider.