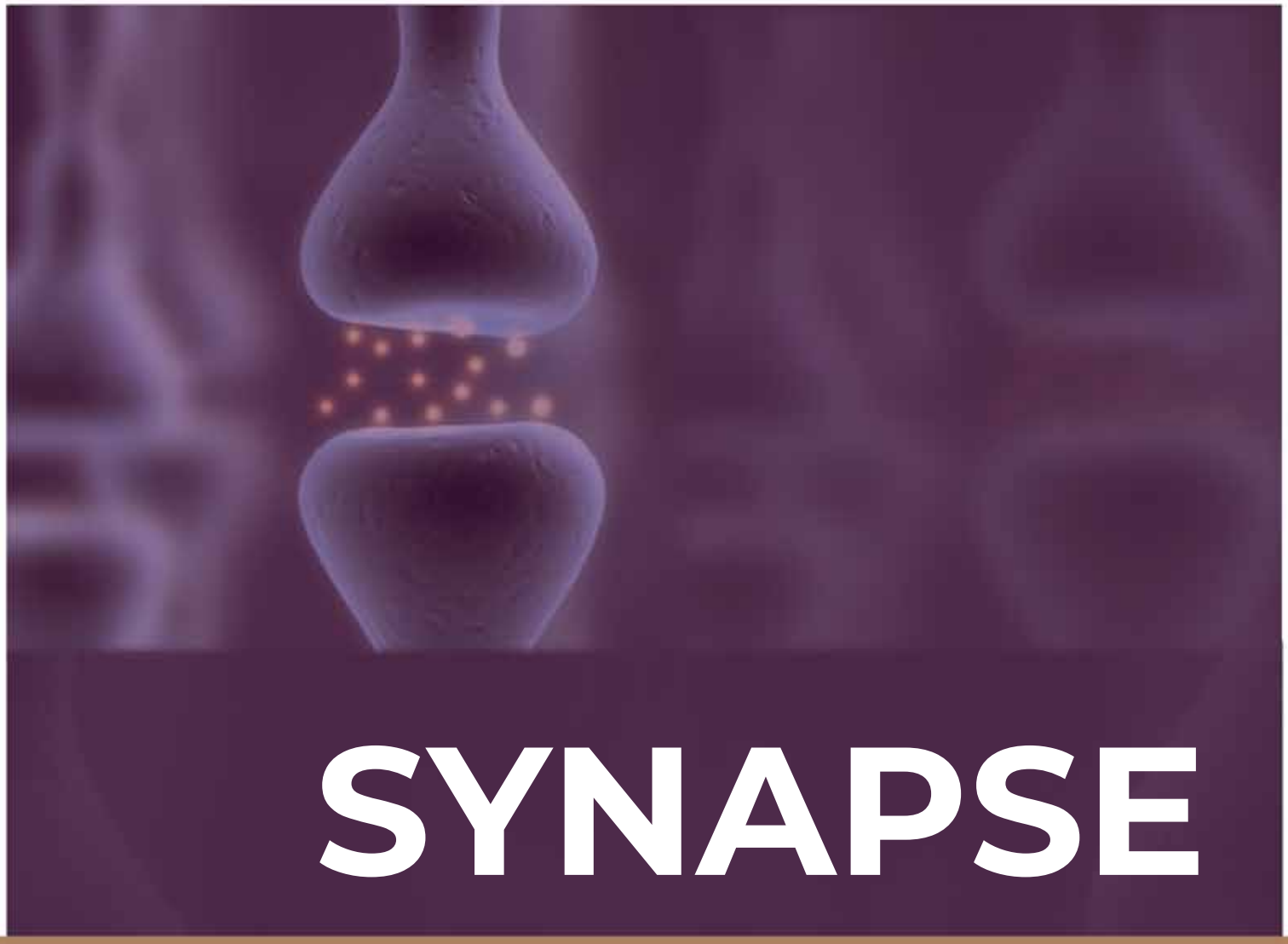

SYNAPSE

A Quarterly update on the Pharmaceutical Industry

Vol. III/Issue I/
January 01, 2019– March 31, 2019

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SYNAPSE

Dear Readers,

Greetings to all. A new year has commenced and it gives us immense pleasure to bring forth the latest issue of our quarterly pharmaceutical and healthcare practice newsletter - Synapse.

Cyril Amarchand Mangaldas, India's premier full-service law firm has an industry leading 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 continuously 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 continue to provide an update on the recent developments in the FDC Ban matter which, as our readers would recollect, we have been following closely in our past issues. We report on the New Drugs and Clinical Trials Rules, 2018 that have been introduced under the Drugs & Cosmetics Rules, 1945. There has been inclusion of eight new devices within notified medical devices. Recent developments and decisions by the Central Government to allow post-facto approvals of applications under the Biodiversity Act, 2002. This edition also reports on some sector specific litigation matters such as challenges to the bans on e-pharmacies, e-cigarettes and online sale of medicines, judgment by the Uttarakhand High Court regarding royalty sharing under Biodiversity Act,2002 to name a few. Some key deals/ transactions have also been reported in the current issue. This and more 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. If you have some additional news or information that you wish to share, please do not hesitate to connect with us.

With this in mind, we present to you Volume III Issue I of our Pharmaceutical and Life Sciences Newsletter Synapse. We hope you enjoy reading this newsletter as much as we have enjoyed creating it for you. Please feel free to send your comments, feedback and suggestions to cam.publications@cyrilshroff.com. We also encourage you to visit our blog at https://corporate.cyrilamarchandblogs.com for more articles.

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Vol. III/Issue I/
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REGULATORY UPDATES

1. New Drugs and Clinical Trials Rules, 2019 Notified

The Ministry of Health and Family Welfare ("MoHFW") vide gazette notification G.S.R. 227 (E)[1] dated March 19, 2019 has notified the New Drugs and Clinical Trials Rules, 2019 ("NDCT Rules"). The NDCT Rules replace Part XA and Schedule Y of the D&C Rules. Some of the key features of the NDCT Rules are as follows:

(a) Compensation and Medical Management

The NDCT Rules provide for compensation to be paid to the legal heir of the trial subject in case of death of the trial subject during a clinical trial or bioavailability or bioequivalence study and compensation to the trial subject in case of permanent disability or any other injury to the suffered by the trial subject. Further, in cases of injury, the sponsor is required to provide free medical management to a subject as long as required as per the opinion of the investigator or till such time it is established that the injury is not related to the clinical trial or bioavailability or bioequivalence study.

(b) Approval of Applications for Clinical Trials

Under NDCT Rules, the decision on permission to conduct clinical trial for a new drug or investigational new drug shall be given within 90 (ninety) working days by the Central Licensing Authority. However, in case the drug is discovered in India, research and development of the drug is being done in India and the drug is also proposed to be manufactured and marketed in India, the application for clinical trial of such drug shall be disposed within 30 (thirty) working days from the date of the receipt of the application.

(c) Waiver from Clinical Trial

Under the NDCT rules, the Central Licensing Authority has been given the power, with the with the approval of the Central Government, to specify the names of countries for waiver of local clinical trials for drugs already approved in those countries.

(d) Stem Cells as New Drugs.

Under the NDCT Rules, New Drugs have been defined to include Stem Cell based products, which shall always be deemed to be new drugs.

2. Prohibition of 80 Fixed Dose Combinations ("FDCs")

The MoHFW vide gazette notification nos. S.O. 180 (E)[2] through S.O. 259 (E) dated January 11, 2019 prohibited the manufacture for sale, sale and distribution of 80 (eighty) FDCs with immediate effect under Section 26A of the Drugs and Cosmetics Act, 1940 ("D&C Act"). No therapeutic justification was found for the ingredients used in these prohibited FDCs and it was found that they may involve risk to human beings.

As our readers would recollect, this set of 80 FDCs were banned by the Central Government pursuant to the recommendation of the DTAB to prohibit their manufacture and sale and were the subject of challenge before the Madras High Court by way of multiple writ petitions. These petitions had been transferred to the Supreme Court wherein the Hon'ble Court vide judgment in Union of India vs Pfizer Limited and Ors. on December 15, 2017 had accepted the recommendation for prohibition and withdrawal of these FDCs. Pursuant to this judgment, the Central Government has now proceeded to issue a fresh ban notification in regard to these 80 FDCs.

3. Draft Amendment to Medical Devices Rules, 2017.

The MoHFW vide gazette notification no. G.S.R. 87 (E)[3] dated February 4, 2019 has published the

[1] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDI2MQ==
[2] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzE3MA==
[3] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzY1Nw==

draft of amendments which the Central Government proposes to make to the Medical Devices testing laboratories of State Government and Central Government from the requirement of accreditation by the National Accreditation Board for Testing and Calibration Laboratories for a period of 2 (two) years from the date of commencement of the amendment. These draft rules were to be taken into consideration after the expiry of a period of 30 (thirty) days from the date on which the copies of the gazette containing these draft rules was made available to public. Objections and suggestion were also invited during this period for consideration by the Central Government.

4. Additional Medical Devices notified as 'Drugs'

The MoHFW vide gazette notification no. S.O. 775 (E)[4] dated February 8, 2019 (after consultation with the DTAB) notified the following devices intended for use in human beings as 'drugs', with effect from April 1,2020, namely:

(a) All Implantable Medical Devices.
(b) CT Scan Equipment.
(c) MRI Equipment.
(d) Defibrillators.
(e) Dialysis Machine.
(f) PET Equipment.
(g) X-Ray Machine.
(h) Bone Marrow Cell Separator.

5. DTAB reviewing and discussing provisions of law for compensation in case of faulty medical devices.

DTAB in its 81st meeting held on November 29, 2018[5], is currently reviewing and considering a proposal to amend Medical Device Rules, 2017 ("MD Rules"), to include provisions for compensation in case of injury or death attributed to malfunctioning of any medical device, any device found to be unsafe or not in compliance with the conditions of licence. The Board noted that in the current MD Rules, there is no provision for payment of compensation in such scenario. DTAB has recommended to constitute a Sub-Committee to examine the issue and to submit a report for further consideration of the Board.

6. Procedure for Regularisation of FDCs

CDSCO vide notification/ letter F. No. 04-146/2007-DC (Part- I)[6] dated February 27, 2019,has prescribed the procedure to be followed for regularisation of FDCs declared to be rational by the DTAB. As our readers would recollect, we had initially reported when the MOHFW had vide Letter File No. 4-01/2013-DC (Misc. 13-PSC) (Pt. II) dated 12.12.20183 communicated the new procedure for obtaining product licenses for FDCs declared as rational by Prof. Kokate Committee and approved by the DCGI from State Licensing Authorities ("SLAs"). In furtherance of this, the procedure for such regularisation of FDCs is as follows:

(a) The applicant shall submit Form 44 mentioning dosage form and strength along with treasury challan of INR 15,000 (Rupees Fifteen Thousand) for each FDC;

(b) Name and composition of FDC;

(c) Copy of product permission issued by state licensing authority ("SLA") to any form prior to November 28, 2017 as documentary evidence;

(d) Copy of manufacturing license in Form 25/ 28 and Form 29 for manufacturers who are not holding product permission from SLA and want to apply for these FDCs;

(e) Serial number of the FDC as per the list available on the website;

(f) Stability studies data (6 (six) months accelerated data of 3 (three) batches); and

[4]https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=Mzc3MA==
[5]https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadCommitteeFiles/dtab29nov18.pdf
6https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDExNg==

Test specifications of the FDC along with method of analysis. All manufacturers who are already holding licenses from SLAs for such FDC and did not obtain NOC from DCGI are required to submit their applications not later than 4 (four) months, failing which their applications will not be considered and their licenses will be considered as being without legal validity.

7. Amendments to the D&C Rules

(a) Information to be Uploaded by Licensees on Online Portal

The MoHFW vide gazette notification no. G.S.R. 19(E)[7] dated January 10, 2019 notified the Drugs and Cosmetics (Amendment) Rules, 2019. Through this amendment, a new Rule 84AB has been added to the D&C Rules. As per Rule 84AB, licensees granted licenses under Part VII of the D&C Rules (which deals with manufacture for sale or for distribution of drugs other than homoeopathic medicines) are required to register with the online portal, namely 'SUGAM' and upload information, as per the format provided in the said portal, pertaining to the licences granted for manufacture for sale or distribution of drugs.

(b) Additing of class of Drugs to Schedule K of D&C Rules

The MoHFW vide gazette notification no. G.S.R. 47(E)[8] dated January 25, 2019 notified the Drugs and Cosmetics (Third Amendment) Rules, 2019. Through this amendment, Schedule K contained in the D&C Rules has been expanded to include a new class of drugs namely, 'Sterile solutions intended for parenteral administration with 100 ml in one container of the finished dosage form for single use manufactured for export only'. These drugs have now been exempted from provisions of Chapter IV of the D&C Act and rules made thereunder which require them to obtain a licence in Form 28D or 28DA have been manufactured for export purpose only under a licence granted by the State Licensing Authority.

8. Draft Amendments to the D&C Rules

(a) Amendments to Conditions for Grant of Approval/ Permission

The MoHFW vide gazette notification no. G.S.R. 187(E)[9] dated March 6, 2019, has published a draft of amendments to the D&C Rules. The proposed amendments pertain to the conditions for grant of approval/ permission as contained in Form 45 (Permission to import Finished Formulation of the New Drug) and Form 46 (Permission / Approval for manufacture of new drug formulation). The conditions for grant of approval/ permission in these licenses require proper name of the drug to be printed or written in indelible ink and appearing in a more conspicuous manner than the trade name, if any, which shall be shown immediately after or under the proper name on the label of the innermost container of the drug or every other covering in which the container is packed. Further, there is a requirement for a conspicuous red vertical line on the left side running throughout the body of the label which shall not be less than 1 mm in width. However, the proposed amendment contemplates the proper name of the drug or fixed dose combination drug other than fixed dose combinations of vitamin and other fixed dose combinations containing three or more drugs, to be printed or written in a conspicuous manner which shall be at least two font size larger than the brand name or the trade name, if any, and in other cases the brand name or the trade name, if any, shall be written below or after the proper name on the label of the innermost container of the drug or every other covering in which the container is packed. Further, instead of just a red vertical line, the proposed amendment contemplates a

[7]https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzEzOA== w
[8]https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzQxNQ==
[9]https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDE0Ng==

caution or warning, in legible black coloured font size in a completely red rectangular box.

These draft rules were to be taken up for consideration after the expiry of a period of 10 (ten) days from the date on which the copies of the gazette containing these draft rules was made available to public. Objections and suggestions were also invited during this period for consideration by the Central Government.

(b) Undertaking Regarding Brand Name

The MoHFW vide gazette notification no. G.S.R. 152(E)[10] dated February 26, 2019, has published a draft of amendments to the D&C Rules. These draft rules contemplate insertion of a sub rule in Rules 71, 71A, 71B, 76 and 76A of the D&C Rules which would require applicants to furnish an undertaking to the licensing authority in case they intend to market a drug under a brand name or a tradename.The undertaking shall be to the effect that such or similar brand name or trade name is not already in existence so that the brand name or the trade name to be used by the applicant shall not lead to any confusion or deception in the market.

These draft rules were to be taken up for consideration after the expiry of a period of 45 (forty five) days from the date on which the copies of the gazette containing these draft rules was made available to public. Objections and suggestion were also invited during this period for consideration by the Central Government.

9. Suggestion and Comments Invited on Man power Norms for Blood Banks

The Central Drugs Standard Control Organization ("CDSCO") vide a public notice F. No. 18-85/2018-DC[11], dated January 10, 2019 invited suggestions and comments on the recommendations of the Expert Working Group constituted by the National Blood Transfusion Council ("NBTC") on inclusion of minimum manpower requirements for blood banks in the Drugs and Cosmetics Rules, 1945 ("D&C Rules").

The NBTC had proposed the staffing pattern and numbers of staff required for blood centres, outdoor blood donation camps / blood mobile van collection, blood component separation and aphaeresis. In view of the same, all stakeholders were requested by the CDSCO to send their comments and suggestions within 21 (twenty one) days of the notice being issued.

10. Draft Amendments to the Biodiversity Act

Background of Act:

It is important for our readers to note that, as per Section 3 of the BD Act, any person who is (i) a non-citizen or (ii) a citizen but non-resident or (iii) a body corporate in India having non-Indian participation participation (i.e., shareholding from entities/ individuals who are non-citizens, or a non-residents, or body corporates not incorporated or registered in India) required to obtain prior approval from National Biodiversity Authority ("NBA") for accessing any biological resources occurring in India or knowledge associated thereto for the purpose of research or for commercial utilization or for bio-survey and bio-utilization.

Further, as per Section 7 of the BD Act, any person who is (i) a citizen of India or (ii) body corporate or organization registered in India without any non-Indian participation is required to intimate the State Biodiversity Authority ("SBA") prior to accessing biological resources in Indiafor the purpose of commercial utilization, or bio-survey and bio-utilization for commercial utilization.

Currently, the BD Act does not allow post-facto approval or regularization of past violations regarding access of biological resources for commercial utilization or for bio-survey and bio-utilization.

[10]https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDExNw==
[11]https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzEzNg==

Recent Update:

Owing to lack of clarity in the interpretation of certain definitions such as "biological resources", "commercial utilization" and "value added products", lack of clarity in application procedure, lack of awareness, lack of institutional enforcement of the BD Act and fear of prosecution; adherence to provisions of the BD Act has been less than expected. As a matter of fact, till date, only 2507 applications have been received by the NBA for approval and only 162 applications have been accorded approval. The authorities have increased prosecution for noncompliance and have been sending show cause notices to entities in this regard.

In order to facilitate and enhance implementation of the BD Act, and in the interest of meeting the objectives of the BD Act, the Central Government by exercising its powers under Section 48 of the BD Act has issued an Office Memorandum bearing number F.N.C-12025/8/15-CS-III on September 10, 2018 ("Office Memorandum 2018"). Salient features of the Office Memorandum 2018 are as follows:

i. An application for approval can be made by the person/entity for the acts occurred in the past (i.e. July 1, 2004 onwards), where prior approval was required to be obtained but not obtained by the person/entity.

ii. The application made under Office Memorandum 2018 shall be reviewed on merits and an approval shall be provided for those cases which otherwise have been approved if the application was made in time.

iii. All applications for approval for the past 14 years i.e. since July 01, 2004 till date would be considered by the authority for approval during such period.

iv. It provided for a window of 100 (hundred) days from the date of issuance of the Office Memorandum 2018 for the authority to review and provide approval. The last date for such window was December 18, 2018.

Further, in public interest towards meeting the objectives of the BD Act, the Central Government by exercising the powers under Section 48 of the BD Act has issued another Office Memorandum bearing number F.N.C-12027/6/19-CS-III on March 18, 2019 ("Office Memorandum 2019") extending the date of compliance till 60 days from date of issuance of Office Memorandum 2019 i.e. May 17, 2019.

Major Litigations & Important Judgements

1. Sale of Medicines through online Pharmacies

The Central Government had, vide Gazette Notification No. G.S.R. 817(E) dated 28.08.2018 released and notified the Draft E-Pharmacy Rules ("E-Pharmacy Draft Rules") which sought to amend the Drugs and Cosmetics Rules, 1945 by inclusion of a specific chapter that pertains to regulation of E-Pharmacies in India. The said notification was published for information of all affected persons and further noted that the said draft rules would be taken into consideration on or after the expiry of a period of forty-five days from the date on which copies of the Gazette of India containing these draft rules are made available to the public.

Proceedings before High Courts.

i. Delhi High Court

A Public Interest Litigation was filed by petitioner Dr. Zaheer Ahmed which came up for hearing before Court No. 1 of the Hon'ble Delhi High Court as W.P.(C) 11711/2018. It was contended before the Hon'ble Court that there was no statutory control over the sale of medicines and further that such sale was in violation of the Drugs and Cosmetics Act, 1940. On 12.12.2018, the Hon'ble Court injuncted the Respondents-Union of India from allowing online sale of medicines without a valid licence. The UOI was directed to ensure that online sale of drugs without a valid license is prohibited until any further orders. This interim stay was further renewed by the Delhi High Court vide Order dated 8.01.2019 and is continuing till date. Meanwhile the Court has asked the Union of India to indicate what steps have been taken by them for formulating the Draft Rules which were released on 28.8.2018 vide G.S.R. 817(E). The matter is currently pending.

ii. Madras High Court

a. Proceedings before Ld. Single Judge

The Hon'ble High Court of Madras in W.P 28716/2018 filed by the Tamil Nadu Chemists and Druggists Association, was pleased to observe that it is necessary for the Central Government to notify the said rules in the interest of the public and online trade. The Hon'ble Court was further pleased to issue directions to the Central Government and the CDSCO to notify the said Draft Rules at the earliest and no later than January 31st, 2019.

b. Proceedings before Division Bench.

Thereafter, the matter came up in appeal before a division bench of the High Court of Madras in CMP No. 23341-23435 in W.A. No.s 2807-2818 wherein the Hon'ble Court on 2.01.2019 stayed the ban on the online sale of e-medicines, until further orders, however, the court did not pronounce on the merits of the case. These interim directions regarding the suspension of the ban are still in place, absent any direction to the contrary from the Hon'ble court.

Note: The afore-mentioned E-Pharmacy Rules are still in draft form and have not been notified as law by the government till date.

2. Divya Pharmacy v. Union of India and others- High Court of Uttarakhand at Nainital Writ Petition (M/S) No. 3437 of 2016.

The Writ Petition was filed by Divya Pharmacy, a company registered in India ("Petitioner") against the Uttarakhand State Biodiversity Board ("Respondent"), challenging the demand letter of the Respondent under ("Fair and Equitable

Equitable Benefit Sharing" ("FEBS") provisions of the Biodiversity Act, 2002 ("BD Act") and Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014 ("Regulations"). The demand letter was raised by the Respondent against the Petitioner for using "Biological Resources" that constitute the main ingredients and raw materials in the manufacture of Ayurvedic and Nutraceutical products manufactured by the Petitioner.

The Hon'ble Court dismissed the Petition and held that the under Section 7 and Section 23 of the BD Act, the SBB has the requisite powers to demand fair and equitable sharing from the Petitioner. The Court held that the Regulation only clarifies and follows what is there in the BD Act and it is intra vires the BD Act. The Court observed that the concept of FEBS is focused on the benefits for the "local and indigenous communities", and further that the Nagoya Protocol makes no distinction between a foreign entity and an Indian entity, as regards their obligation towards local and indigenous communities in this regard. The rights of "indigenous and local communities" were extremely important and emphatically declared in the Nagoya Protocol. These rights have to be protected, equally from outside as well as from within. The Court also observed that the BD Act makes a distinction between a "foreign entity" and a "domestic entity", as far as FEBS is concerned.

3. **Delhi High court sets aside ban on e-cigarettes and vaping devices. Litejoy International Pvt Ltd. and Ors. Vs. Union of India and Ors. W.P.(C) 2351/2019.**

The Central Government had issued a notification dated 22.02.2019 requesting the State licensing authorities to ensure that 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, are not sold (including online sale), manufactured distributed, traded, imported and advertised in their jurisdictions. This was challenged by various manufacturers before the Delhi High court by way of writ petitions. The Central government further issued a circular on 27.11.2018 to the customs authorities to request implementation of the previous notification and ensure that import of consignments involving ENDS is carried out in accordance with the D&C Act and Rules only.

On March 18, 2019, the Delhi High court stayed the ban and circular, recording a finding that on a prima facie view, it does not appear that the said devices are covered under the ambit of the D&C Act that the devices in question are neither sold as therapeutic devices, nor as medicines for internal or external use of human beings, or animals intended to be used for in the diagnosis treatment of any disease, as required under the definition of 'drug' under section 3(b) of the D&C Act.

The Ld. Single Judge further noted that during the 48th meeting of Drugs Consultative Committee constituted under Section 7 of the D&C Act, held on 24.07.2015, the committee expressly noted that E-cigarettes are not covered under the definition of the term 'drug' and therefore do not come under the purview of regulation under the D&C Act.

Therefore, since all the ENDS devices are outside the purview of the D&C Act, the Central government did not have the jurisdiction to ban their manufacture, sale, distribution and advertisement and the ban was accordingly stayed. The matter is now listed for hearing on 17.05.2019.

It is pertinent to mention here that a public interest litigation[12] was previously filed in the matter challenging the lack of regulation of ENDS devices

[12] W.P.(C) 10624/2017 'Seema Sehgal vs. Union of India & Ors.'.

which came up before the Division bench of the Delhi High court on 13.03.2019 where the prayer was limited to the extent of non-action of the Union of India. The Division Bench stated that post such regulatory measures being taken by the government, a grievance against such action itself was a separate cause of action different from the prayer of the PIL and should be taken up on merits before the Ld. Single judge seized of the matter. The matter was accordingly taken up before the Ld. Single judge on 18.03.2019 wherein the ban was stayed.

Major Deals

1. Bain, Piramal-led fund to infuse Rs 992 crore in Panacea Biotec Ltd.

A joint venture of Bain Capital Credit and Piramal Enterprises Ltd, namely India Resurgence Fund is set to invest up to $144 million or Rs 992 crore in Panacea Biotec Ltd[13], a New Delhi-based listed pharmaceutical and bio-technology Company. Pursuant to this, subject to exercise of warrants, the afore-mentioned fund and its affiliates will collectively own 10.4 percent of the company on a fully diluted basis. Panacea Biotec had earlier reported a loss of Rs 71.88 crore in the financial year 2017-18 based on a revenue of Rs 579.93 crore and this investment will be used for a one-time settlement with existing lenders, working capital and growth requirements[14].

2. NetMeds acquired health start-up KiVi health.

Popular e-pharmacy NetMeds, has recently acquired the health and technology start-up, KiViHealth, which is essentially a clinic management platform and digital health information system with a proprietary digital prescription tool that allows doctors to generate digital prescriptions, founded in 2015 by Indian School of Business (ISB) alumni Bhanu Mahajan and Rajandeep Singh[15]. KiVi Health is said to manage over 2 million patient records and provides services to more than 2,000 doctors through its website and mobile application. [16]Netmeds is reportedly set to invest close to $10 million for the growth and integration of the health start-up.

It is pertinent to note here that the requirement of a digital prescription by a doctor to buy medicines online, is in line with the legal requirements laid down by the draft e-pharmacy rules which are yet to be notified by the Central Government. As reported in the litigation section of this issue, the Delhi High Court has currently stayed the operation of e-pharmacies, while the Madras High court has withdrawn such ban till further orders in this regard. We will keep our readers regularly updated in the matter with regard to any further developments in the matter.

3. General Atlantic invests in Mumbai based Rubicon Research.

US based Growth equity firm General Atlantic has acquired a significant stake in Mumbai based drug delivery technology company Rubicon Research reportedly for up to USD 100 million[17]. Rubicon was founded in 2000 in India acts as an outsourcing partner for global pharmaceutical firms and provides solutions for bioavailability enhancement, gastric retention, taste masking, and customizing the release profiles of drugs. They make speciality and branded generics products as well as over-the-counter products.[18]Rubicon is looking to increase its manufacturing footprint globally and this strategic investment will go a long way in its research efforts to bring innovative medicines and drug delivery technologies into the market. [19]

This transaction comes in the wake of private equity firm Everstone Capital agreeing to exit Rubicon Research by selling its controlling stake to General Atlantic. It has been reported that all other existing shareholders continue to maintain their shareholding in the company.

[13] //economictimes.indiatimes.com/articleshow/68783259.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst
[14] https://www.vccircle.com/bain-piramal-fund-invests-144-mn-in-panacea-biotec/
[15]http://timesofindia.indiatimes.com/articleshow/68554096.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst [16]//economictimes.indiatimes.com/articleshow/68558448.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst
[17]https://www.financialexpress.com/industry/general-atlantic-acquires-significant-shareholding-in-rubicon-research/1542230/.
[18]https://www.vccircle.com/everstone-scores-one-of-its-best-exits-as-general-atlantic-strikes-a-control-deal/.
[19]https://www.business-standard.com/article/pti-stories/general-atlantic-acquires-significant-stake-in-rubicon-research-119040800881_1.html.

4. Radiant Life-Care acquired control of Max Hospitals.

Radiant Life Care Pvt. Ltd which manages and operates multiple health care facilities and super-speciality hospitals, being backed by private equity firm KKR and Co., has agreed to acquire control of Max Healthcare Institute Ltd. [20]Pursuant to the transaction, the resultant combined entity will be India's third-largest hospital chain by revenue. The merged entity will operate more than 3,200 beds through 16 hospitals across India and will also be the fourth-largest by capacity.[21]

The acquisition will be undertaken through a series of transactions, including Radiant's purchase of a 49.7% stake in Max Healthcare from South Africa based hospital operator Life Healthcare in an all cash deal. This will be followed by a de-merger of Radiant's healthcare assets into Max Health-care which will result in KKR and Radiant promoters together acquiring a majority stake in Max Healthcare. [22] The combined business is expected to create the largest hospital network in North India and further provide significant growth potential and compelling business synergies.

5. Bristol Myers Squibb to acquire Celgene for 74 billion USD.

Bristol-Myers Squibb, a leading global pharma ceutical company, and Celgene Corporation have announced a merger agreement under which Bristol-Myers Squibb will acquire Celgene in a cash and stock transaction with an equity value of approximately $74 billion. Under the terms of the agreement, Celgene shareholders will receive 1.0 Bristol-Myers Squibb share and $50.00 in cash for each share of Celgene. [23] The transaction will create a focused specialty biopharma company to specifically address the drug product needs of patients with cancer, inflammatory and immunologic disease and cardiovascular disease through innovative medicines and scientific capabilities. The combined company is projected to have close to nine products with more than 1 billion USD in annual sales and further significant potential for growth in the core disease areas of oncology, immunology and inflammation and cardiovascular disease. The transaction has subsequently been approved by Bristol-Myers Squibb and Celgene shareholders and is expected to be completed in the third quarter of 2019.[24]

[20]http://www.radiantlifecare.com/.
[21]https://www.livemint.com/Home-Page/xnre4vAPsGR06XMNBKY2IL/Max-India-to-sell-stake-in-Max-Healthcare-to-Radiant-KKR.html.
[22]//economictimes.indiatimes.com/articleshow/67228958.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst.
[23]https://news.bms.com/press-release/corporatefinancial-news/bristol-myers-squibb-acquire-celgene-create-premier-innovative
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