cyril amarchand mangaldas
advocates & solicitors

Dear Readers,

It gives us immense pleasure to bring forth the fourth issue of our quarterly pharmaceutical and healthcare practice newsletter- *Synapse*.

Cyril Amarchand Mangaldas, India's premier full-service law firm has an industry first dedicated Pharmaceutical, Healthcare and Life Sciences practice. Our class leading practice specialists are always on top of the latest developments in the sector.

This publication is part of our thought leadership initiative and was conceptualised and created keeping in mind the need to keep our clients better informed of the latest developments in the pharmaceutical industry in a succinct format. I am happy to report that our clients have greatly appreciated this initiative at sharing and disseminating knowledge in relation to the changing landscape of the pharmaceutical and life sciences industry especially given the increase in regulatory scrutiny by the regulator in the past few years. The trust and confidence that our clients repose in us pushes us to new boundaries as we scale new industry heights.

In the current issue, we shed light on the latest notification by the Ministry of Health and Family Welfare ("**MoHFW**") in relation to the Draft Rules ("**Draft Rules**") amending the Drugs and Cosmetics Rules, 1945 ("**D&C Rules**") in order to regulate the sale of drugs through E-Pharmacies[1]. Additionally, a draft bill, to regulate the collection, transmission, disclosure and usage of digital health data, was also released by the MoHFW[2]. In the Medical Devices sector, the National Coordination Centre-Materiovigilance Programme of India has released a Draft Guidance Document for Medical Devices[3].

Moving to ban notifications, we start with the FDC ban issue, the CDSCO issued a fresh set of notifications on September 12, 2018 whereby 328 FDCs have been prohibited on grounds of safety, irrationality and lack of therapeutic justification. In addition, the Government issued notifications banning the commercial production of Oxytocin, which has been subsequently stayed by the Delhi High Court.

On the corporate side, the National Company Law Tribunal Mumbai rejected Ajanta Pharma Limited's scheme of amalgamation and arrangement between the company and its shareholder Gabs Investments Private Limited on the grounds of General Anti Avoidance Rules. Some notable transactions have also been covered.

This and more that has happened in the industry and we have made an attempt to capture some of the major topics that may be of interest to our readers. With this in mind, we present to you Volume II Issue II of our Pharmaceutical and Life Sciences Newsletter *Synapse*. We hope you would enjoy reading this newsletter as much as we have enjoyed creating it. Please feel free to send your comments, feedback and suggestions to synapse@cyrilshroff.com. Your feedback enables us to better our efforts and make our publication more valuable to our readers. We also encourage you to visit our blog at https://corporate.cyrilamarchandblogs.com for more articles. Please do write to us in case we can provide additional information on any topic covered in this newsletter.

On a more personal note, as we move into the festive season, we wish you and your families a healthy, prosperous and joyous festival season and send our best wishes to all our readers.

Regards,
Cyril Shroff
Managing Partner
Cyril Amarchand Mangaldas
e: cyril.shroff@cyrilshroff.com

---

[1] We have a detailed article in this regard which can be accessed at https://corporate.cyrilamarchandblogs.com/2018/09/medicines-mail-india-regulatory-story/
[2] Stakeholder comments have been solicited.
[3] Stakeholder comments have been solicited.

I. REGULATORY UPDATES

1. Regulation of E-pharmacies.

Initially the ambit of online transactions was limited to fast moving consumer goods ("**FMCGs**") and other service industries such as travel and tourism. Now, the pharmaceutical industry has also stepped into the arena of e-commerce to form a part of this rapidly growing industry. Recognizing the need to regulate this, on August 28, 2018, the Government acting through the MoHFW and in consultation with the Drugs Technical Advisory Board ("**DTAB**") notified the Draft Rules amending the D&C Rules in order to regulate the sale of drugs through means of an E-Pharmacy. These Draft Rules are to be enacted as a specific part in the D&C Rules, namely Part VI-B titled 'Sale of Drugs by E-Pharmacy'

This comes in the wake of a Report submitted by a sub-committee constituted by the DTAB to examine the issue of 'Regulating the Sale of Drugs over the Internet under the D&C Rules'.

The Draft Rules define an '*e-pharmacy'* as a '*business of distribution or sale, stock exhibit or offer for sale of drugs through web portal or any electronic mode*'[4]. The Draft Rules require all e-pharmacies to mandatorily register with the licensing authority to distribute and sell, stock or exhibit or offer for sale drugs through an e-pharmacy. Further, the rules provide for presence of a registered pharmacist to verify details of the patient, the registered medical practitioner and to arrange for the dispensation of drugs in terms of the prescription as issued to the patient. It has been clarified that an e-pharmacy cannot deal in drugs covered by the Narcotic Drugs and Psychotropic Substances Act, 1985 ("**NDPS Act**"), tranquilizers as well as drugs listed under Schedule X of the D&C Rules.

The Draft Rules are a heartening measure as they embrace new technology, and if implemented will provide much needed regulatory certainty and a definitive framework for the smooth functioning of this new sales method in the Industry especially given the wide outreach of data services in the country and the increasing reliance on e-commerce by customers.

The South Chemists and Distributors Association has filed a writ petition, *South Chemists and Distributors Association & Anr. v. Union of India &Ors., W.P. (C) 10611/2018,* in the Delhi High Court challenging the legality of operation of E-pharmacies. The Petitioners have contended that allowing E-pharmacies to operate is in violation of their fundamental rights under Articles 14, 19 and 21 of the Constitution since it denies the pharmacy stores a level-playing field. The 2016 report of the sub-committee constituted by the Drugs Consultative Committee ("**DCC**") under the DCGI has also been relied upon in the petition to contend that sale through e-pharmacies was already held to be illegal in India. A single bench of the Delhi High Court has *vide* order dated October 5, 2018,[5] issued notice in this petition seeking shutdown of online pharmacies that are engaged in the sale of drugs and prescription medicines online. The next date for hearing in this matter is February 25, 2019. We are following the matter and will keep our readers updated in this regard.

2. Digital Information Security in Healthcare Act ("DISHA").

The MoHFW introduced a draft bill called the *Digital Information Security in Healthcare Act* ("**DISHA**") with the aim to regulate the emerging usage of electronic mediums in healthcare and more specifically to regulate the collection, transmission, disclosure and usage of digital health data. This digital health data can range from information regarding physical or mental health of a person, clinical or treatment records, any information collected during the course of treatment and tests of any clinical/pathological investigation, thus covering a very wide ambit. It is applicable to all entities capable of accessing or collection of such data including companies, corporations, individuals, government departments as well as any other artificial juridical persons. It treats a person as the 'owner' of any health data and is an extension of the right to privacy and autonomy guaranteed by the 9 judge bench of the Apex Court in *Justice K. S. Puttuswamy v. Union of India.*[6]

DISHA was published on the MoHFW website on March 21, 2018 and comments were invited to be submitted by April 21, 2018.[7] The Preamble to DISHA states the following objectives of the proposed legislation:

---

[4] Section 67-I (a) of the D&C Rules, proposed to be inserted.
[5] http://delhihighcourt.nic.in/dhcqrydisp_o.asp?pn=229700&yr=2018
[6] (2017) 10 SCC 1.
[7] https://mohfw.gov.in/sites/default/files/R_4179_1521627488625_0.pdf

(a) establishment of National and State eHealth Authorities and Health Information Exchanges;

(b) standardization and regulation of the processes related to collection, storage, transmission and use of digital health data;

(c) ensuring reliability, data privacy, confidentiality and security of digital health data.[8]

3. Oxytocin ban. Update.

As our readers would recall, the MoHFW *vide* press release dated June 27, 2018[9] had announced a ban on import of oxytocin and its formulations and a restriction on manufacture of oxytocin for domestic use to only the public sector *vide* gazette notification dated April 27, 2018.[10] In pursuance to this the CDSCO *vide* notification dated August 2, 2018 has directed all zonal and sub-zonal offices of CDSCO to keep a vigilant eye to ensure that oxytocin is not being imported and to submit quarterly action reports. The matter has been litigated before the Delhi High Court and the operation of the ban has been deferred till November 2018. We have captured the same in the litigation update section below.

4. New name for CDSCO.

The CDSCO *vide* notification dated September 6, 2018 announced the decision to change the name of the regulatory body since it is not indicative of its roles and duties. CDSCO had also invited suggestions to be submitted within two weeks of the publishing of the notification. Some of the names being considered are Indian Drugs Administration ("**IDA**") and Indian Medical Products Administration ("**IMPA**").

5. Move to strengthen SUGAM Portal in pursuance of e-governance norms.

After making applications for New Drugs, Fixed Dose Combinations ("**FDC**") and Subsequent New Drugs ("**SND**") mandatory on the SUGAM portal *vide* notice dated April 27, 2018, MoHFW has *vide* notification dated August 8, 2018, extended the SUGAM Portal services to include submission of registration certificates and import licenses for blood products. After the meeting conducted on September 6, 2018 with stakeholders, the MoHFW *vide n*otification dated August 18, 2018 declared that no physical applications will be accepted beyond September 26, 2018 and all applications must be submitted on the SUGAM portal. In addition, the MoHFW has also disallowed physical applications for the registration and re-registration for Ethics Committees beyond September 1, 2018 *vide* notification dated August 1, 2018.

6. Notified Bodies for Audit of Manufacturing Sites under Medical Devices Rules, 2017.

CDSCO *vide* notification dated August 6, 2018 announced the list of notified bodies registered with CDSCO to carry out audit of manufacturing sites in pursuance of Rule 20 of the Medical Devices Rules, 2017 ("**MDR, 2017**")[11] which deals with the procedure for application for manufacture for sale or for distribution of Class A or Class B medical device. Rule 20 of MDR, 2017 prescribes that as a part of the application process for Class A and Class B medical devices such notified bodies registered with CDSCO must carry out an audit of the manufacturing sites within 180 days of the grant of the license in case of Class A medical devices and within 90 days after application is made for the grant of the license in case of Class B medical devices.

As discussed in the previous issue of Synapse, MDR, 2017 categorize medical devices into four categories based on their risk type- low risk, Class A and B; and high risk, Class C and D. For approvals and licensing in devices falling under categories C and D, the central government will be directly involved. These notified bodies and may, on an as-required basis, be called upon by the State Licensing Authority to assist in the regulation of Class C and Class D medical devices as well.[12]

---

8 https://mohfw.gov.in/sites/default/files/R_4179_1521627488625_0.pdf
9 http://www.pib.nic.in/PressReleaseIframePage.aspx?PRID=1536659#.WzMm0xGaIC4.twitter
10 http://egazette.nic.in/WriteReadData/2018/185017.pdf
11. http://cdsco.nic.in/writereaddata/List%20of%20Notified%20Body.pdf
12 https://www.andamanmed.com/india-new-medical-device-rules-2017/

7. Clarifications regarding certain FAQs under Drugs and Cosmetics Act, 1940 ("D&C Act").

CDSCO *vide* letter dated August 8, 2018 to State Drugs Controllers and Zonal and Sub-zonal offices of CDSCO issued clarifications with respect to queries related to additional products under existing licenses and various certificates like Good Manufacturing Practices ("**GMP**") compliance, GMP certification, World Health Organization ("**WHO**") GMP certificate, non-conviction certificate, validity certificate, market standing certificate etc. for medical devices and In-Vitro Devices ("**IVDs**"). CDSCO has already provided answers to these questions as FAQs[13] published on the CDSCO website. The specific answers to these queries were reiterated in this letter as follows:

"5. What will be procedure to obtain additional products on existing valid licences, in similar category of Medical Devices/IVD's after 01.01.2018?

Answer: Application form, fees and documents will have to be submitted on new Medical Device portal as per MDR-2017 to obtain the new licence.

62. Whether GMP compliance and GMP certification is applicable to medical devices and IVDs as per Medical Devices Rules, 2017 as it ask for compliance to Quality Management System (QMS) & there is no mention of need for compliance to GMP?

Answer: As per Medical Devices Rules, 2017, there is no mention of requirement for compliance to GMP, but there is need for compliance to QMS and other rules. Therefore, now, there is no requirement of GMP certificates for Medical Devices & IVDs.

63. Despite no mention in rule for domestic purposes, if requested by importing country, who will issue the WHO GMP certificate for medical devices and IVDs?

Answer: Licensing Authority who has issued the valid license to manufacture for sale will continue to issue WHO GMP certificate (Only on the request of importing country).

64. Who will issue the other certificates like Non-Conviction Certificate, Validity Certificate, Market Standing certificate etc. which are not mentioned in rules but are required on request of procurement / tendering agencies?

Answer: The Licensing Authority who has issued license shall issue such certificates."

8. Draft Guidance Document for Medical Devices released by National Coordination Centre ("NCC")-Materiovigilance Programme of India ("MvPI")

The National Coordination Centre ("**NCC**")-Materiovigilance Programme of India ("**MvPI**") has released a Draft Guidance Document for Medical Devices on August 1, 2018 on the CDSCO website.[14] Comments were invited from the stakeholders which were to be submitted by September 1, 2018.

This is the first edition of the "Standards for Medical Devices-A Reference Document" intended for the Indian Stakeholders released by the Indian Pharmacopoeia Commission ("**IPC**"). The intent behind releasing this document was to contextualize and formalize India's commitment to ensure maintenance of quality of health care system by improving, through monitoring, quality of medical devices and minimize safety risks to patients.

This document covers, *inter alia*, classification of medical devices, quality management system, process for registration of medical devices in India, guidance on grouping of medical devices for product registration, fees and charges for medical devices, labelling requirements, quality standards for medical devices, life cycle & technical specifications, post market vigilance and safety requirements etc.

The manufacturers, traders/distributors, importers, clinical establishments, healthcare professionals and the general public can utilise this document as a comprehensive reference document about the standards, regulatory and other requirements for medical devices in India. This document can also be used as a reference document by the licensing authority in the matters relating to medical devices.[15]

[13] http://cdsco.nic.in/writereaddata/Latest%20Updated%20%20FAQ%20MDR_2017_14_06_2018.pdf
[14] http://cdsco.nic.in/writereaddata/Guidance%20Document%20ipv.pdf
[15] http://cdsco.nic.in/writereaddata/Quality%20Control.pdf

9. **CDSCO notifies Central Medical Device Testing Laboratory Quality Control HIV kits**

CDSCO *vide* notification dated July 24, 2018 announced that Disease Specific In-Vitro Diagnostic Laboratory (**"DS-IVDL**") of National Institute of Biologicals ("**NIB**"), engaged in quality testing of serological and molecular diagnostic kits (qualitative) of Human Immunodeficiency Virus ("**HIV**"), Hepatitis C. Virus ("**HCV**") and Hepatitis B. Virus, ("**HBV**"), has been notified as Central Medical Device Testing Laboratory ("**CMTDL**") *vide* gazette no. S.O. 2237 (E) dated June 1, 2018 for diagnostics for HIV, HCV and Hepatitis B Surface Antigen ("**HBsAg**").

10. **Guidance List of Labs for Performance Evaluation of In-vitro Diagnostic Medical Devices released**

CDSCO *vide* document dated August 7, 2018 released a list of laboratories- a suggestive list, that can be used by manufacturers of In-Vitro Diagnostic Medical Devices in order to get performance evaluation of In-Vitro Diagnostic Medical Devices intended for HIV, HBV, HCV, Blood Grouping reagent, Blood glucose test reagent, Cancer, Tuberculosis, Malaria, Dengue, Chikungunia, Syphilis, Typhoid, Influenza, Toxoplasma gondii, Rubella virus, Cytomegalovirus, Herpes simplex virus ("**ToRCH**"), Chlamydia, Pneumonia, Methicilline-Resistant Staphylococcus Aureus, Entero virus, Marker for congenital disorder e.g. Screen test for Down's Syndrome, Sexually transmitted agent i.e. Treponema pallidum, Neisseria gonorrhoeae, Human Papilloma Virus, Herpes Virus, and other life threatening Infections / agent.

Such a report might be required by the State Licensing Authority for Class B In- Vitro Diagnostic Medical Devices and the Central Licensing Authority for Class B, C and D In- Vitro Diagnostic Medical Devices in pursuance of the proviso of Clause (h), Paragraph (ii), part II of Fourth Schedule of MDR 2017, wherein, it is stated that:

> *"In case of in-vitro diagnostic medical devices, performance evaluation report by the manufacturer shall be submitted by the applicant.*
>
> *Provided that when the State Licensing Authority specifically requires for Class B or the Central Licence Authority for Class B, Class C and Class D in-vitro diagnostic medical devices, as the case may be, applicant shall submit the report issued by the central medical devices testing laboratory or a medical device testing laboratory registered under rule 83 or by any laboratory accredited by the National Accreditation Board for Testing and Calibration Laboratories or by any hospital accredited by National Accreditation Board for Hospitals and Healthcare Providers or by any Central Government or State Government Laboratory of any hospital or of any institute, specified by the concerned State Licensing Authority or the Central Licensing Authority."*[16]

II. LITIGATION UPDATES.

1. **Fixed Dose Combination ("FDC") drug ban matter - 328 FDCs Banned.**

Readers would recollect that in 2016, the government had banned 344 plus FDC's. The matter was litigated till the Supreme Court which eventually passed judgement dated December 15, 2017 (*Union of India & Anr. v. Pfizer Limited & Ors., Civil Appeal No. 22972/2017))* upholding the powers of the central government to ban drugs under Section 26A of the D&C Act whilst remanding the FDC's to the DTAB for reconsideration on the ground that the previous expert committee report suffered from serious perversities. The court directed a fresh examination by the DTAB and had further laid down parameters within which such examination would be conducted.

Pursuant to the directions of the Hon'ble Supreme Court on December 15, 2017, the government constitute a DTAB committee under the Chairmanship of Dr. Nilima Kshirsagar to examine

16. http://cdsco.nic.in/writereaddata/Category%20wise%20testing%20laboratory%20list(1).pdf

the banned 344 FDCs + 5 FDCs *vide* S.O. No. 705 (E) to 1048(E) dated March 10, 2016 and S.O. No. 1851(E) to 1855(E) dated June 8, 2017. The committee issued notices to all stakeholders/ petitioners and invited parties to make submissions for each of the banned FDC's. After presentations that lasted for a fortnight, the government issued a press release on September 12, 2018[17] stating that the MoHFW *vide* gazette notification nos. S.O. 4379(E) to S.O. 4706(E) dated September 7, 2018[18] has prohibited the manufacture for sale, sale or distribution for human use of 328 Fixed Dose Combinations (FDCs) with immediate effect. It has also restricted the manufacture, sale or distribution of six FDCs subject to certain conditions.

It is pertinent to note that at the time of publishing of the above noted press release, neither the fresh ban notification referred to in the press release nor the Report of the DTAB Sub-committee was available. Surprisingly, the government uploaded the ban notifications on the midnight of September 13/14, 2018.

As expected, industry members raced to the Delhi High Court challenging the fresh ban notifications *inter alia* contending that the government had moved and issued the ban notification in contravention of the parameters as set by the Hon'ble Supreme Court. It was further contended that the DTAB did not consider representations made by parties in terms of these parameters and further issued its report without considering the data that was presented to the committee. The government was yet again accused of *non-application of mind* and *arbitrary* action. A challenge to the very legal existence of the DTAB was also mounted by some petitioners.

The single bench of the Delhi High Court heard the matter wherein during the course of the hearing, the counsel for the Government went through the provisions of the report to explain the rationale behind the ban of 328 FDCs in order to satisfy the court with respect to the standard of review adopted by the sub-committee. Finding some merit in these submissions and some merit in the submissions of some of the Petitioners on the issue of contradictory stands taken in the report and non-application of mind in arriving at the ban for certain FDC's, the court passed an interim order whereby, the petitioners challenging the ban were asked to stop manufacturing the drugs and provide details of the batches already in circulation in the market. The court also directed the government to file a detailed affidavit providing information for individual FDC's and the reasons behind ban for every FDC and the material considered by the sub-committee to indicate the efficacy of the FDC versus the efficacy of the individual formulations. The court also ordered that no coercive action shall be taken against the Petitioners in the meanwhile[19]. A slew of petitions has since been filed before the Delhi High Court however, the court is dealing with each case on its own merits and has asked the government to place all petitions in groups based on the committee's comments and observations qua each FDC. Petitioners have also been asked to refile their petitions ensuring that each petition bear details of only one FDC.

Meanwhile, the matter had its fair share of action before the Supreme Court as well. Readers would recollect that the Supreme Court had, in its judgement removed all pre-1988[20] FDC's from the purview of the DTAB review and quashed the ban notifications in this regard. The court had given the government liberty to institute a *de-novo* review of these FDC's. Interestingly the government ignored representations made by concerned petitioners during its review (even pre 1988 FDC's were included in the review on the same lines as other FDC's). This action of the government was challenged on the ground that the DTAB was acting in excess of the mandate given by the Supreme Court in this regard as these FDC's were never meant to be reviewed in the first place. The court ordered the government and the DTAB to refrain from proceeding with the 15 FDC's that find mention in the list of pre 1988 FDC's. The Supreme Court however, held that the government is free to initiate *de novo* proceedings in this regard. Subsequently additional parties also approached the Supreme Court to be included in this list. The Supreme Court has since stayed operation of the fresh ban notifications in so far as the same pertains to any pre 1988 FDC. The matter is currently pending.

We have been part of this matter since its inception and have been following the same very closely. The second round of litigation is much more focused on the merits of each case and it would be incumbent on each petitioner to present its case on

[17] http://pib.nic.in/PressReleaseIframePage.aspx?PRID=1545741
[18] http://cdsco.nic.in/writereaddata/banned%20FDC%20letter.pdf
[19] The Petitioners argued that since the FDC's had been banned, any sale thereof would expose the Petitioners (and their Directors) to criminal liability for violations as provided under the D&C Act and Rules. The court gave due credence to this argument.
[20] The requirement for registration came after the notification release in September 1988, therefore all FDC's in existence prior to September 1988 were kept outside the purview of this requirement by the Supreme Court.

merits in terms of the data presented to the DTAB committee, the observations qua each FDC as made in the report and the final ban notification that has ensued post this review. It is also pertinent to note that success in this matter would depend on how effectively parties can present their scientific data points on the issue of safety, rationality, therapeutic justification and marry the same into effective legal submissions especially considering that this is a case requiring a deep dive into the decision/ policy making powers of the government, a territory that courts seldom venture into. It is noted that the previous grounds of arbitrary action by the government, no opportunity of hearing granted etc., would no longer suffice in the absence of supporting scientific averments. The scope of review is now narrower and will require extensive understanding of the scientific data behind each FDC and how it is distinguished from the observations contained in the committee report.

The above said, we cannot rule out the possibility of the government filing a transfer petition before the Supreme Court especially given the fact the Supreme Court is apprised of the matter. If this happens, then one can expect a swift decision in the matter – one that will lay this controversy to rest for good. We note that the scope of review is now narrower and further that the number of parties actively fighting this has reduced drastically primarily owing to the fact that notwithstanding the exit of petitioners manufacturing the pre-1988 FDCs, most if not all have either moved to other approved combinations or withdrawn their FDCs from the market. Many are using the time granted to effectively dispose of stocks existing in the market. We cannot rule out new *de novo* action on the pre 1988 FDC's given the vigor with which the government has been fighting this matter. We will keep our readers updated on the latest developments in this regard.

2. Oxytocin Ban challenged in the Delhi High Court.

Our readers would recollect that the government has vide notification dated April 27, 2018 ("**Impugned Notification**"),[21] issued restrictions on the commercial manufacture of the drug containing the Active Pharmaceutical Ingredient ("**API**") Oxytocin and announced the import ban on oxytocin *vide* press release dated June 27, 2018.[22]

There are three petitions by BGP Product Operations GMBH (W.P. (C) 6084/2018), All India Drug Action Network (W.P. (C) 8555/2018), and Neon Laboratories (W.P. (C) 8666/2018) (collectively referred to as the "**Petitioners**" hereinafter) challenging the Impugned Notification being heard by a Division Bench of the Hon'ble Delhi High Court.

The Petitioners contended that the Impugned Notification is an overreach powers under section 26A of the D&C Act by the central government since oxytocin does not pose any risk to human life which cannot be curbed with regulation. It was also contended that the distinction created between the private and public sector manufacturers is contrary to section 31A of the D&C Act and violative of their fundamental rights under Article 14 of the Constitution.

The main contention of the Petitioners was that the sudden issuance of the Impugned Notification is arbitrary and had been issued without application of mind to the reports of DCC and DTAB. In order to support their contention, they have cited the judgment of the Hon'ble Supreme Court in the case of *Union of India v. Pfizer Ltd., 2018 (2) SCC 39* wherein it was held that the Central Government must take into account the recommendation of the expert committees despite not being obliged to consult the DCC and the DTAB before taking any measure. The Petitioners have also expressed concerns about the short supply of oxytocin in the wake of the ban.

The Central Government, on the other hand, has claimed that regulating the domestic sale of Oxytocin was always under active consideration by the government and based on the DCC deliberations in their 46th meeting, the ban was the best way to curtail the misuse of oxytocin in the veterinary sector. In response to the concerns about short supply of oxytocin, it was argued that based

[21] http://egazette.nic.in/WriteReadData/2018/185017.pdf
[22] http://www.pib.nic.in/PressReleaseIframePage.aspx?PRID=1536659#.WzMm0xGaIC4.twitter

on the birth rate statistics, Karnataka Antibiotics & Pharmaceuticals Ltd. ("**KAPL**"), the only company allowed to manufacture oxytocin, has the capacity to meet the demand.

The Court after consideration of the DCC and DTAB reports which emphasize that prohibition and restricted sale are extreme steps to curb the menace of oxytocin abuse, passed an order to the effect that the Impugned Notification, which sought to bring the prohibition in force with effect from July 1, 2018 and which was later postponed to September 1, 2018[23] by notification dated June 29, 2018, should be suspected/stayed for one month *vide* order dated August 31, 2018.[24]

The Delhi High Court *vide* order dated September 28, 2018 has scheduled the next hearing for October 25, 2018 and held that order dated August 31, 2018 shall be in effect for another month and the Impugned Notification shall not take effect before November 1, 2018.[25]

3. Delhi High Court on interpretation of 'Scheduled Formulation' under National List of Essential Medicines, 2015 ("NLEM"): *Modi-Mundi Pharma Pvt. Ltd. v Union of India & Ors.*[26] and

The Hon'ble Delhi High Court on July 17, 2018, passed a judgment in the case of *Modi-MundiPharma* wherein it opined that drugs developed through incremental innovation or novel drug delivery system could only be included under the NLEM for the purpose of fixing the ceiling price, procurement if they were explicitly listed in that sense. In other words, the court clarified on what kind of drugs are included.

The Petitioner, a pharmaceutical company approached the Delhi High Court against the order passed by the National Pharmaceutical Pricing Authority ("**NPPA**") in relation to fixation of ceiling price of the formulation "Tramadol 100mg CR 10" (hereinafter referred to as "**Tramadol CR 10**"). The Petitioners contended that the Tramadol CR 10 was only listed in the NLEM 2015 in the Capsule and Injection forms whereas their formulation uses a Continuous Controlled Release Dual Mechanism Drug Delivery System ("**CR-Technology**") was not specifically included in the NLEM-2015 and is thus not a 'scheduled formulation' within the meaning of the DPCO-2013.

Explanations (1) and (2) to the NLEM 2015 are at the core of the present controversy. The essence of Explanation (1) is that in case of every drug that is included in the NLEM, a dosage form is listed alongside. A drug shall be deemed to be included in the list of scheduled formulations under DPCO if the same is for the same *strength* of the medicine and *route of administration* without *significant difference in terms of pharmacokinetics or pharmacodynamics or efficacy-safety* from the listed medicine.

As an extension of this, Explanation 2 provides that formulations developed through *incremental innovation* (an additional innovation over an existing quality) or *novel drug delivery systems* (continuous/ sustained release) cannot be included unless specifically mentioned in the list alongside the medicine.

The petition was allowed and the court concluded that if there is an improved formulation, developed through incremental innovation involving technology, to overcome certain disadvantages associated with the use of conventional formulations, the same would not be read as part of NLEM 2015 unless specifically mentioned. Therefore, Tramadol CR10 was removed from the purview of the Impugned notification ceiling its price.

4. Mere quantitative differences insufficient to establish any material difference from the Scheduled Formulation: *Indoco Remedies Ltd. v. Union of India & Anr.*[27]

Indoco Remedies Limited ("**Petitioner**") was engaged in the manufacture and marketing of drugs and pharmaceuticals including a 60 ml Cetirizine Syrup of the strength 5mg/5ml ("**the Formulation**"). The NPPA had fixed the ceiling price of Cetirizine syrup with strength 5mg/ml which was covered in Schedule –I of DPCO, 2013.

The Petitioner contended that the Formulation was a Non-Scheduled Formulation since the strength and dosage of the Formulation is different from the one in the Schedule I to the DPCO-2013, which included only Cetirizine Tablets of 10 mg and

---

[23] http://cdsco.nic.in/writereaddata/2018_06_29_GSR%20602(E)_Extention%20of%20implementation.pdf
[24] http://delhihighcourt.nic.in/dhcqrydisp_o.asp?pn=200034&yr=2018
[25] http://delhihighcourt.nic.in/dhcqrydisp_o.asp?pn=224646&yr=2018
[26] Modi-Mundipharma Pvt. Ltd. v. Union of India and Ors., W.P. (C) 11802/2016.
[27] Indoco Remedies v. Union of India, W.P.(C) 7597/2018.

Syrup of 5 mg/ml placing reliance on the judgment by the Delhi High Court in the case of *Modi-Mundipharma Pvt. Ltd. v. Union of India and Ors., W.P. (C) 11802/2016*.

The Court *vide* order dated July 26, 2018 differentiated the facts of this case from the *Modi-Mundipharma* case and held that mere quantitative differences would be insufficient to establish any material difference from the scheduled formulation. The Court concluded that in the present case, there was no material difference between the Formulation and the Cetirizine as included in NLEM, 2011 and that the Formulation was a mere dilution of the strength (of Cetirizine) as specified in Schedule I as opposed to the innovative delivery system in the *Modi-Mundipharma* case.

The court concluded stating as follows:

"It is impossible to accept that legislative intent was to exclude formulations from Schedule I merely on the basis of dilution or concentration in the strength of the medicines as specified."

5. *NCLT Rejects Ajanta Pharma's Scheme of Merger on Grounds of Tax Avoidance*

Recently, the National Company Law Tribunal Mumbai, ("**NCLT**") rejected Ajanta Pharma Limited's ("**Ajanta Pharma**") scheme of amalgamation and arrangement between the company and its shareholder Gabs Investments Private Limited ("**GIPL**") on the grounds of General Anti Avoidance Rules ("**GAAR**").

According to the Scheme, GIPL was proposed to be merged into Ajanta Pharma, followed by reduction of the share capital of GIPL. Ajanta Pharma was to subsequently issue equity share individually to promoters. This was to simplify the shareholding structure in the Ajanta Pharma.

GAAR is a set of rules under the Income Tax Act, 1961 ("**IT Act**") aimed to curb tax evasion and is contained under Chapter X-A of the IT Act. The rules define an Impermissible Avoidance Arrangement ("**IAA**") and where an arrangement is found to be an IAA, the consequences listed under the rules can follow which may include the corporate structure being disregarded and the arrangement being treated as null and void. The objections raised by the Indian Income Tax Authorities were that, the scheme was an IAA deliberately set up to avoid taxes. They provided calculations that a loss of more than 400 crore would be caused to the state revenue if the aforesaid scheme was implemented.

The NCLT observed the financials of the promoters and the Ajanta Pharma and rejected the scheme of arrangement as it was not held to provide unfair advantage to the common promoters of the both companies involved and against public interest. It is to be noted that this is the first merger scheme where the Income Tax Authorities have invoked the provisions of the GAAR.

6. Bombay High Court states, "Drugs are not sweets" in *Glenmark Pharmaceuticals v. Curetech Skincare & Anr.*[28]

In *Glenmark Pharmaceuticals Ltd. vs. Curetech Skincare and Anr.,* Mr. Justice Kathawalla of the Bombay High Court imposed costs of INR 1.5 crores against the defendant found to be 'habitually' committing trademark infringement of pharmaceutical products. The court observed that the defendant had blatantly copied the word mark, art work, colour scheme, font style, manner of writing, trade dress of the Plaintiff's product and had a set modus operandi of copying brands of other companies. The decision is significant for the quantum of damages awarded and the Court stated that the aggravated damages were on account of repeated infringement despite assurance given to the court against it.[29] It is to be noted that the entire compensation money was to be directed to be paid into the Chief Minister's Distress Relief Fund, Kerala on account of the floods in Kerala.

III. MAJOR DEALS AND TRANSACTIONS

1. Aurobindo Pharma enters into agreement to acquire the commercial operations and three manufacturing facilities in the US from Sandoz, a Novartis generics division, for $900 million

Aurobindo Pharma ("**Aurobindo**"), a Hyderabad-based company, on September 6, 2018 announced its acquisition of the commercial operations and three manufacturing facilities in the United States of America from Sandoz, a Novartis generics division, for USD 900 million.

This acquisition, one of the biggest international pharmaceutical deal by an Indian company, will

[28] ComIP (L)No. 1063 OF 2018
[29] https://spicyip.com/2018/09/drugs-are-not-sweets-bombay-hc-imposes-exemplary-costs-for-pharma-trademark-infringement.html

provide Aurobindo access to "authorised generics and in-licensing products, branded dermatology products, three manufacturing facilities at Hicksville - NY (Derma) Melville - NY(Derma) Wilson- NC (OSD), and 100 per cent shareholding in Eon Labs, a wholly-owned subsidiary of Sandoz. Additionally it will add approximately 300 products, including projects in development, as well as commercial and manufacturing capabilities in the US, complementing and expanding the group's portfolio."[30]

This deal, financed through debt, has resulted in Aurobindo becoming the second largest generic drug manufacturer in the United States of America surpassing other generics drug giants such as Mylan, Lupin and Taro, a subsidiary of Sun Pharma.

2. **Coca-Cola, Zydus Cadila battle for Kraft Heinz India brands**

The world's largest beverage company, Coca Cola and the Zydus Cadila Group have been competing for the consumer portfolio of Kraft Heinz in India, which has been seeking USD 1 Billion for its assets, with Nestle, Emami and ITC. This portfolio includes Complan, the milk drink for children.[31] Zydus Wellness ("**Zydus**"), based out of Ahmedabad, is the listed consumer business subsidiary of Zydus Cadila Healthcare. The acquisition of the consumer portfolio of Heinz can be an addition to its existing line of personal and skin care, sugar substitutes and health foods. For Coca Cola, on the other hand, this acquisition could prove extremely fruitful by providing it entry into market products such as glucose, and milk-based drinks.

3. **Nestle and Unilever placing bids to acquire UK pharmaceutical giant Glaxosmithkline's Indian nutritional foods unit**

Nestle and Unilever, the biggest global consumer product companies, are bidding for the acquisition of Indian nutritional foods unit of UK pharmaceutical company Glaxosmithkline plc. ("**GSK**"), with the ownership of health food drinks ("**HFDs**") such as Horlicks and Boost, both extremely popular brands of health drinks among children and women. This deal is estimated at USD 4 billion.[32] With the leading position in the HFD market, GSK currently owns a market share of around forty four percent.

4. **KKR-Radiant buys 49.7% stake in Max Health for $293 million**

Life Healthcare, a hospital group headquartered in South Africa, has sold the whole of its forty nine point seven percent stake in Max Health to Radiant Hospital ("**Radiant**") based in Mumbai backed by private equity player KKR for USD 293 million. This transaction has made Radiant a significant player in the business of healthcare.[33]

Life Healthcare and Max India have ownership of 49.7 per cent stake each of Max Healthcare, which is a subsidiary of Max India. This transaction will propel Radiant to the ranks of Apollo Hospital and IHH Fortis.

Max Healthcare is the third largest hospital chain in India with a capacity of twenty five hundred beds at fourteen facilities. In the year 2012, Life Healthcare acquired 26 percent stake in Max Healthcare for INR 516 Crores, subsequently increasing its investment in 2014 by investing an additional INR 716 Crores in the company.

5. **Medical device maker Stryker to buy K2M Group for about $1.4 bln to enter the spinal implant business**

Stryker Corporation ("**Stryker**"), medical device manufacturing company headquartered in Michigan USA, announced on August 30, 2018 its decision to buy smaller rival K2M Group Holdings Inc., at a deal price of USD 1.4 billion, adding K2M's fast-growing spinal implant technology to its business.[34] K2M, whose revenue in 2017 stood at nearly USD 300 million, is an up and coming player in the medical devices market as compared to Johnson & Johnson and Zimmer Biomet that hold a dominant position in the medical devices market.

Stryker has offered USD 27.50 for every share of K2M, which includes a premium of 26 percent to K2M Group's closing price on August 29, 2018. This move will help Stryker solidify its position in the spinal implant market which is the largest segment of orthopaedic implants.

---

30 https://economictimes.indiatimes.com/markets/stocks/news/aurobindo-buys-us-units-of-sandoz-for-900-million/articleshow/65713712.cms
31 https://economictimes.indiatimes.com/industry/cons-products/food/coca-cola-zydus-cadila-battle-for-kraft-heinz-india-brands/articleshow/65694661.cms
32. https://health.economictimes.indiatimes.com/news/pharma/global-giants-enter-fray-for-gsks-4bn-horlicks-unit/65850196
33. https://health.economictimes.indiatimes.com/news/hospitals/kkr-radiant-buys-49-7-stake-in-max-health-for-293-million/65879946
34 https://health.economictimes.indiatimes.com/news/medical-devices/medical-device-maker-stryker-to-buy-k2m-group-for-about-1-4-bln/65620646

6. Slump Sale of Solara Active Pharma Sciences Limited's Mahad Unit to Sequent Scientific Limited

Sequent Scientific Limited ("**Sequent**"), an integrated pharmaceutical company dealing in animal health (API and formulations) and Solara Active Pharma Sciences ("**Solara**"), an API manufacturing company, have entered into an agreement of business transfer for the acquisition of the EU-GMP API unit at Mahad, Maharashtra ("**Mahad unit**") for a consideration of INR 46.4 Crores.

Where Solara decided to part with the Mahad unit since it was not in synergy with multi product and US focussed business, Sequent stands to gain from the addition of the acquired Mahad unit with turnover of INR 394.4 Million in 2017[35] to its existing manufacturing facilities in Vizag and Tarapur.[36]

---

[35] http://equitybulls.com/admin/news2006/news_det.asp?id=236092

[36] https://www.business-standard.com/article/news-cm/sequent-scientific-to-acquire-solara-active-pharma-sciences-eu-gmp-api-facility-at-mahad-118092200273_1.html

cyril amarchand mangaldas
advocates & solicitors

Cyril Shroff
Managing Partner
E : cyril.shroff@cyrilshroff.com

Ashwin Sapra
Partner