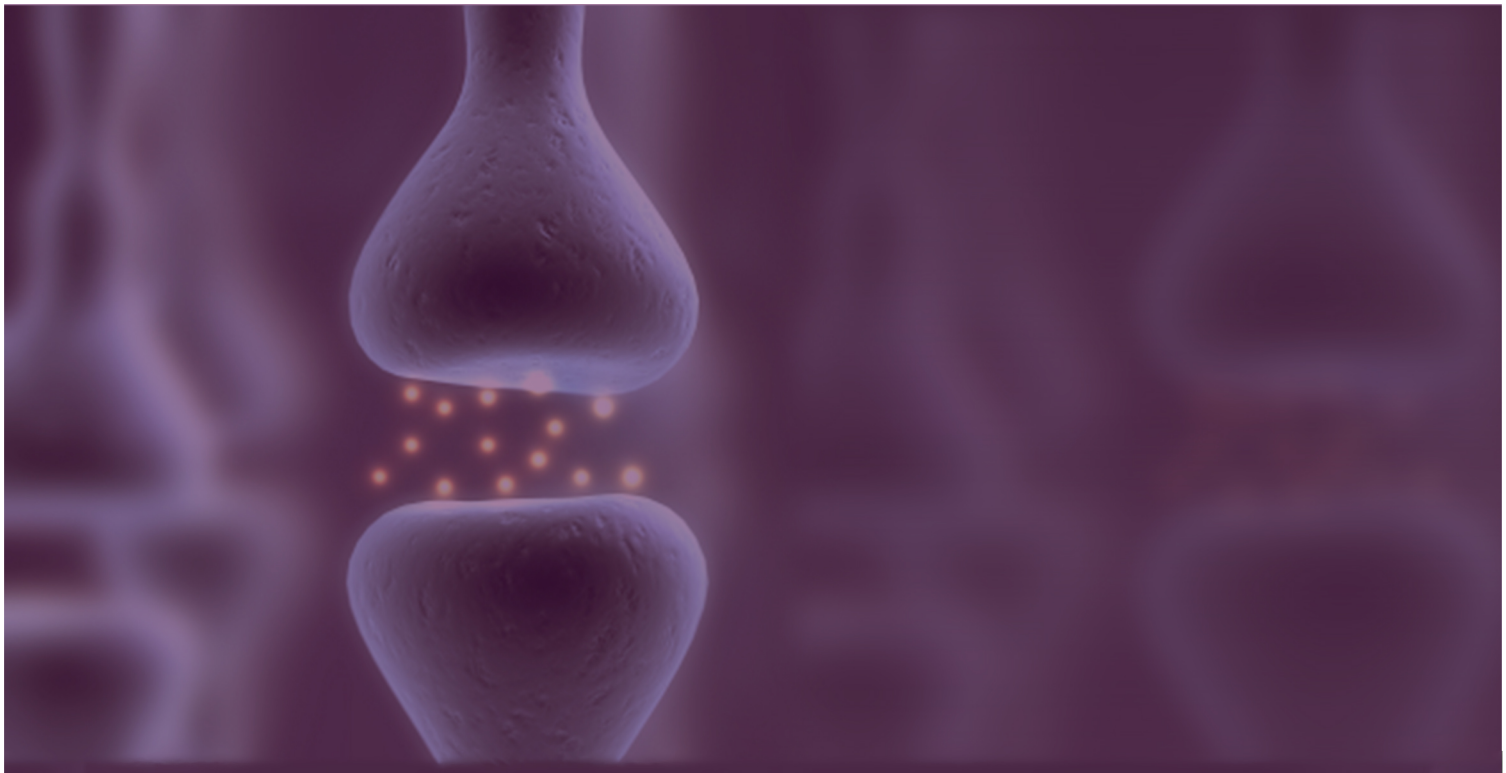

SYNAPSE

A Quarterly update on the Pharmaceutical Industry

Vol. III/Issue III/
July 01, 2019 – September 30, 2019

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SYNAPSE

Dear Readers,

Cyril Amarchand Mangaldas, India's premier full-service law firm has an industry leading and dedicated, Pharmaceutical, Healthcare and Life Sciences practice and our class leading practice specialists are always on top of the latest developments in the sector. It gives us immense pleasure to present to you the latest issue of our quarterly pharmaceutical and healthcare practice newsletter- Synapse.

In this edition, we have compiled some important events and developments that took place during the last quarter (July 01, 2019- September 30, 2019). During this period, the pharmaceutical and healthcare sector saw continual regulatory, M&A and litigation activities.

The Drugs Consultative Committee and the Drugs Technical Advisory Board held their scheduled meetings during this period. The decisions taken during these meetings will have tremendous impact on the pharma sector and will gradually start getting reflected in government policy and may even manifest themselves in the form of legislative and regulatory changes. Notably, the National Medical Commission Act, 2019 established the National Medical Commission, which will supersede the Medical Council of India. Further, the production, manufacture, import, export, transport, sale, distribution, storage and advertisement of electronic cigarettes has been banned through an ordinance promulgated by the Ministry of Law and Justice.

Amongst the notable litigations in this quarter, the Supreme Court heard the Oxytocin ban case, and referred the same to a larger bench for final decision on various questions of law, including, whether a drug included in the National List of Essential Medicines would be subject to the provisions of Section 26A of the Drugs and Cosmetics Act, 1940 and whether the exercise of power by Central Government in this regard was legislative or executive in nature. Furthermore, with the aim to facilitate speedier accreditation and transparency under the Ayushman Bharat Yojana, the National Health Authority has framed a new accreditation system, (*granting Gold, Silver and Bronze rating- based on facilities being provided*) for smaller hospitals operating in rural areas.

We have always tried to keep our readers abreast of the latest developments in this dynamic sector. With this in mind, we present to you Volume III Issue III of our Pharmaceutical and Life Sciences Newsletter Synapse. We hope you enjoy reading this newsletter as much as we have enjoyed curating and creating it for you.

As always, your feedback makes us improve our efforts. Please feel free to send your comments, feedback and suggestions to synapse@cyrilshroff.com. We also encourage you to visit our blog at https://corporate.cyrilamarchandblogs.com for more articles.

Regards,
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Vol. III/Issue III/
July 01, 2019 –
September 30, 2019

REGULATORY UPDATES

1. 57th Meeting of Drugs Consulative Committee[1]

The 57th meeting of the Drugs Consultative Committee (**DCC**) took place on August 20, 2019 at Goa. Some of the important decisions that were taken by the DCC in this meeting are mentioned herein below:

(i) *Recommendations regarding regulation of over the counter (**OTC**) drugs*

The DCC took note of the report prepared and submitted by a sub-committee of DCC under the chairmanship of Shri. N.K. Ahooja, *Drugs Controller, Haryana* (**Ahooja Committee**) in relation to the regulation of OTC drugs. The DCC observed that the Ahooja Committee made various recommendations in relation to definition, classification and regulation of OTC drugs. Basis these representations made by the Ahooja Committee, the DCC recommended that: (a) suitable amendment(s) should be made in Schedule K (*exemptions and conditions for exemption from the provisions of Chapter IV of the Drugs and Cosmetics Act, 1940* (***D&C Act***))of Drugs & Cosmetics Rules, 1945 (**D&C Rules**) and (b) the Ahooja Committee should identify the list of OTC drugs, along with conditions, and prepare a draft for amending (**D&C Rules**).

A detailed analysis of the OTC drug regulation is also available at https://corporate.cyrilamarchandblogs.com/tag/over-the-counter-drugs-regulations-in-india/

(ii) *Recall system for drugs that are not of standard quality*

The DCC took note of the representations made by the sub-committee under the chairmanship of Shri. K.V. Rajendranath Reddy, *IPS, Ex-DG, DCA, Andhra Pradesh* (**Reddy Committee**) in relation to:

(a) establishment of effective recall system of pharmaceutical drugs which are found of 'not of standard quality'; and (b) review of existing product recall guidelines prepared by Central Drugs Standards Control Organization (**CDSCO**) and updating the same. The Reddy Committee had recommended certain short term, medium term and long term goals to further strengthen the recall system. The DCC provided its affirmation to the representations made by the Reddy Committee in relation to the formulation of rules and regulations *vide* amendment of the D&C Rules, in order to list down the individual responsibilities of wholesalers, distributors, and retailers during the recall process.

(iii) *Issue of re-packing of active pharmaceutical ingredients (**API**) into smaller packs by wholesalers for sale*

The DCC observed during the captioned meeting that in some cases the wholesalers' re-pack the API into smaller packs and sell the same to the formulators for manufacturing the finished formulation. The DCC deliberated upon the matter and recommended that re-packing of APIs by wholesalers is, not allowed under the D&C Rules and such re-packing has a potential for breach of integrity and quality of the API. The concerned authorities were accordingly directed to: (a) issue notices/letters to licensees within their jurisdiction; (b) hold consultations with the representatives/associations of licensees; (c) spread awareness about the existing position of law regarding re-packaging of API and the repercussions on the breach of the same; and (d) collect information and submit the same to the CDSCO.

2. 83rd Meeting of the Drugs Technical Advisory Board (DTAB)[2]

The 83rd meeting of the DTAB took place on June 11, 2019 at New Delhi. Some of the important

[1] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=OTz
[2] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=OT5

decisions that were taken by the DTAB in this meeting are mentioned herein below:

(i) *Regulation of electronic nicotine delivery systems (**ENDS**)*

The DTAB observed that ENDS solutions and emissions contain certain chemicals, which are largely similar with the toxics contained in the traditional tobacco. The DTAB also observed that the DCC had revisited its earlier decision and had now come to the conclusion that ENDS fall within the definition of "drug" as defined under Section 3(b) of the D&C Act.

The DTAB, therefore, recommended that the manufacture, sale (*including online sale*) and distribution of ENDS and like products should be prohibited under Section 26A of the D&C Act and that their import (*including personal purpose*) should also be prohibited under Section 10A of the D&C Act.

Post this recommendation, the Ministry of Law and Justice on September 18, 2019 notified the Prohibition of Electronic Cigarettes (*Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement*) Ordinance, 2019. A brief snippet on the aforesaid ordinance is mentioned at paragraph 9 of regulatory updates mentioned in this newsletter.

(ii) *Finalization of e-pharmacy rules*

The draft of the final notification containing amendments to the D&C Rules, to provide for a separate part for the regulation of e-pharmacies was placed before the DTAB for its review. The DTAB, after detailed deliberations, recommended the finalization of the draft rules after taking into account the suggestions and representations of the concerned stakeholders. Readers would recollect that this has been subject matter of litigation before the courts. We have covered this at length in our previous issues of Synapse (*Vol. III Issue II*).

3. Constitution of Medical Devices Technical Advisory Group (MDTAG)

The CDSCO, *vide* Office Order dated July 22, 2019[3], constituted the MDTAG under the chairmanship of the Drugs Controller General of India to advise the CDSCO in relation to regulation of medical devices. The MDTAG will also examine the issues in relation to implementation of medical device related regulations and give suggestions to strengthen the regulatory regime. The MDTAG will be expected to meet once at least in every 4 (Four) months to discuss its findings and concerns.

4. Price Fixation of Orthopaedic Knee Implants

The National Pharmaceutical Pricing Authority (**NPPA**), in continuation to its notifications issued *vide* S.O. 2668(E) dated August 16, 2017 and S.O. 3987(E) dated August 13, 2018[4], issued an order on August 13, 2019, in relation to fixation of ceiling price of the orthopaedic knee implants and its continuous governance under the paragraph 20(1) of the DPCO, 2013 (*Monitoring the prices of non-scheduled formulation*). The aforesaid order of the NPPA shall remain valid for a period of 1 (One) year starting from August 16, 2019 (*i.e. up to August 15, 2020*) and the ceiling price would be reviewed again, thereafter.

5. Trade Margins on Orthopaedic Knee Implants

The NPPA, *vide* an Office Memorandum dated August 29, 2019[5] clarified that hospitals, nursing homes and clinics are allowed to add trade margin to orthopaedic knee implants as per the prescribed rates (*i.e. of 16% (Sixteen Percent*)) subject to overall limits of price ceiling.

6. Drugs and Cosmetics (Eleventh Amendment) Rules, 2019.

The Drugs and Cosmetics (*Eleventh Amendment*) Rules, 2019 have been notified *vide* gazette notification no. 499 (E), dated July 17, 2019[6]. This amendment *inter alia* provides for the perpetual validity of the

[3] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDNg==
[4] http://www.nppaindia.nic.in/wp-content/uploads/2019/08/Knee-English-notification1.pdf
[5] http://www.nppaindia.nic.in/wp-content/uploads/2019/08/NPPA-OM-dt.-29.08.19-on-Knee-Implants-for-Trade-Margin.pdf
[6] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDY3OA==

following licenses granted under the D&C Rules (subject to payment of license retention fee):

(i) Form 28 *(Licence to manufacture for sale or for distribution of drugs specified in Schedules C and C (1) excluding those specified in Schedule X);*

(ii) Form 28A *(Loan licence to manufacture for sale or for distribution of drugs specified in Schedules C and C(1) excluding those Specified in Schedule X);*

(iii) Form 28B (*Licence to manufacture for sale or for distribution of drugs specified in Schedules C, C(1) and X*);

(iv) Form 28D (*Licence to manufacture for sale or for distribution of large volume parenterals/ sera and vaccine/ recombinant DNA (r-DNA) derived drugs specified in Schedules C and C(1) excluding those specified in Schedule X*); and

(v) Form 28 DA (*Loan license to manufacture for sale or for distribution of large volume parenterals/ sera and vaccine/ recombinant DNA (r-DNA) derived drugs excluding those specified under Schedule X*).

7. Draft Amendment to the D&C Rules

A draft of amendments to the D&C Rules has been notified *vide* Gazette notification no. GSR 567(E), dated August 8, 2019[7].

The draft amendment proposes to insert a sub-rule in Rule 96 of the D&C Rules in order to require every API (*bulk drug*) manufactured or imported in India to bear a 'quick response code' on its label at each level of packaging that stores data or information readable with software application to facilitate tracking and tracing. The stored data or information shall include the following minimum particulars: (i) unique product identification code; (ii) name of the API; (iii) brand name (if any); (iv) name and address of the manufacturer; (v) batch no.; (vi) batch size; (vii) date of manufacturing; (viii) date of expiry or retesting; (ix) serial shipping container code; (x) manufacturing licence no. or import licence no.; and (xi) special storage conditions required (if any).

8. National Medical Commission Act, 2019 (NMC Act)

The NMC Act has been notified *vide* the Gazette notification no. 49, dated August 8, 2019[8]. The NMC Act intends to repeal the Indian Medical Council Act, 1956 and constitute the National Medical Commission (**NMC**), which shall supersede the Medical Council of India. Certain Salient features of the NMC Act are mentioned herein below:

(i) *The NMC*

The NMC Act provides for the constitution of the NMC by the Central Government. The powers and functions are two-fold and include, *inter alia*, the laying down of policies and regulations for: (a) maintaining high quality and standards in medical education; and (b) regulating medical institutions, medical research and medical professionals. By extension, the NMC has also been empowered to lay down policies and codes to ensure: the observance and promotion of professional ethics in the medical profession and during provision of care by medical practitioners; assess requirements in healthcare, including human resources for health and healthcare infrastructure; and develop a road map for meeting such requirements.

(ii) *Autonomous boards*

The NMC Act provides for constitution by the Central Government of the following autonomous boards under the supervision of the NMC:

[7] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDgyNg
[8] http://egazette.nic.in/WriteReadData/2019/210357.pdf

(a) Under-Graduate Medical Education Board;

(b) Post-Graduate Medical Education Board;

(c) Medical Assessment and Rating Board; and

(d) Ethics and Medical Registration Board.

(iii) *Medical advisory council (**MAC**)*

The NMC Act provides for the constitution of an advisory body, known as MAC by the Central Government to act as the primary platform through which the States and Union Territories may put forth their views and concerns before the NMC and help in framing the overall agenda, policy and action relating to medical education and training.

(iv) *Community health providers (**CHP**)*

In a notable addition, the NMC Act provides for the power of the NMC to grant a limited licence to practise medicine at mid-level as a CHP. The CHPs would be allowed to prescribe specified medicine, independently, in primary and preventive healthcare. However, in cases other than primary and preventive healthcare, the CHP will be able to prescribe medicine only under the supervision of duly registered medical practitioners.

(v) *Common entrance and exit tests*

The NMC Act mandates a 'National Eligibility-cum-Entrance Test' to regulate the admission of undergraduate and postgraduate super-specialty medical education in all medical institutions which are governed under the provisions of the NMC Act. Additionally, the NMC Act also seeks to initiate a common final year undergraduate medical examination, to be known as the 'National Exit Test', which shall be organized for granting licences to practise medicine as medical practitioners and for enrolment in the State Register or the National Register.

Note: *Though the NMC Act has been notified vide Gazette notification no. 49 dated August 8, 2019, Section 1(3) of the NMC Act provides that: "It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint, and different dates may be appointed for different provisions of this Act and any reference in any such provision to the commencement of this Act shall be construed as a reference to the coming into force of that provision." No such notification has come out yet.*

Meanwhile, The National Medical Commission (Submission of List of Medical Professionals) Rules, 2019 have been notified vide Gazette notification no. G.S.R. 649(E)[9], dated September 12, 2019, and the National Medical Commission (Manner of Appointment and Nomination of Members, their Salary, Allowances and Terms and Conditions of Service, and Declaration of Assets, Professional and Commercial Engagements) Rules, 2019 have been notified vide Gazette notification no. G.S.R.650 (E)[10], dated September 12, 2019.

For more detailed information on the NMC Act, please visit our blog at - https://corporate.cyrilamarchandblogs.com/2019/09/national-medical-commission-act-2019-part-1/

9. Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Ordinance, 2019

The Ministry of Law and Justice, *vide* Gazette notification no. 59, dated September 18, 2019, notified the Prohibition of Electronic Cigarettes (*Production, Manufacture, Import, Export, Transport, Sale, Distribution,*

[9] http://egazette.nic.in/WriteReadData/2019/212494.pdf
[10] http://egazette.nic.in/WriteReadData/2019/212501.pdf

storage and Advertisement) Ordinance, 2019[11]. Broad salient features of this ordinance are mentioned herein below:

(i) The term 'electronic cigarette' is defined to mean an electronic device that heats a substance, with or without nicotine and flavours, to create an aerosol for inhalation and includes all forms of ENDS, heat non burn products, e-hookah etc., but does not include any product licenses under the D&C Act.

(ii) The activities of production, manufacture, import, export, transport, sale, distribution, storage and advertisement of electronic cigarettes is prohibited.

(iii) No person, being the owner of a place, can permit the place to be used for storage of electronic cigarettes and the stock of all electronic cigarettes is required to be surrendered to the authorities. Further, this ordinance is applicable even to individuals who might be in possession of electronic cigarettes.

(iv) Punishments for contravention of the provisions of this ordinance include monetary penalty, imprisonment or both.

Readers would recollect that banning of e-cigarettes has been subject matter of considerable litigation before courts across India. In-fact the Government notified a ban on these products, which notification was stayed by the Hon'ble High Court of Delhi. We have covered the same in our previous issues of Synapse (*Vol. III, Issues II*).

The said ordinance has since been challenged by some manufacturers/importers before the Hon'ble Calcutta High Court. The Hon'ble Court granted an interim stay on the operation of Sections 5(a) and 5(b) of the aforementioned ordinance which *inter alia* required the submission of existing stock of electronic cigarettes to the authorised officers, and disposal of such stock by the authorised officer. More details are provided in the litigation update section of this newsletter.

10. Fixed Dose Combinations (FDC) Ban Update

In furtherance to our exhaustive discussion on the captioned matter, in our previous issues of Synapse (V*ol. III, Issues II*), we understand that the CDSCO, *vide* a Notice dated August 19, 2019[12], decided that manufacturers/stakeholders who are holding licenses from the State Licensing Authorities in respect of the 294 (Two Hundred and Ninety Four) FDCs declared as rational by the DTAB, can submit their applications by December 2, 2019 along with fee as specified in New Drugs and Clinical Trials Rules, 2019.

The CDSCO has also clarified that for the 83 (Eighty Three) FDCs mentioned in the list of rational FDCs, which are already approved in a particular strength and dosage form, the applicant/stakeholder can directly approach the 'State Licensing Authority' for obtaining a manufacturing license (*except for strengths and dosage form approved after February 27, 2019*).

11. Compensation in Cases of Faulty Medical Devices.

There has been a lot of discussion around the requirement of a proper mechanism to deal with issues of patient compensation in cases of faulty medical devices. In this regard, the DTAB has constituted a committee headed by Dr. B.D. Athani to deliberate on the issue of inclusion of provisions for grant of compensation to patients in cases of injury or death due to any medical device found malfunctioning/unsafe or not in compliance with conditions of licenses so granted. It has been reported that the Athani Committee is likely to propose a compensation formula and a payment mechanism to the DTAB, which would in turn propose the same to the Government for final release as a draft amendment in the existing law.

[11] http://ntcp.nhp.gov.in/assets/document/The-Prohibition-of-Electronic-Cigarettes-production-manufacture-import-export-transport-sale-distribution-storage-and-advertisement-Ordinance-2019.pdf

[12] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDMg

MAJOR LITIGATION & IMPORTANT JUDGEMENTS

Before the Hon'ble Supreme Court of India

1. The Oxytocin Ban Case

The Ministry of Health & Family Welfare, *vide* Gazatte notification no. GSR 411(E), dated April 27, 2018, prohibited private sector companies from manufacturing and distributing Oxytocin for domestic use (**Oxytocin Notification**). The Oxytocin Notification was challenged across multiple writ petitions by pharmaceutical companies, manufacturers and non-governmental organisations before the Delhi High Court in Writ Petition nos. WP(C) 6084/2018, WP(C) 8555/2018, WP(C) 8666/2018 and WP(C) 9601/2018.

The Hon'ble Delhi High Court framed the following questions of law:

(i) Did the Oxytocin Notification fall within the scope of Article 19(6) of the Constitution of India?

(ii) Was the Oxytocin Notification *ultra vires* the provisions of the D&C Act?

(iii) Whether the Oxytocin Notification was arbitrary and therefore, unsustainable?

The Hon'ble Delhi High Court held that:

(i) While the Central Government is empowered to prohibit the manufacture, sale, distribution etc. of a product, the D&C Act does not authorise the creation of a monopoly, including a State monopoly. The court was of the opinion that Section 26A of the D&C Act does not and cannot be considered as a law that creates State monopolies or enables the creation of State monopolies;

(ii) Further, the Court evaluated and reviewed various Governmental documents in relation to the issuance of the Oxytocin Notification and found that it was issued as a direct consequence of the directions given by the Hon'ble Himachal Pradesh High Court in a separate matter, without consideration of scientific and empirical data underlying the issue. No instance of any wrongdoing by the licensed manufacturers was cited. Therefore, a complete prohibition for domestic manufacture of Oxytocin by licensed manufacturers was not called for;

(iii) There were multiple public interests involved in the matter, such as interests of pregnant women who may require Oxytocin, and therefore, in judicial review, while a court cannot be expected to carry out a merits review, when the matter pertains to right to life and lifesaving medicines, the court cannot understate its duty to scrutinise the record and ensure that all materials pointing to the inevitability or the compelling nature of the choice exercised by the executive in fact exist.

The impugned Oxytocin Notification was, held to be unreasonable and arbitrary, and was thus quashed by the Hon'ble Delhi High Court.

The Central Government filed an appeal against the Hon'ble Delhi High Court's judgment before the Hon'ble Supreme Court[13]. The Hon'ble Apex court after hearing contentions in the matter, decided to refer the matter to a larger bench (more than two judges) for a definitive legal pronouncement on the following substantial questions of law:

(i) Whether a drug included in the National List of Essential Medicines would be subject to the provisions of Section 26A of the D&C Act?

[13]Civil Appeal Nos. 6588-6591 of 2019.

(ii) Whether the Oxytocin Notification had resulted in the creation of a monopoly in favour of a public sector undertaking, and if so, whether it was protected by Articles 14 and 19(6) (ii) of the Constitution?

(iii) Whether the classification made by the Oxytocin Notification between public and private sector companies would achieve the object and purpose of preventing illegal use of the drug?

(iv) Whether it would be in the public interest to restrict the manufacture of a lifesaving drug to a single public sector undertaking, to the complete exclusion of private-sector companies?

(v) Whether there was relevant and objective material before Central Government to form the basis of satisfaction to exercise the power under Section 26A of the D&C Act?

(vi) Whether the object of curbing the clandestine manufacture and unregulated use of Oxytocin could be achieved by imposing a ban on the manufacture of licensed drugs by private-sector companies?

(vii) Whether the exercise of power by Central Government under Section 26A of the D&C Act was legislative or executive in nature?

(viii) Whether invoking the powers under Section 26A of the D&C Act was in conflict with the exercise of powers conferred under the Essential Commodities Act, 1955?

(ix) Whether the Oxytocin Notification had resulted in creating a monopoly in favour of the State, and whether it had satisfied the rigour of Article 14 read with Article 19(6) (ii) of the Constitution?

(x) Whether the material relied on by the Central Government in this regard was sufficient?

The matter is currently pending before the Hon'ble Supreme Court and will have far reaching consequences on the industry as whatever judgement is finally passed, the same would be applicable *in rem* and would clarify the extent of powers of the Central Government to ban drugs.

A detailed analysis of this Oxytocin ban judgment is also available on our Firm's blog at - https://corporate.cyrilamarchandblogs.com/2019/09/the-oxytocin-ban-story/

Before the Hon'ble Delhi High Court

2. Interim Measures in Relation to 'Stem Cell Derived Products'

The New Drugs and Clinical Trials Rules, 2019 (**NDCT Rules**) were notified by the Ministry of Health and Family Welfare *vide* Gazette notification no. GSR227(E), on March 19, 2019 [14]. Rule 2(w) of the NDCT Rules defines a 'new drug' to mean *inter alia* a 'stem cell derived product'. Due to the inclusion of 'stem cell derived product' in the definition of a 'new drug', medicines used in stem cell treatments provided by various clinics and hospitals require appropriate licenses and approvals under the NDCT Rules. Such medicines could not be administered without obtaining the necessary licenses and approvals. Due to this reason, some of the clinics providing stem cell treatment had discontinued offering certain treatments to their patients while they obtained the necessary licenses and approvals.

In this background, multiple petitions were filed before the Hon'ble Delhi High Court by affected patients, pointing out that serious prejudice would be caused to the health of the petitioner-patients, during the time period in which the licenses and approvals are obtained.

[14] https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf.

The Hon'ble Delhi High Court held that the treatment being provided to the patients should not be impeded and as an interim measure, directed the concerned clinics to continue providing treatment to the patients till such time the regulator comes to a conclusion as regards applicability of approval requirements in relation to such treatments being offered to patients.

Before the Hon'ble Calcutta High Court

3. Interim stay on certain provisions of the Prohibition of Electronic Cigarettes (*Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement*) **Ordinance, 2019**

The Prohibition of Electronic Cigarettes (*Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement*) Ordinance, 2019 was challenged before the Hon'ble Calcutta High Court[15] by some manufacturers/importers who alleged that the said ordinance infringed the right to choose less harmful alternative to combustible tobacco cigarettes and that the imposition of a complete ban was manifestly arbitrary, disproportionate and excessive. The Hon'ble Calcutta High Court, *vide* an order dated October 1, 2019[16] granted an interim stay against the operation of Sections 5(a) and 5(b) of the ordinance. Consequently, the requirement for submission of existing stock of ENDS to the authorized officers and disposal of said stock by the officers, has been stayed. The matter is slated to come up for hearing again on November 14, 2019.

OTHER NEWS

1. Government of NCT of Delhi asks Delhi High Court to Scrutinize Hospitals Run By the Central Government on Same Parameters

The Government for NCT of Delhi has made a plea to the Hon'ble Delhi High Court seeking directions that the All India Institute of Medical Sciences and Safdarjung Hospital, which are run and operated by the Central Government, be scrutinized under the same parameters as that of hospitals which are run and operated by the Delhi Government.

The Delhi Government on August 27, 2017 requested the Hon'ble High Court of Delhi to widen the ambit and mandate of the expert committee, which was constituted to scrutinize the: (a) existing infrastructure; (b) manpower requirements; and (c) other functional aspects of the hospitals which are run and operated by the Delhi Government to include an evaluation of select hospitals of Central Government (*such as All India Institute of Medical Sciences and Safdarjung Hospital etc.*) and hospitals/health care facilities being run by the municipal corporations (*such as Hindu Rao, Kasturba Hospital etc.*) and government hospitals in adjoining districts of Ghaziabad, Baghpat, NOIDA, Gurugram and Faridabad in the national capital region[17].

2. Hospitals to Get Gold, Silver, Bronze Ratings Based on Facilities Provided

The National Health Authority (NHA) (*Apex body responsible for implementing India's flagship public health insurance/assurance scheme 'Ayushman Bharat Pradhan Mantri Jan Arogya Yojana' (**Ayushman Bharat Yojana***)), has framed a new accreditation system which would help smaller hospitals to get licences and operate in rural areas under Ayushman Bharat Yojana[18].

Presently, the National Accreditation Board for Hospitals and Healthcare Providers (**NABH**) has an existing accreditation system which takes 6 (Six) – 8 (Eight) months for a hospital to getaccredited. However, with healthcare

[15] In AST 40 of 2019 and AST 41 of 2019.
[16] http://164.100.79.153/judis/kolkata_app/index.php/casestatus/viewpdf/AST_40_2019_01102019_O_239.pdf
[17] https://health.economictimes.indiatimes.com/news/hospitals/delhi-government-to-hc-review-hospitals-under-centre too/70870579
[18] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/hospitals-to-get-gold-silver-bronze-ratings-based-on-facilities-provided/articleshow/71157218.cms?from=mdr

infrastructure lacking in tier 2 and tier 3 cities and remote rural areas, the NHA has framed a new accreditation system which would help smaller hospitals also to get licences and operate in rural areas under Ayushman Bharat Yojana[19]. Rather than rejecting accreditation of smaller hospitals, the centre would give them a lower rating at a cheaper cost so that people know what facilities to expect. The accreditation system, developed with the help of Quality Council of India, would bring down the accreditation cost significantly, which ranges from INR 80,000-1,50,000 (Indian Rupees Eighty Thousand to Indian Rupees One Lac Fifty Thousand) to INR 10,000 (Indian Rupees Ten Thousand). The gold rating would be the best while the bronze rating would be given to the lowest rung.

It is to be noted that the new system will be based on self-assessment and would be evidence-based. Once the self-assessment is done, there will be a desktop assessment done by Quality Council of India, followed by an external assessment after which a certificate would be generated. The whole process would take around 25 (Twenty Five) to 35 (Thirty Five) days, instead of the 6 (Six) to 8 (Eight) months required by NABH certification. Thus, the new system will be both economically efficient and less time consuming.

3. Government of Punjab Relaxes Restrictions Imposed on Sale of Opioid Painkillers

In order to check misuse of tramadol and tepentadol (*both opioid painkillers*) by drug abusers, the Food and Drugs Administration (**FDA**), Punjab, on July 29, 2019 passed an order restricting availability of the said drugs at only identified number of chemist shops located inside or outside Government and private hospitals. However, the same was met with criticism from psychiatrists as both the said medicines were being used for treatment of many opioid use disorder patients who cannot access buprenorphine or other substitution treatments due limited availability. Thus, doctors feared that the restriction would have a negative impact on the drug de-addiction programme[20].

The doctors took up the issue with principal health secretary, Mr. Anurag Agarwal during a meeting on August 9, 2019. Consequently, joint commissioner (drugs), FDA, Punjab, Dr. Pardeep Kumar on August 13, 2019 issued an order whereby certain restrictions were imposed on the sale and distribution of tramadol and tepentadol. In the said order, directions by the Drug Controller General of India have also been cited, wherein the doctors were asked to use both the medicines for acute pain, that too, only for a period not exceeding 5 (Five) days as they have high potential for respiratory depression and addition[21].

4. Arrest of Deputy Drug Controller of the Central Drugs Standard Control Organisation

The Central Bureau of Investigation on August 18, 2019 arrested a Deputy Drug Controller of the CDSCO, in an attempt to crack down on the corruption in CDSCO. Though there are no specifics of the charges of corruption, it has been reported that the said person has been suspended with immediate effect. The Union Health Ministry in a statement said that the CDSCO has a zero tolerance policy towards corruption and is committed to act stringently against any such acts[22].

5. China's Revised Drug Laws

The People's Republic of China has recently revised its pharmaceutical laws to remove drugs that are legal in foreign countries but

[19] https://www.medicalbuyer.co.in/hospitals-to-get-gold-silver-bronze-ratings-based-on-facilities-provided/
[20] https://timesofindia.indiatimes.com/city/chandigarh/pb-relaxes-curbs-on-sale-of-opioid painkillers/articleshow/70666283.cmsd/
[21] https://health.economictimes.indiatimes.com/news/industry/punjab-relaxes-curbs-on-sale-of-opioid painkillers/70668483/
[22] https://www.business-standard.com/article/pti-stories/health-ministry-suspends-deputy-drug-controller facing-corruption-charges-119081800601_1.html

not approved in China from the category of fake medicines. This is seen as a good sign by Indian generic manufacturers as it may allow entry of Indian generic medicines in the country.

China's top legislature, the Standing Committee of National People's Congress, passed the revised law on August 27, 2019 to enhance management and supervision of the pharmaceutical market following numerous fake drugs and vaccine cases that had triggered a call for stronger measures to ensure drug safety[23].

CORPORATE TRANSACTIONS

1. Glenmark in Talks to Sell Up To 30% in API Business to PremjiInvest

Glenmark Pharmaceuticals Limited is engaged in advanced discussions with private equity fund PremjiInvest to sell its 25% (Twenty Five Percent) to 30% (Thirty Percent) stake in its subsidiary, Glenmark Life Sciences Limited (*a newly incorporated company engaged in the manufacturing and marketing of API products*), for USD 150,000,000 (USD One Fifty Million) valuing the business at USD 600,000,000 (US Dollar Six Hundred Million) – USD 700,000,000 (US Dollar Seven Hundred Million)[24].

2. Kedaara Capital Invests USD 55,000,000 (US Dollars Fifty Five Million) in Lenskart

Kedaara Capital Investment Managers Limited (**Kedaara Capital**), an operationally oriented private equity firm, based in India, has invested over USD 55,000,000 (US Dollars Fifty Five Million) in eyewear solutions company Lenskart Solutions Private Limited[25] (**Lenskart**).

According to the publically available information, it can be noted that Lenskart has had issued 61,43,000 (Sixty One Lacs Forty Three Thousand) Series F compulsorily convertible cumulative preference shares, at a premium of INR 636.06 (Indian Rupees Six Hundred and Thirty Six point Zero Six) per share, to 2 (Two) entities operated by Kedaara Capital: (i) Kedaara Capital Fund-II; and (ii) Mauritius-registered Kedaara Norfolk Holdings Limited. The financing round is expected to have valued Lenskart at USD 1,150,000,000 (US Dollar One Billion One Hundred and Fifty Million)[26].

The investment in Lenskart is Kedaara Capital's first foray in the country's broader consumer technology sector, having largely focused on manufacturing, consumer and financial services segments thus far.

3. NCLT Okays Merger of Monsanto India with Bayer CropScience

The National Company Law Tribunal (**NCLT**) Mumbai on September 13, 2019 approved the merger of biotech company Monsanto India Ltd with Bayer CropScience Aktiengesellschaft (**Bayer**). In June 2018, German chemical and pharma major Bayer AG had announced completion of the USD 63,000,000,000 (US Dollar Sixty Three Billion) mega-deal to acquire US-based biotech major Monsanto to create the world's biggest agro-chemical and seed company.

Bayer had in May received approval from the fair trade regulator Competition Commission of India, paving way for the completion of

[23] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/chinas-new-drug-law-may-open-door-for-indian-generic-medicines-report/articleshow/70864639.cms?from=mdr
[24] https://www.cnbctv18.com/healthcare/glenmark-may-sell-up-to-30-stake-in-api-business-to-premjiinvest-says-report-4228311.htm
[25] https://health.economictimes.indiatimes.com/news/industry/kedaara-capital-invests-55m-in-lenskart/71139920
[26] https://www.dealstreetasia.com/stories/lenskart-kaarya-attainu-shoekonnect-154269/

the global merger. Bayer took shareholders' approval for the merger during the first quarter of 2019-20 and was waiting the final approval of the NCLT to make the global merger effective in India. Scheme will become effective after Bayer files the certified copy of the NCLT order along with the amalgamation scheme.

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