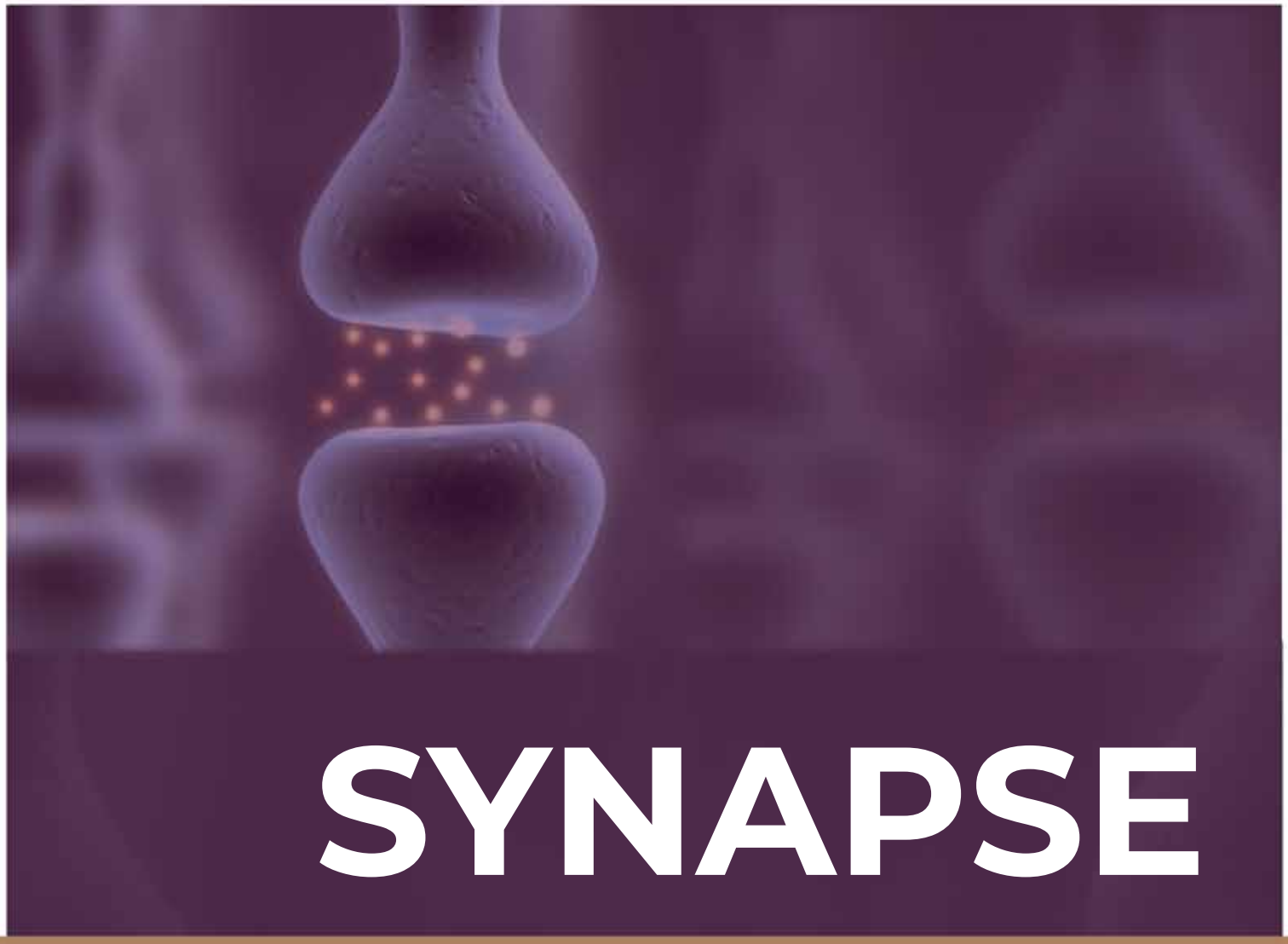

SYNAPSE

A Quarterly update on the Pharmaceutical Industry

Vol. III/Issue II/
April 01, 2019 – June 30, 2019

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advocates & solicitors

SYNAPSE

Dear Readers,

Cyril Amarchand Mangaldas, India's premier full-service law firm has an industry leading 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. Despite being election season, the pharmaceutical and healthcare sector saw incessant regulatory, M&A and litigation activity. It has been a busy quarter for the sector.

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. For instance, the DCC has recommended the regulation of Electronic Nicotine Delivery Systems under the auspices of the Drugs and Cosmetics Act, 1940 while the DTAB has recommended the regulation of all non-notified medical devices in a phased manner. Organ Preservation Solution was notified as a "drug" and will now be regulated under the Medical Devices Rules, 2017. The DTAB continues to deliberate on issues related to payment of compensation in cases of medical devices. Compensation rules in relation to death and disability in cases of clinical trials were announced.

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 II 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 II/
April 01, 2019 – June 30, 2019

1. 56th Meeting of Drugs Consulative Committee[1]

The 56th meeting of the Drugs Consultative Committee (**DCC**) took place on June 1, 2019 at New Delhi. Amongst other things, some of the important decisions that were taken by the DCC in this meeting are as follows:

(a) *Inclusion of Electronic Nicotine Delivery Systems (ENDS) and devices that enable delivery of nicotine under the definition of 'drug' under the Drugs and Cosmetics Act, 1940*

The DCC in its 48th meeting held on July 24, 2015 had concluded that e-cigarettes are not covered under the definition of 'drug' and as such resultantly do not come under the purview of the Drugs and Cosmetics Act, 1940 (**D&C Act**). It was concluded that these products could not be regulated under the provisions of the D&C Act.

Health being a state subject, states are free to make their own regulations. In this regard. some states, including Haryana, Karnataka, Maharashtra, Uttar Pradesh and Haryana declared ENDS as unapproved drugs under the D&C Act and Drugs and Cosmetics Rules, 1945 (**D&C Rules**). Further, the Central Government, through the Ministry of Health and Welfare (**MoHFW**), issued an advisory on August 28, 2018, advising states and union territories to ensure regulation of such products under the D&C Act. The DCC also noted that 'nicotine' is covered under the definition of 'drug' as contained in Section 3(b) of the D&C Act and various nicotine preparations such as nicotine patches and nicotine lozenges are approved by the DCGI under the D&C Act and D&C Rules. The DCC also noted that ENDS are promoted as a smoking cessation aid, but, their efficacy and safety as a quitting aid has not yet been firmly established. It was noted that though some smokers claim to have cut-down smoking while using ENDS, the total nicotine consumption seems to remain unchanged. Moreover, a considerable number of ex-smokers who have reported to stopping of cigarette use with the aid of ENDS, as continue to use the latter product, thus, sustaining nicotine dependence.

Therefore, the DCC observed that under the provisions of "drug" in the D&C Act, any product intended to be used as aid for smoking cessation is covered, and various drugs have been approved as aid for smoking cessation under the provisions of the D&C Act and D&C Rules. Accordingly, the DCC decided to revisit its decision taken in the 48th meeting and recommended that ENDS devices and like products fall under the definition of "drug" as defined under Section 3(b) of the D&C Act. This was a total about face on its previous stand.

(b) *Institution of sub-committee for recommendations on a proposal for making uniform quantity of sample requirement to be drawn by drugs inspectors for test or analysis*

The DCC took note of a meeting of heads of zonal, sub-zonal and port offices, and directors of laboratories of the CDSCO that took place on January 30, 2019 to discuss the issue of quantities of samples required to be drawn by the drugs inspectors for testing at drugs testing laboratories. In this meeting, it was decided to prepare and circulate the quantities of samples required for testing and analysis of drugs, cosmetics, vaccines and medical devices, and accordingly, these sample quantities were placed before the DCC.

The DCC opined that detailed examination is required to take further action in this regard, and therefore, constituted a subcommittee under chairmanship of Shri. Shobhit, Dy. Drugs Controller, Madhya Pradesh to examine and give recommendation in the

[1] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=OTE1

matter within three months to DCC for further consideration.

(c) ***Amendment of Schedule H of D&C Rules to exempt Centchroman 30mg tablets and Ethinyloestradiol I.P. 0.03 mg in combination with Levonorgestrol I.P. 0.15 mg in Tablet***

Under Schedule K of the D&C Rules, exemption from taking a sale licence for chemical contraceptives having inter alia the composition- Centchroman-30 mg; Levonorgestrel-0.15 mg with Ethinyloestradiol-0.03 mg; and Levonorgestrel-0.1 mg with Ethinyloestradiol-0.02 mg, is provided. However, Centchroman and Ethinyloestradiol are also specified in the Schedule H of the D&C Rules.

The DCC considered a representation from HLL Lifecare Limited (**HLL**) wherein it was represented that HLL is manufacturing and supplying regular oral contraceptive pills to the MoHFW under National Family Welfare Programme under various brand names and labelling these products was initially done by mentioning "Schedule K" on all the packing material as these products are covered under the "Schedule K". However, the authorities raised objections to this and necessitated labelling to be done in accordance with Schedule H requirements, namely printing of Rx, red box and Schedule H warning. HLL implemented this request, however, this had impeded its ability to supply these products under the MoHFW schemes as Schedule H drugs cannot be advertised, which is essential in order to educate the people about proper use of the product, and further, it can only be sold with a prescription of a registered medical practitioner whereas Social marketing products are meant for providing affordable contraceptive in remote areas.

The DCC considered the representation made by HLL and recommended the amendment of Schedule H of the D&C Rules to exempt Centchroman 30mg tablets and Ethinyloestradiol I.P. 0.03 mg in combination with Levonorgestrol I.P. 0.15 mg in Tablet from schedule H.

2. 82nd Meeting of the Drugs Technical Advisory Board[2]

The 82nd meeting of the Drugs Technical Advisory Board (**DTAB**) took place on April 2, 2019 at New Delhi. Amongst other things, some of the important decisions that were taken by the DTAB in this meeting are as follows:

(a) ***Evaluation of Prof. C.K. Kokate Committee report with respect to Fixed Dose Combinations***

A committee under the chairmanship of Prof. C.K. Kokate (**Kokate Committee**) had been set up by the MoHFW in September, 2014 to examine the safety and efficacy of fixed dose combinations (**FDC**) which were licensed by the state licensing authorities for manufacture without approval of DCGI. The DTAB noted that the Kokate Committee had categorized FDCs into "irrational (category 'a')", "requiring further deliberation (category 'b')", "rational (category 'c')" and "FDCs requiring generation of data (category 'd')", and found 324 FDCs as irrational, after evaluating all the data submitted and available information, 28 FDCs as rational, 2 FDCs which require further generation of data and 4 FDCs which require further deliberation.

The report of the Kokate Committee, wherein it had been recommended that FDCs wherever recommended as "irrational (category 'a')" should not be allowed for their continued manufacturing and marketing and should be prohibited under the D&C Act, was placed before the DTAB for further

[2]https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=ODc5

consideration. The DTAB recommended to constitute a sub-committee under the chairpersonship of Dr. Nilima Kshirsagar to evaluate the second assessment report of the Prof. C.K. Kokate Committee with respect to FDCs considered as irrational.

(b) ***Exemption from obtaining Form 29 for test/ analysis of approved drugs***

The DTAB was apprised that a licence to manufacture drugs for sale or distribution is granted in Form 25 or Form 28 under the D&C Rules, whereas, licence to manufacture drugs for the purposes of examination, test or analysis is granted in Form 29 under Rule 89 of the D&C Rules. Rule 89 of the D&C Rules, clearly states that a licenses in Form 29 is required to be obtained if the person proposing to manufacture a drug for the purpose of examination, test or analysis does not hold a licence in Form 25 or Form 28 in respect of such drugs.

The DTAB accordingly recommended the amendment of the D&C Rules to exempt the manufacturers from obtaining license in Form 29 for manufacturing of approved drugs, if the manufacturers already possess licence in Form 25/Form 28 in the same dosage form, subject to the condition that the information about the manufacturing of such drugs for examination, test or analysis shall be uploaded on the SUGAM Portal.

(c) ***QR Coding on packing of APIs***

The DTAB took note of the important role of supply chain, security and integrity in proper storage condition, in enhancing quality of Active Pharmaceutical Ingredients (**API**). Therefore, the DTAB recommended the amendment of D&C Rules for making it mandatory to have QR coding on labels of APIs for tracing the origin and movement of APIs from manufacturers to formulators.

(d) ***Amendment of Schedule V of Medical Devices Rules, 2017***

Schedule V of Medical Device Rules, 2017 deals with Quality Management System for Medical Devices and in-vitro diagnostic medical devices and it is largely based on requirements of ISO 13485:2003. These provisions have been updated by ISO effective from March 1, 2019. The DTAB, therefore, recommended the amendment of Schedule V of Medical Device Rules, 2017 to bring it in line with ISO 134185: 2016.

(e) ***Inclusion of surgical gowns, surgical drapes and incision drapes as "medical devices" under Section 3(b)(iv) of D&C Act***

The DTAB took note of the fact that, at present, 23 (twenty three) notified medical devices are regulated under the D&C Act, and further through other notifications, 4 (four) devices and 8 (Eight) devices comes under the definition of medical devices effectively from January 1, 2020 and April 1, 2020 respectively. In a meeting of the Committee of Secretaries on Technical Textiles, under the chairmanship of the DGHs, which took place on October 5, 2018, it was proposed that surgical gowns, surgical drapes can be considered under Section 3(b)(iv) of the D&C Act. . Further, a meeting was held on March 27, 2019 for the regulation of surgical drapes and surgical gowns under the Section 3(b)(iv) of the D&C Act, and the DTAB found that the stakeholders were agreeable for the regulation of said products.

The DTAB therefore, agreed to the recommendation of notification of surgical gowns, surgical drapes and incision drapes as medical devices under the Section 3(b)(iv) of the D&C Act.

(f) ***Regulation of non-notified medical devices***

It has been the focus of the government to extend regulatory control over medical

devices that are currently not notified under the D&C Act. The DTAB considered representations from various stakeholders for regulating non-notified medical devices on account of concerns regarding safety, quality and performance of various medical devices, including diagnostic kits manufactured/imported in the country. Various medical devices like equipment, analyzers, instruments etc. used in various healthcare facilities for diagnosis, treatment, mitigation are currently out of scope of regulations framed under D&C Act.

In view of the need for comprehensive regulation of all medical devices, MoHFW constituted a committee in February, 2019. This committee had recommended that all medical devices should be regulated in a phase wise manner.

In the first phase, all manufacturers and importers of all non-regulated medical devices should register the details of the devices manufactured/imported on a special SUGAM portal.

In the second phase, registration of Class A & B devices as well as Class C & D devices would be followed by mandatory licensing. The committee had also prepared a draft notification to cover all medical devices under Section 3(b)(iv) of the D&C Act, along with exemptions. Further, committee recommended the creation of vertical under CDSCO lead by Additional Drug Controller.

The DTAB agreed to notify all medical devices as "drug" under Section 3(b)(iv) of D&C Act and further agreed that CDSCO should be strengthened with respect to manpower and infrastructure to regulate all medical devices.

3. Draft amendment to the D&C Rules

The MoHFW vide gazette notification no. G.S.R. 447(E)[3] dated June 24, 2019, has published a draft of amendments to the D&C Rules. The proposed amendments pertain to insertion of a definition of 'Marketer' in the D&C Rules.

The proposed definition of *'Marketer' states that "'Marketer' means a person who as an agent or in any other capacity adopts any drug manufactured by another manufacturer for marketing of such drug by labelling or affixing his name on the label of the drug with a view for its sale and distribution."*

Apart from introducing definition of 'Marketer', another rule is proposed to be introduced as Rule 84E, which places responsibility for quality of a drug as well as other regulatory compliances on the marketer who sells or distributes that drugs along with the manufacturer. Further, the name of the marketer of the drug and its address, in case the drug is marketed by a marketer, would also be required to be printed on the innermost container of the drugs, provided if the drug is contained in an ampoule or a similar small container, name of the marketer would be enough.

These draft rules were to be taken up for consideration after the expiry of a period of 30 (thirty) days from the date on which the copies of this gazette notification was made available to public. Objections and suggestion were also invited during this period for consideration by the Central Government.

4. Notification of Medical Devices (Third Amendment) Rules, 2019

With a view towards giving the Medical Devices Rules more teeth, The MoHFW vide gazette notification no. G.S.R. 318 (E)[4] dated April 18, 2019, has notified amendments to the Medical Devices Rules, 2017. The amendments pertain to Rule 91 of the Medical Devices Rules, 2017 which deals with export of medical devices. Rule 91 provide for issuance of free sale certificate or certificate about quality, safety and performance in relation to medical devices, as required by concerned

[3]https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDUxNQ
[4]https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDMzNA

authority of importing country. Prior to this amendment, an application for issuance of certificate was required to be made before the Central Licensing Authority only. However, vide this amendment, an application for certificate for class C & D devices is to be made to the Central Licensing whereas for certification of class A & B medical devices, the application shall be made to State Licensing Authority.

5. Notification of 'Organ Preservative Solution' as 'drug'

The MoHFW vide gazette notification no. S.O. 1500(E)[5] dated April 2, 2019, has notified "organ preservative solution" as "drug" within the meaning of Section 3(b)(iv) of the D&C Act, with immediate effect.

6. Registration Certificate for import of Radiopharmaceuticals[6]

A meeting of the CDSCO with stakeholders took place in New Delhi on April 12, 2019 to discuss the requirement of Import Licenses and Registration Certificates for radiopharmaceuticals under the D&C Act and D&C Rules. The DCGI informed participants in attendance that Import Licenses for import of radiopharmaceuticals were earlier issued under Rule 24 of the D&C Rules, which permits the issuance of Import License without a Registration Certificate. However, this is an emergency provision, and the DCGI was of the opinion that this should not be construed as the general practice. The stakeholders informed the DCGI that they were importing the radiopharmaceuticals under the waiver already received by them and that the domestic production was inadequate to meet the demand for radiopharmaceuticals. They were, however, informed that high demand and large business volume cannot be considered as an emergency.

Accordingly, the stakeholders agreed to apply for the grant of Registration Certificate for the product for which they had applied for the Import License within or for maximum period of 6 (six) months. Where the application for grant of Import License Where the application for grant of Import License without registration certificate had already been made, the Import License will be granted subject to the condition that the registration certificate is obtained within a period of 6 (six) months.

Therefore, going forward, it is unlikely that Import License for radiopharmaceuticals will be granted by the CDSCO without a Registration Certificate under Rule 24.

7. Procedure for subsequent applicants in respect of FDCs falling under category'd'.

Manufacturers of category 'd' FDCs had earlier been asked to conduct Phase IV studies in a post market scenario to enable the regulator to take a decision on these FDC's. We note that certain manufacturers had requested a waiver from conducting Phase IV clinical trials, and consequently, the Prof. Kokate Committee recommended classifying categorization of these FDCs into FDCs which require Phase IV clinical trials, and FDCs for which active post marketing surveillance shall be conducted and report of the same submitted for further evaluation. Accordingly, the CDSCO, vide a public notice dated May 22, 2019[7], has published a pathway as it intends to waive Phase IV clinical trials. In this regard, it has been decided that the following documents shall be required in case of manufacturers already holding licenses obtained from the State Licensing Authority (**SLA**) before October 1, 2012:

i. Form CT-21;
ii. Fee as specified in Schedule VI of New Drugs and Clinical Trials Rules, 2019;
iii. Name and Composition of the FDC;
iv. Product permission issued by the SLA;
v. Copy of manufacturing license in Form 25/28
vi. Serial no. and name of FDC as per Annexure A of the notice;

[5]https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDI4OA
[6]https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadAlertsFiles/ImportLicenseRadiopharmaceuticals.pdf
[7]https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDQ2MA

vii. Phase IV trial protocol/ commitment for conducting Active Post Marketing Surveillance Study/ Bio-equivalence study protocol (as the case may be)

In case of new manufacturers for proposed FDCs, in addition to the documents listed above, Data from Stability Studies (6 months accelerated), and Test Specifications of the FDC along with Method of Analysis are required to be submitted. Manufacturers that hold licenses issued by the SLA before October 1, 2012, but have not yet applied to the DCGI, have been given a time period of 6 (six) months to submit their applications in this regard.

8. FDC ban updates:

(a) *Submission of information for evaluation of FDCs by DTAB sub committee*

The DCGI, *vide* a public notice dated May 29, 2019[8] , gave the manufacturers of FDCs and relevant stakeholders, time till June 30, 2019 to submit information with respect to FDCs which had been classified as 'irrational' in the Prof. Kokate Committee Report, in the prescribed format (in Annexure A, as annexed to the notice) along with supporting documents to the sub-committee instituted by the DTAB under the chairmanship of Dr. Nilima Kshirsagar.

(b) *Applications regarding FDCs which require further generation of data*

The CDSCO, *vide* a letter dated December 12, 2018, had requested State/ UT Drug Controllers to direct manufacturers of certain FDCs to submit clinical trial protocols/ PMS data for obtaining NOC from the DGHS for further generation of data in terms of their safety and efficacy. These FDCs, numbering 49 (forty nine), had been identified as requiring further generation of data in terms of their safety and efficacy by conducting clinical trials. The study protocols were required to be submitted by April 1, 2019. Vide a separate letter, also dated December 12, 2018, the CDSCO had requested State/ UT Drug Controllers to direct manufacturers of 17 (seventeen) identified FDCs to submit data/ information in the prescribed form, as the data provided by the manufacturers earlier as considered inadequate to prove their rationality, safety and efficacy. This information was required to be submitted by February 28, 2019.

Again *vide* a letter dated April 12, 2019[9], State/ UT Drug Controllers were informed that only a few applications had been received in this regard. Therefore, they were requested to once again direct the manufacturers of the 49 (forty nine) and 17 (seventeen) FDCs identified earlier, to submit the required information, latest by June 30, 2019.

9. Classification of newly notified medical devices

The DCGI, *vide* a public notice dated May 15, 2019[10], has notified the classification of newly notified medical devices, in accordance with the requirements of Medical Devices Rules, 2017.

The Following medical devices have been classified under risk Class C:

i. CT Scan equipment;
ii. MRI equipment;
iii. Defibrillators;
iv. Dialysis Machine;
v. PET equipment
vi. X-ray machine;
vii. Nebulizer;
viii. Glucometer (under IVD category); and
ix. Organ preservative solution.

[8]https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDQ2OQ
[9]https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDMwOQ
[10]https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDM5Ng

Apart from these, 'Bone Marrow Cell Separator', 'Blood Pressure Monitoring Devices', and 'Digital Thermometer' will be regulated under risk Class B.

As we have consistently updated our readers, this is an ongoing effort on part of the regulator to increase regulatory control over all medical devices in the country.

10. Non-inclusion of 'healthcare' in defination of 'service' in Consumer Protection Bill

Healthcare services have been excluded from the definition of '*services*' in the latest draft[11] of the Consumer Protection Bill. This Bill aims to replace the Consumer Protection Act, 1986. Interestingly, *healthcare* had been included within the meaning of "service" in an earlier draft[12]of the Consumer Protection Bill, 2018 which was passed by the Lok Sabha in December 2018, but has since lapsed.

The demands of healthcare professionals for better legal protections and safeguards, arising out of reported incidents of violence against them, may have prompted the dropping of "healthcare" from the definition of "*service*". However, it must be noted that the definition of "*service*" in the Consumer Protection Bill, 2018 was a general definition which only listed out certain kinds of services as specimens. Therefore, non-inclusion of "*healthcare*" in this definition may not mean that healthcare services are outside the scope of consumer laws. Further, the Hon'ble Supreme Court has recognised healthcare as a "*service*" under the Consumer Protection Act, 1986. Accordingly, any answer to the question- whether or not healthcare would be covered under any new consumer protection legislation, would require an appropriate judicial test to be applied in order to pass muster as law.

[11]https://www.prsindia.org/sites/default/files/bill_files/THE%20CONSUMER%20PROTECTION%20BILL%2C%202019%20Bill%20ext.pdf
[12]http://164.100.47.4/billstexts/lsbilltexts/asintroduced/1_2018_LS_Eng.pdf

Major Litigation & Important Judgements

Supreme Court

1. ***Constitutional Validity of Sections 23(1) and 23(2) of the Preconception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 ("PCPNDT Act"). Federation of Obstetrics and Gynecological Societies of India ("FOGSI") Vs. Union of India AIR 2019 SC 2214.***

   A writ petition challenging the constitutional validity of Section 23(1) and 23(2) of the PCPNDT Act was filed in the Hon'ble Supreme Court by FOGSI on the grounds that these provisions violated Articles 14, 19(1)(g) and 21 of the Constitution. Decriminalisation of anomalies in paperwork/record keeping/ clerical errors were sought.

   Under Section 23(1), all contraventions of the PCPNDT Act are treated similarly and attract similar punishment of imprisonment and fine. Further, under Section 23(2), the State Medical Council can suspend the registration of a medical practitioner till a case is disposed of.

   The Petitioners *inter alia* submitted that the PCPNDT Act fails to distinguish between criminal offences and the anomalies in paperwork like incomplete 'F'-Forms, clerical mistakes such as writing NA or incomplete address, no mentioning of the date, etc., and thereby charging medical practitioners with similar punishments for heinous crime of female foeticide and sex determination and for unintentional mistakes in record keeping. It was also submitted that suspension of registration till a case is finally decided violates Article 21 as it assumes guilt even before the same has been established.

   The Respondents on the other hand contended that as sex determination is committed in privacy and as both the parties are working together, therefore, it becomes difficult to detect the commission of the offence, and hence sometimes non-maintenance of records or incomplete records may provide substantial evidence towards the commission of offence. It was also contended that Form 'F' gives insight into the reasons for conducting ultrasonography and incomplete Form 'F' raises presumption of doubt against the medical practitioner. The non-maintenance of records is not merely a technical or procedural lapse in the context of sex determination, instead, it is the most significant piece of evidence for identifying the accused.

   The Hon'ble Supreme Court held that the medical profession has highly specialised nature and considering the nature of services rendered by medical professional, proper maintenance of records is an integral part of the medical services. The Court found that Form 'F' is not merely a clerical requirement. If important information is kept vague or missing from the Form, it would defeat the very purpose of the PCPNDT Act. The Court held that the PCPNDT Act enjoys a presumption of constitutionality. Maintaining information is a fundamental and basic requirement for conducting a test and when a Form has not been filled up, the act is dishonest, fraudulent and can be termed intentional also. Therefore, the provisions in the PCPNDT Act cannot be termed as vague or arbitrary or illegal or unreasonable. Accordingly, the writ petition was dismissed.

Delhi High Court

2. ***Extension of stay on ban on e-cigarettes and vaping devices. Litejoy International Pvt Ltd. and Ors. Vs. Union of India and Ors. W.P.(C) 2351/2019.***

   On March 18, 2019, the Delhi High court had stayed the order of banning sale (including online sale), manufacture, distribution, trade, import and advertisement of Electronic Nicotine Delivery systems ("**ENDS**") including e-Cigarettes, Heat-Not Burn devices, Vape, e-Sheesha, e-Nicotine Flavoured Hookah, and other devices that enable nicotine delivery till the next date of hearing, which was set as May 17, 2019. The Hon'ble Court, passed an order on March 18, 2019, stating that, prima facie, such products do not fall within the definition of a 'drug' and was pleased to grant a stay on the operation of the circular and communication in this regard.

   The next date of hearing in this matter is August 22, 2019.

3. ***Stay order in Anti Profiteering case against Abbott Healthcare. Abbott Healthcare Private Limited & Anr. Vs. Union of India & Ors. W.P.(C) 4213/2019***

   The Hon'ble Delhi High Court, *vide* an order dated April 24, 2019 granted a stay on further proceedings against Abbott healthcare Pvt. Ltd. ("**Abbott**"), in a writ petition filed by Abbott challenging an order passed by the National Anti-Profiteering Authority ("**NAPA**") on March 5, 2019. The order dated 5.03.2019 pertains to a product of the Company, namely "Melaglow Rich", and alleges that the benefit of the variation in the GST rates after July 1, 2017 was not being passed on to the consumer.

   Vide the impugned order, NAPA had found Abbott in contravention of the Central GST requirements by issuing incorrect invoices thereby committing an offence under

   Section 122(1)(i) of the Central Goods and Services Tax Act, 2017 ("**CGST Act**") and would, therefore, liable for penalty under the said provision read with Rule 133 (3) (d) of the CGST Rules, 2017. In the writ petition, Abbott challenged the vires of Section 171 of the CGST Act and Chapter 15 of the CGST Rules and in particular Rules 126, 127 and 133. During the proceeding, the NAPA has proposed to investigate the pricing of all of the products of Abbott, not limited to the single product for which the complaint was made, however, Abbott contended that this is beyond the powers of NAPA as provided under Rule 128, 129 and 133 of CGST Rules..

   The Hon'ble Court observed that there are similar petitions pending where constitutional validity and vires of the NOOA said provisions of NAPA have been challenged, which had raised a similar challenge of the constitutional validity of these provisions apart from challenging the orders of the NAPA. Similar writ petitions are W.P. (C) 378 of 2019 (Hindustan Unilever Ltd. v. Union of India) and W.P. (C) 2347 of 2019 (Jubilant Foodworks Ltd. v. Union of India). Abbott also brought it to the Court's attention that they had undertaken to pay the demanded amount of Rs.96,59,716.26 along with the applicable interest as per the CGST

Bombay High Court

4. ***Termination of pregnancy exceeding 20 weeks allowed without permission of High Court if mother's life is in danger. XYZ Vs. Union of India & Ors. 2019(3)BomCR400.***

   The Hon'ble Bombay High Court has recently held that a registered medical practitioner may medically terminate pregnancy which

has exceeded 20 weeks, without permission from the High Court, only where he is of opinion, formed in good faith, that the termination of such pregnancy is immediately necessary to save the life of the pregnant woman. Further, where a pregnant woman, the length of whose pregnancy has exceeded 20 weeks seeks to terminate such pregnancy on the ground that its continuance would involve grave injury to her physical or mental health or where there is a substantial risk that if the child were born, it would suffer from such physical or mental abnormalities as to be seriously handicapped, such pregnant woman will have to seek permission from the High Court, and the High Court can, in exercise of its extra ordinary jurisdiction under Article 226 of the Constitution, permit medical termination of such pregnancies, in contingencies set out in clauses (i) and (ii) of section 3(2)(b) of the Medical Termination of Pregnancy Act, 1971 ("**MTP Act**").

These findings found place in a judgment of the Bombay High Court dated April 3, 2019 in writ petitions raising question as to whether in exercise of its jurisdiction under Article 226 of the Constitution, the Court can permit the Petitioners to medically terminate pregnancies, the length of which exceed 20 weeks, i.e. the ceiling prescribed in section 3 (2) of the MTP Act. The Court, upon a conjoin reading of Section 3 and 5 of the MTP Act, observed that the medical termination of pregnancy which exceeds 20 weeks can be undertaken only by registered medical practitioner in a case where he is of the opinion, formed in good faith, that the termination of such pregnancy is immediately necessary to save the life of the pregnant woman. The Court also held that the expression "life" as it appears in Section 5 of the MTP Act is to be construed liberally and therefore, the Court can, in exercise of its extraordinary jurisdiction under Article 226 of the Constitution of India, permit the Petitioners to undergo medical termination of their pregnancies in contingencies set out in clauses (i) and (ii) of section 3(2)(b) of the MTP Act.

Major Deals

1. **Mfine raised venture capital debt and Series B funding**

   Mfine, a tech start-up in the healthcare sector, which operates an AI powered aggregator platform to connect doctors and patients, has recently raised Rs. 31 crore in venture capital debt from Alteria Capital[13]. This is in addition to the $17.2 million raised by the Bengaluru based start-up in its Series B round of funding, which was led by Stellaris Venture Partners, Prime Venture Partners, SBI Investment, and Beenext[14]. The Company's current network includes around 160 hospitals across 5 (five) cities with aims to bring 250 hospitals with more than 2500 doctors onto its platform. The Company would be increasing its investment in artificial intelligence, mobile engineering and hardware integration.

2. **Sale of Australian business of Strides Pharma**

   Bengaluru based pharmaceutical company Strides Pharma Science Limited has announced the sale of its Australian business[15]. Strides Pharma had been operating in the Australian market through the investment made by its subsidiary Strides Pharma Global in Arrow Pharma. Now, Strides Pharma Global has decided to sell its investment to Arrow Pharma for Australian $394 million. The transaction is expected to close by July 10, 2019.

[13]https://health.economictimes.indiatimes.com/news/industry/mfine-raises-venture-debt-from-alteria-capital/70049109 [14] https://www.vccircle.
[14]https://techcrunch.com/2019/04/23/mfine-raises-17-2m/?renderMode=ie11
[15]https://www.livemint.com/companies/news/strides-to-exit-australia-announces-acquisitions-in-north-america-1548785634953.html

Strides Pharma has also announced its decision to acquire Vensun Pharmaceutical Inc. of USA for $18 million. The Company's Canadian subsidiary Strides Canada Pharma Inc. has also entered an arrangement to acquire 80% stake in Canada's Pharmapar Inc. for $3 million.

3. Agreement between Sun Pharma and China Medical System Holdings

A subsidiary of Sun Pharma has entered into a subsidiary of China Medical System Holdings for development and commercialisation of dermatology products[16], namely Tildrakizumab and Cyclosporine. This agreement covers commercialisation opportunities in various regions including Greater China, Hong Kong, Macau, Mainland China, and Taiwan. Under the agreement, China Medical System Holdings is expected to pay Sun Pharma an initial upfront payment in addition to regulatory and sales milestones payments and royalties. The specific terms of the payment arrangement have, however, not been disclosed.

The term of this agreement has been disclosed to be 15 (fifteen) years from the first commercial sale of the products in Greater China, with an option to extend it by another 3 (three) years, subject to the terms and conditions contained in the agreement.

4. Agreement between Glenmark and Novartis

Glenmark Farmaceutica, a subsidiary of Glenmark Pharmaceuticals, has entered into an exclusive agreement with Novartis Biosciences SA in relation to 3 (three) respiratory products of Novartis in Brazil. The agreement will come into effect from July 1, 2019 onwards.

Under this agreement, Glenmark will be responsible for promoting, commercialising and distributing the products- Seebri (Glycopyrronium bromide), Onbrize (Indacaterol) and Ultibro (combination of Indacaterol and Glycopyrronium) in Brazil. Novartis will, however, continue to manufacture these products and hold all regulatory registrations for them.

5. Series B funding of Brinton Pharmaceuticals Limited

Brinton Pharmaceuticals Limited has received up to $8 million from India Alternatives Investment Advisors as part of its Series B funding[17]. The main focus area for Brinton Pharmaceuticals Limited is dermatology and the Company has also expanded into the paediatric dermatology and respiratory segments. As part of this investment, India Alternatives Investment Advisors will acquire a significant minority stake in the Company. Previously, in 2017 Tata Capital Healthcare Fund had also invested in Brinton Pharmaceuticals Limited.

6. Issue of NCDs by Alembic Pharma

In June, 2019, Alembic Pharmaceuticals Limited announced the decision taken by its board of directors to issue non-convertible debentures for raising up to Rs. 300 crore[18]. It was announced that the non-convertible these funds was however, not communicated. debentures would be issued in either 1 (one) or 2 (two) tranches. The reasons for raising these funds was however, not communicated.

7. Promoters to divest stake in JB Chemicals

The promoters of JB Chemicals and Pharmaceutical Ltd. have decided to divest their 57% stake in the Company[19]. The Company is primarily an API manufacturer. The investment bank Avendus has been mandated to look for buyers for the sale of

[16]https://health.economictimes.indiatimes.com/news/pharma/sun-pharma-arm-enters-pact-with-china-medical-system/69982236
[17] https://health.economictimes.indiatimes.com/news/pharma/brinton-pharmaceuticals-receives-series-b-funding-from-india-alternatives/69796430
[18]https://health.economictimes.indiatimes.com/news/pharma/alembic-pharma-to-raise-up-to-rs-300-crore-via-ncds/69755516
[19]https://health.economictimes.indiatimes.com/news/pharma/jb-chemicals-promoters-to-offload-57-stake/69540392

their stake. Lupin Pharma and the healthcare arm of Piramal Enterprises are among the potential buyers for acquiring this stake[20].

8. JV between Alembic Pharma and Chinese firms

In May, 2019, Alembic Pharmaceutical Ltd. entered into a joint venture agreement with Chinese companies SPH SINE Pharmaceutical Laboratories Co. Ltd[21]. and Adia (Shanghai) Pharma Co. Ltd . The joint venture agreement relates to the sale of Alembic Pharma's products in China. Under the terms of this agreement, initially the joint venture will commercialize the products of Alembic Pharma in China, and thereafter, there are plans to also set up a manufacturing facility in China.

The equity in the joint venture will be held in the ratio of 51%, 44% and 5% by SPH SINE Pharma, Alembic Pharma and Adia Pharma respectively, and initially the joint venture will launch a portfolio of oral solids followed on later by injectables, ophthalmology, dermatology and oncology products.

9. Acquisition of Myra by Medlife

Bengaluru based e-pharmacy start-up Medlife acquired Myra, another start-up in the arena, in an all stock deal[22]. This move is expected to help Medlife expand its services to 22 (twenty two) cities in the near future. This move from Medlife comes as a consequence of the challenges faced by Medlife when it tried to experiment with express deliveries in Bengaluru. Myra's expertise in this segment is expected to enable Medlife to gain access to the express delivery segment. Medlife had recently raised Rs. 118.95 Cr ($17 Million) in equity funding from the Prasid Uno Family Trust[23].

10. Agreement between Zydus Cadila and SIFI

In April 2019, pharmaceuticals company Zydus Cadila announced its agreement with SIFI, an Italy based ophthalmic products firm, to market intraocular lenses in India.[24]It was also announced that SIFI's intraocular lenses have already been approved by the CDSCO in India and that these surgical lenses are an advanced solution for cataract refractive surgery and the correction of astigmatism and presbyopia.

[20]https://economictimes.indiatimes.com/markets/stocks/news/lupin-piramal-healthcare-in-race-for-stake-in-jb-chemicals/articleshow/69885287.cms
[21]https://health.economictimes.indiatimes.com/news/pharma/alembic-inks-jv-with-china-firms/69226620
[22]https://health.economictimes.indiatimes.com/news/pharma/medlife-acquires-myra-to-take-epharma-service-to-22-cities/69194020
[23]https://inc42.com/buzz/exclusive-epharma-startup-medlife-gets-17-mn-top-up/
[24]https://health.economictimes.indiatimes.com/news/pharma/zydus-cadila-inks-pact-with-italys-sifi-to-market-intraocular-lenses-in-india/69111149

Notes

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