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Dear Readers,

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 shed light on the recent development in the FDC Ban matter which we have been following closely, new rules introduced under the Drugs & Cosmetics Act, 1940 with regard to regulation of cosmetics, notification of four new medical devices within notified medical devices, amongst other key regulatory changes. This edition also reports on some interesting litigation matters such as the ban on e-pharmacies, the setting aside of the Oxytocin ban, the judgement of the Hon'ble Supreme Court on medical negligence to name a few. Some key transactions have also been reported. We have tried to cover everything that has happened in the quarter that has gone by. 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. 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 II Issue III 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](mailto:cam.publications@cyrilshroff.com). We also encourage you to visit our blog at <https://corporate.cyrilamarchandblogs.com> for more articles.

Regards,

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## I. REGULATORY UPDATES

### 1. FDC Ban Update

#### (a) 328 FDCs (Re) Banned

Pursuant to the judgement of Hon'ble Supreme Court, FDC's that were subject matter of a large scale ban back in 2016 were sent to the Drugs Technical Advisory Board ("DTAB"). The DTAB conducted its review and gave its suggestions to the Central Government on the matter in the form of a detailed report. Acting on this report, the manufacture, sale/distribution of 328 Fixed Dose Combinations ("FDCs") was prohibited by the Central Government *vide* notification nos. S.O. 4379 (E) to S.O. 4706 (E) dated 7.9.2018. The DTAB opined that these FDCs do not have any therapeutic justification for the ingredients and/or these FDCs may pose risks to human health. In light of this development, the Central Drug Standard Control Organization ("CDSCO") *vide* F.No.04-01/2013-DC (Misc-13-PSC) Part-II dated 14.09.2018 directed all the State/Union Territory Drug Controllers to direct the concerned manufacturers, distributors and wholesaler/retailers to stop the production with immediate effect. We have captured this in detail in the *litigation update* section of this issue.

#### (b) Data Inadequate to Prove Rationality

According to the recommendations of the DTAB, there were 17 FDCs for which data provided by the manufacturer was considered *inadequate* to prove its rationality, safety & efficacy. CDSCO *vide* letter F. No. 04-146/2007-DC dated 12.12.2018<sup>1</sup> requested all the State/UT Drugs Controllers to direct all concerned manufacturers of the above mentioned 17 FDCs, under their jurisdiction, to submit the information/data in the prescribed format in hard copy as well as soft copy (i.e. in CD form) by 28.02.2019. In case of non-submission of data, CDSCO may make its decision on the basis of information available before it in light of the judgement of the Hon'ble Supreme Court in *Union of India v. Pfizer*<sup>2</sup> dated 15.12.2017

#### (c) New Procedure to Obtain Product License for Rational FDCs

The Ministry of Health and Family Welfare ("MoHFW") has *vide* Letter File No. 4-01/2013-DC (Misc. 13-PSC) (Pt. II) dated 12.12.2018<sup>3</sup> communicated the new procedure for obtaining the product license applicable only with respect to FDCs declared as rational by Prof. Kokate Committee and approved by Drugs Controller General of India ("DCGI") from State Licensing Authorities ("SLAs"). Currently, for such FDCs the government has issued an NOC in respect of the applicants under an *18 months* policy decision.<sup>4</sup> Initially, for grant of NOCs to such subsequent applicants, the applications were processed as per the procedure suggested in letters dated 16.3.2017 and 5.6.2017.<sup>5</sup>

The new application procedure includes submission of a TR-6 challan of INR 15,000/- to the CDSCO along with the SLA as per the provisions of Drugs and Cosmetics Rules, ("D&C Rules"). Additionally, details of the FDC, serial no. on the list, stability studies data (3 months accelerated), test specification with Method of Analysis as well as Label and other documents must be provided. The SLA will grant product license as per D&C Rules.

#### (d) Further Requirement of Data for Safety and Efficacy

*Vide* notification/ letter F. No. 04-146/2007-DC dated 12.12.2018,<sup>6</sup> the manufacturers of the 49 FDCs requiring further generation of data in terms of safety and efficacy by conducting clinical trial according to the recommendations of DTAB have been requested to submit the Clinical Trial protocol/PMS data for obtaining NOC from DCGI for further generation of data in terms of safety and efficacy. The study protocols are required to be submitted in hard copy as well as soft copy (i.e. in CD form) latest by 01.04.2019. In case of non-submission, the CDSCO is likely to take its decision on the basis of information available before it in light of the judgement of the Hon'ble Supreme Court.

1. [https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=MjI0MQ==](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MjI0MQ==)  
(2018) 2 SCC 39.

3. [https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=MjIzOQ==](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MjIzOQ==)

4. [https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=MjIzNg==](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MjIzNg==)

5. [http://www.cdsco.nic.in/writereaddata/noticefdc5\\_6\\_2017.pdf](http://www.cdsco.nic.in/writereaddata/noticefdc5_6_2017.pdf)

6. [https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=MjI0MA==](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MjI0MA==)

## 2. Devices Classified as ‘Drugs’ under Drugs and Cosmetics Act, 1940 (“D&C Act”)

The MoHFW *vide* notification S.O. 5980(E)<sup>7</sup> dated 3.12.2018 (after consultation with the DTAB) specified the following devices intended for use in human beings as ‘drugs’ with effect from the 1.1.2020, namely:-

- (a) Nebulizer;
- (b) Blood Pressure Monitoring Devices;
- (c) Digital Thermometer; and
- (d) Glucometer.

## 3. Draft Guidelines on Good Distribution Practices for Pharmaceutical Products.

CDSCO released the draft Guidelines on Good Distribution Practices of Pharmaceutical Products (“the Guidelines”) *vide* Notice File No: 15-14/2018-DC dated 25.9.2018<sup>8</sup> with the intent to maintain the quality of the pharmaceutical products for which adequate control over the chain of distribution is required to be maintained. More specifically, the Guidelines seek to ensure the quality and identity of pharmaceutical products during all aspects of the distribution process including procurement, purchasing, storage, distribution, transportation, documentation and record-keeping practices.

The Guidelines would be applicable to all persons and outlets involved in any stage of the storage and distribution of pharmaceutical products which would encompass all entities involved in trade and distribution of pharmaceutical, including the manufacturers of bulk, finished products, wholesalers, as well as others such as suppliers, distributors, Government institutions, international procurement organization, donor agencies and certifying bodies, logistics providers, traders, transport companies and forwarding agents and their employees as well as health workers. For biological products, these Guidelines would be applicable in addition to the Guidelines on Good Distribution Practices for Biological Products.<sup>9</sup>

## 4. D&C Rules Amendment Act, 2018: Increase in Application Fee for Import Licenses

The Central Government has amended the D&C Rules *vide* Drugs and Cosmetics (Amendment) Rules, 2018 (“**2018 Amendment**”) G.S.R.1193(E) dated 12.12.2018<sup>10</sup> with immediate effect to increase the application fees for grant of various import licences, registration certificates for Drugs and Cosmetics and permission for import of New Drugs and Fixed Dose Combinations under the Rules. The following changes have been brought into effect by the 2018 Amendment:

TYPE OF LICENSE	RULE	OLD FEE	NEW FEE
Import License (Form 8)	24(1)	INR 1000	INR 10000
Form 8 Additional Drug	24	INR 100	INR 1000
Form 8 Duplicate Copy	24(3)	INR 250	INR 1500
Registration Certificate (“RC”) (Form 40) for each site	24A	USD 1500	USD 10000
Form 40 Additional Drug	24A	USD 1000	USD 5000
Inspection Fee for Visit of Manufacturing Site	24A(5)	USD 5000	USD 25000
Duplicate Copy of RC	24A(7)	USD 300	USD 1800
License for Examination, Test, Analysis (Form 12)	34(3)	INR 100	INR 5000
Form 12 Additional Drug	34(3)	INR 50	INR 2000
Form 44 Import of New Drug	122A (1)	INR 50000	INR 250000
Form 44 Subsequent Application	122A (1)	INR 15000	INR 100000
Form 44 Import FDCs	122D	INR 15000	INR 100000
RC for Cosmetics Form 42	129A	USD 250 for each brand	USD 2000 for each brand of cosmetic and a fee of USD 50 for each variant

<sup>7</sup> [https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=MzE0Mw==](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzE0Mw==)

<sup>8</sup> [https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=MTk3MA==](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTk3MA==)

<sup>9</sup> <http://www.cdsco.nic.in/writereaddata/GUIDELINES%20GDP.pdf>

<sup>10</sup> [https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=MjM1MQ==](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MjM1MQ==)

All applications covered under the 2018 Amendment received on or after 12.12.2018 are required to be accompanied by the increased fees in accordance with the revised fee prescribed by the 2018 Amendment.

## 5. Safety Guidelines for Isotretinoin

Reacting to concerns relating to the safety of Isotretinoin, an orally administered drug used to treat severe acne, the CDSCO *vide* Letter F.No.12-01/18-DC (PT-238) dated 19.12.2018<sup>11</sup> issued safety guidelines in respect of the use of the same.

Manufacturers have been directed to observe the following:

- (a) Label should contain the following warning:

'The drug should be sold by retail on the prescription of Dermatologists only.'

- (b) Pack of the drug should carry following Box warning-

'This medicine may cause severe birth defects. You must not take this medicine if you are pregnant or may likely become pregnant during treatment. You should also avoid pregnancy for 6 months after stopping the treatment.'

- (c) The patients must sign a consent form before undertaking the treatment of Isotretinoin as per the format enclosed.
- (d) Manufacturer should provide package insert along with their product which should be in major vernacular languages.

Retailers on the other hand have been directed to sell by retail only on prescription of a Dermatologist and have also been advised to maintain details of such sales in accordance with the provisions of the D&C Rules.

## 6. Kerala Clinical Establishments (Registration and Regulation) Act, 2018

The Kerala Clinical Establishments (Registration and Regulation) Act, 2018 ("**Kerala Act**")<sup>12</sup> will

come into effect from 1.1.2019. Under the Kerala Act, health establishments in Kerala will be registered on an online portal which can be accessed by patients to inquire about the cost of medical treatments and will also enable them to compare the medical facilities provided by each hospital.

The definition of *clinical establishments* (Section 2 (c)) under the Kerala Act is as wide as the definition of 'clinical establishments' under the Clinical Establishments (Registration and Regulation) Act, 2010. Section 16 of the Kerala Act prohibits any person from running a clinical establishment unless it has been duly registered in accordance with the provisions of the Kerala Act. Section 15 lays down the conditions for license which include furnishing the information as may be notified by the State government from time to time. The Kerala Act also has penal provisions, section 26 and 27, which prescribe a penalty of up to INR 500000 (Five Lacs) for contravention of the provisions of this Act and for non-registration.

According to news reports, implementation of this would begin with three districts, Palakkad, Thrissur and Malappuram.<sup>13</sup>

## 7. DPCO Amendment Order, 2019 ("the 2019 Order")

The Ministry of Chemicals and Fertilisers ("**MoCF**") has *vide* order S.O. 39(E) dated 3.1.2019<sup>14</sup> amended the Drug Price Control Order, 2013 ("**DPCO 2013**"), which governs price fixation of scheduled formulations and monitors maximum retail prices of all drugs, including the non-scheduled formulations. The 2019 Order makes the following amendments:

### (a) Source of Market-Based Data

Para 9(A)(1) of the DPCO 2013 has been amended to state that the source of market-based data shall be the data available with the pharmaceutical market data specialising company, which was earlier specified as IMS Health, as decided by the government, and if the government deems it necessary, it may validate such data by appropriate survey or evaluation. A new subsection Para 9(A)(7) has been inserted which states that for fixing or

<sup>11</sup> [https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=MjQxOQ==](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MjQxOQ==)

<sup>12</sup> [https://kerala.gov.in/documents/10180/59470/Law%20\(Legislation%20-%20H\)%20Department%20-%20Notification%20-%20ACT%202020OF%202018%20-%20THE%20KERALA%20CLINICAL%20ESTABLISHMENTS%20\(REGISTRATION%20AND%20REGULATION\)%20ACT.%202018%20-%20No.%2011935-Leg.H1-2017-Law?version=1.0&t=1533026372000](https://kerala.gov.in/documents/10180/59470/Law%20(Legislation%20-%20H)%20Department%20-%20Notification%20-%20ACT%202020OF%202018%20-%20THE%20KERALA%20CLINICAL%20ESTABLISHMENTS%20(REGISTRATION%20AND%20REGULATION)%20ACT.%202018%20-%20No.%2011935-Leg.H1-2017-Law?version=1.0&t=1533026372000)

<sup>13</sup> <https://www.thenewsminute.com/article/kerala-govt-mandates-online-registration-health-institutions-jan-1-94104>

<sup>14</sup> [http://pharmaceuticals.gov.in/sites/default/files/Gazette%20Notification\\_DPCO.pdf](http://pharmaceuticals.gov.in/sites/default/files/Gazette%20Notification_DPCO.pdf)

revising the ceiling price for formulations, the government may, if it is necessary so to do, consider market based data available for any month, as deemed fit.

#### **(b) Exemption from Application of DPCO, 2013**

Paragraph 32(i) of the DPCO 2013, which pertains to exemptions granted to certain drugs from price control, has been amended to exclude from price control, new drugs patented under the Indian Patents Act, 1970 for a period of five years from the date of commencement of commercial marketing of such patent drug by the manufacturer in the country. Further, drugs for treating orphan diseases as decided by MoHFW have also been exempted from the application of DPCO, 2013 by addition of Paragraph 32 (iv) to DPCO, 2013.



### **8. Advertising of Ayurvedic Drugs (Including Siddha And Unani) Restricted**

In an attempt to curb the misleading advertisements, the Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (“AYUSH”) *vide* notification G.S.R. 1230(E) notified the D&C (Eleventh Amendment) Rules on 21.12.2018 introducing regulation on advertisements of Ayurvedic, Unani and Siddha drugs. The amendment adds Rule 170 to the D&C Rules which prohibits publication of any advertisement relating to any drug for the use of diagnosis, cure, mitigation, treatment or prevention of any disease, disorder, syndrome or condition by a manufacturer or his agent, of Ayurvedic, Siddha or Unani drugs.

Rule 170 also lays down the requirement of a Unique Identification Number (“UIN”) for advertising any Ayurvedic, Siddha or Unani drug for other purposes. Manufacturers of Ayurvedic,

Siddha or Unani drugs need to apply to the State Licensing Authority for such UIN for the advertisement issued or aired before the said notification, within a period of three months from the date of publication of this notification.

The application for advertisement can be rejected in the following cases if it is incomplete; or the intended advertisement does not contain contact details of the manufacturer; or the contents of the advertisement directly or indirectly tantamount to vulgarity or obscenity; or it refers to any Ayurvedic, Siddha or Unani drug in terms which suggest or calculated to lead to the use of that drug or medicine for the enhancement of height and dimensions or capacity of performance of male or female sexual organs; or it depicts photographs or testimonials of celebrities or government officials; or it refers to any government or autonomous organization of the government; or it gives a false impression about the true character of Ayurvedic, Siddha or Unani drug; or if it makes a misleading or exaggerated claim about the effectiveness of the said drug.

Existing advertisements, which do not fall in the prohibited category, need to apply for the UIN before 21.04.2019. The State Licensing Authority has been granted the power to suspend or cancel manufacturing licenses of violators.<sup>15</sup>

### **9. Draft Cosmetics Rules, 2018**

The MoHFW *vide* gazette notification no. G.S.R. 1153 (E) dated 29.11.2018 released the Draft Cosmetics Rules, 2018 (“**Draft Rules**”). This move has been taken with the intent to cure gaps in the current regulatory framework of cosmetics and increase accountability of manufacturers and importers. The Draft Rules will be applicable to the cosmetics as defined in clause (aaa) of the section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940).

Some of the key features of the Draft rules have been covered as follows:

#### **(a) Regulatory Authority**

DCGI will be responsible for enforcement of rules pertaining to the import of cosmetics and grant of approval to test laboratories that apply for testing cosmetics and their raw materials under Rule 57. The role of the Central Licensing Authority (“**CLA**”) would be

<sup>15</sup> <http://www.millenniumpost.in/kolkata/centre-to-impose-restrictions-on-ads-by-agents-of-ayurvedic-sidha-or-unani-drugs-335147>

limited to co-ordinating with the State licensing Authorities (“SLAs”) in enforcement of these rules. SLAs will be responsible for regulation of manufacture, sale, stock, exhibit or offer for sale or distribution of all categories of cosmetics.

**(b) License to Manufacture**

Application for grant of a licence or loan licence to manufacture for sale or for distribution can be made to the SLA through an online portal/offline in Form COS-5 for licence or in Form COS-6 for loan licence accompanied with a fee. No license can be granted for a new cosmetic<sup>16</sup> without the prior permission from the CLA.

**(c) Record of Manufacture to be Maintained**

The Draft Rules mandate maintenance of records of details of every batch of cosmetics and raw materials used by the manufacturer for a period of three years after the date of expiry of such batch.

**(d) BIS Standard Compliance**

If a cosmetic is of Indian origin, it must be labelled and packed in accordance with standards prescribed by the Bureau of Indian Standards (“BIS”).

**(e) Prohibitions**

The Draft Rules prohibit the import of cosmetics whose manufacture, sale or distribution is prohibited in their country of origin, cosmetics which do not have the “use before or use by” date displayed on the label, cosmetics containing hexachlorophene, and cosmetics which have been tested on animals after 13.10.2014. Small quantities of cosmetics the import of which is prohibited under section 10 of the D&C Act, can be imported for personal use.<sup>17</sup>

**10. Standard Operating Procedures (“SOPs”) for Food Safety Officers (“FSOs”) to monitor compliance with Food Safety and Standards (Organic Foods) Regulations, 2017**

The Food Safety and Standards Authority of India (“FSSAI”), has released a set of SOPs for its

FSOs, to monitor compliance with the Food Safety and Standards (Organic Foods) Regulations, 2017 (“Organic Food Regulations”). The SOPs are aimed at serving as guidance points for the FSOs for inspection of organic products and traceability related documents.

These SOPs have listed out provisions (with which any food offered or promoted for sale as ‘organic food’) is required to comply with under regulation 4 of the Organic Food Regulations. Additionally, the requirement for labelling, sampling and analysis of organic foods have been specified. The SOPs also list out the checks that may be conducted at the ‘retailer end’ such as *inter alia* the check for traceability through purchase records to ensure that products have been purchased from a certified manufacturer or processor or a *bona fide* distributor, checks for compliance at ‘manufacturer, processor, handler/ packer end’, and checks for ‘import of organic food products’.

The SOPs would serve as a guidance note in carrying out their functions under the Food Safety and Standards Act, 2006, the Organic Food Regulations and other relevant regulations. Since these SOPs have listed out the compliances that the FSOs would be checking for, other entities such as manufacturers, processors and retailers may also use them as a reference point to ensure compliance at their end and limit the chances of FSOs making adverse findings against them.

**II. MAJOR LITIGATIONS AND IMPORTANT JUDGMENTS**

**1. Delhi and Madras High Courts ban online sale of medicines.**

Acting in response to a public interest litigation that was filed before the Delhi High Court, a division bench of the said court on 12.12.2018, banned the online sale of medicines. The primary basis thereof was that there exists no regime to regulate such online sale and therefore the same is against public interest and safety.

As we updated our readers in the previous edition, the Government on 28.8.2018, acting through the MOHFW and in consultation with the Drugs Technical Advisory Board (“DTAB”) notified the draft rules to amend the D&C Rules in order to regulate the sale of drugs through means of an E-Pharmacy. These Draft Rules are yet to be enacted,

<sup>16</sup> New cosmetic refers to the cosmetic, any of the ingredients of which have not been generally regarded as safe by the central licensing authority or the regulatory authority of any other country or by the standard text relating to safety of ingredients of cosmetics.

<sup>17</sup> <http://www.pharmabiz.com/NewsDetails.aspx?aid=112621&sid=1>

as part VIB in the D&C Rules, titled ‘Sale of Drugs by E-Pharmacy’. The draft rules require all e-pharmacies to mandatorily register with the Licensing Authority to enable them to distribute and sell, stock or exhibit or offer for sale drugs through an e-pharmacy. The draft rules also require the presence of a registered pharmacist to verify details of each patient, the Registered Medical Practitioner and to arrange for the dispensation of the drugs in accordance with the prescription presented. This was closely followed by an order of a single judge of the Madras High Court on 17.12.2018 whereby the court imposed a complete ban on the sale of medicines online until the central government formally notifies the draft rules for the regulating e-medicine marketplace. The Madras high court also asked the government to notify the rules by the end of January 2019. However, this order was subsequently stayed by a division bench of the same court on 2.1.2019 which expressed no order on merits.

Meanwhile, the matter came up before the Delhi High court on 8.1.2019 wherein the court refused to stay the ban despite a contradicting order of the Madras High court and in continuation of its interim order, extended the ban on online sale of drugs up till 6.2.2019.

## 2. FDC Ban Matter-Delhi High Court sets aside ban on Wockhardt’s FDC drug.

As our readers would recall, we have been following the FDC Ban matter closely over the past year and a half. Pursuant to the Hon’ble Supreme Court’s judgment on 15.12.2017 which ordered the DTAB to proceed de novo against all the FDC Drugs which it has banned previously, the DTAB on 7.9.2018 again passed an order banning 328 FDC drugs based on a Report passed by the DTAB. This was challenged via multiple petitions before the Delhi High Court. The matter was argued at length on the issue of whether the DTAB had followed the guidelines that the Supreme Court had laid down in its judgement of December 2017 in *UOI Vs Pfizer and others*. The single judge of the delhi High Court passed an order setting aside the ban on Wockhardt’s drug ‘Ace Proxyvon Tablet 10T’ administered for relief from pain and inflammation due to rheumatoid arthritis. Other petitions were dismissed. The Court looked at the limited aspect of whether the DTAB sub-committee formed for the purpose of examining all the FDCs provided a clear justification for banning a particular drug, and if they had applied their mind to examine whether it was necessary in larger public interest to regulate, restrict, or proscribe the

manufacture, sale or distribution of specific FDCs and why restriction/regulation of the same would not suffice.

wherein

## 3. Delhi High Court sets aside notification banning manufacture of Oxytocin.

The central government had vide notification dated April 27, 2018 (“**Impugned Notification**”) issued restrictions on the commercial manufacture of the drug containing the Active Pharmaceutical Ingredient (“API”) Oxytocin and announced a ban on import of the said drug vide press release dated June 27, 2018. Petitions challenging the ban were filed before a division Bench of the Hon’ble Delhi High Court. The division bench pronounced the judgment in this matter on December 14, 2018. Major issues framed for consideration in this case were whether the Impugned Notification falls within the scope of Article 19(6) of the Constitution, whether the Impugned Notification is ultra vires the provisions of the D&C Act and whether the Impugned Notification is arbitrary and therefore unsustainable.

The bench noted that that the Impugned Notification cannot be justified on the basis of Article 19(6), which deals with reasonable restrictions on the rights under Article 19(g). By excluding the private sector completely from the manufacture of oxytocin, the result is monopolization of this occupation by the government. Such a power had not been granted to the Central government under Section 26A off the D&C Act, which did not extend to taking over the business of the Petitioner, rather than regulating, restricting, or prohibiting it in accordance with Section 26A.

On the issue of exercise of power under Section 26A, the bench also noted that under Section 26A of the D&C Act, the power to regulate by the Central Government can be used to partially or completely prohibit a drug in a suitable case, however, such exercise of the central government’s power must only be done based on relevant data. The Court relied on the Supreme Court judgment in *Union of India v. Pfizer* to elaborate on the powers of the Central government under section 26A. In the present case, since the basis for complete prohibition on manufacture of oxytocin was based on *reports* about the dangers of misuse of Oxytocin, the bench inquired into the truth in that statement. The court noted that Oxytocin is not a harmful drug, in fact it is a drug strongly

recommended by the World Health Organization used to stop haemorrhaging during childbirth and is on the National List of Essential Medicines, 2015. After a perusal of the materials placed on record, the court also did not find any merit in the contention that Oxytocin poses any health risk to human lives due lack of concrete data to bolster their claim. No instances of misuse of licenses was established and there was no concrete evidence to prove that oxytocin poses a risk to cattle health either.

The Court also held that in dealing with diverse or competing interests, the legislature or the executive should maintain a proper balance between adverse effects which the legislation or administrative order may have on the rights, liberties or interests of persons and the purpose which is intended to be served. The bench held that this balance was not maintained by the Central Government while passing the order and thus the decision is arbitrary and unreasonable. The court allowed the petitions and quashed and set aside the impugned notification.

#### 4. Supreme Court dismisses case of medical negligence against surgeon in case of consent provided by patient.

In the case of *Dr. S.K. Jhunjhunwala v. Mrs. Dhanwanti Kumar and Anr.*<sup>18</sup> The Hon'ble Supreme Court set aside the order of the National Consumer Disputes Redressal Commission ("NCDRC") which had held a surgeon guilty of medical negligence for performing conventional surgery to remove gall bladder of a woman instead of laparoscopic surgery.

The Supreme Court considered the aspect of patient consent in detail and held that the overall consent of a patient to a procedure included consent for the doctor to perform such additional operation or procedure including the administration of a blood transfusion or blood plasma as they or he may consider substituting necessary or proper in the event of any emergency or if any anticipated condition is discovered during the course of the operation. In the present case, before the surgery, there was noticeable inflammation around the patient's gall bladder, pursuant to which the doctor informed the husband of the woman and decided to go with conventional surgery according to the circumstances. The Court

further held that suffering of any ailments by the patient post the surgery by itself would not constitute medical negligence and it was necessary to prove an improper performance of the surgery to establish specific evidence for a case of medical negligence.

#### 5. Supreme Court judgment under Section 27(b)(ii) and Section 28 of the D&C Act, reduces sentence of imprisonment.

The Supreme Court recently pronounced its judgment under Section 27(b)(ii) and Section 28 of the D&C Act in the case of *State v Manimaran*<sup>19</sup> where they reduced the sentence of imprisonment for an accused under the aforesaid sections. The accused did not have the requisite licence to the premises for the sale of drugs as required under Section 18(c) of the D&C Act. The High court had sentenced him to one year rigorous imprisonment under Section 27(b)(ii) and section 28 of the D&C Act, however, he was acquitted by the High Court in a revision petition.

However, in view of the fact that the accused did not have a prior conviction, and more importantly, was not aware of the requirement of obtaining the license, the Supreme Court upheld his conviction and reduced the sentence to three months rigorous imprisonment while invoking the proviso to 27(b)(ii) wherein the sentence term of one year can be reduced 'in the interest of justice'.

### III. MAJOR DEALS

#### 1. Alexion Pharmaceutical's acquisition of Syntimmune.

Alexion Pharmaceuticals Inc. ("Alexion") is set to buy privately held biotech company Syntimmune for a total value of up to \$1.2 billion. This will provide Alexion access to Syntimmune's lead drug for treating warm autoimmune hemolytic anemia, a rare form of blood disorder.<sup>20</sup> This will provide much needed bolstering to Alexion's portfolio and diversify it to include crucial clinical-stage rare diseases. This acquisition was preceded by Alexion's major investment of \$855million in Wilson Therapeutics with its lead drug to treat the rare Wilson's disease.<sup>21</sup>

<sup>18</sup>. Civil Appeal no. 3971 of 2011.

<sup>19</sup>. Criminal Appeal no. 1493 of 2018.

<sup>20</sup>. <https://in.reuters.com/article/us-syntimmune-m-a-alexion-pharms/alexion-to-buy-biotech-firm-syntimmune-for-up-to-1-2-billion-idINKCN1M61DU>.

<sup>21</sup>. <https://www.biopharma-reporter.com/Article/2018/10/03/Alexion-continues-rare-disease-M-A-with-Syntimmune-acquisition>.



## 2. Merck buys Antelliq animal health

U.S.A based major pharmaceutical company, Merck & Co, has finalized the acquisition of the French company Antelliq Group for about \$2.4 billion.<sup>22</sup> Antelliq is a digital technology company focused on animal health including services for veterinarians, farmers and pet owners.

## 3. Astellas acquires Potenza therapeutics

Subsequent to a successful collaboration for over three years, between Astellas Pharma Inc. (“Astellas”) and Potenza Therapeutics (“Potenza”) to produce immuno-oncology drugs, Astellas has acquired Potenza for up to \$404.7 million. Potenza is a Japanese, US east coast company which aims to produce several new drugs that aim to treat various cancers.<sup>23</sup> This deal increases the buyer’s cancer immunotherapy portfolio as they now have access to three major breakthrough drugs for cancer which are in clinical development stages.

“I am pleased that these therapies will now have access to the resources of a large international company, with world-class R&D and the strategic and financial backing to support the development of these innovative potential new medicines for

cancer patients in need,” Potenza President and CEO Dan Hicklin said in the statement.<sup>24</sup>

## 4. Indian start-up NetMeds receives \$35 million funding.

Indian pharmaceutical start-up company, NetMeds Marketplace Pvt. Ltd, founded in 2010 by a Chennai based business man Pradeep Dadha, has received \$35 million in funding from South-Asian conglomerate Daun Penh Cambodia Group (“DPCG”), a distributor and importer of medicines. NetMeds has previously raised \$14million from Tanncam Investment, a Cambodian investment holding company, which help to scale-up the operations of the company in India.

NetMeds provides online access to non-prescription/over the counter as well as prescription drugs through its mobile application available on both iOS and Android devices. In case of prescription drugs, once users upload their drug prescription onto the app, the company pharmacists subsequently examine the prescription to assist with proper dosage, duration, and other points of validity before completing the purchase order.<sup>25</sup>

<sup>22</sup> <https://www.biospace.com/article/merck-buys-animal-health-company-antelliq-for-2-4-billion/>.

<sup>23</sup> <https://www.chicagobusiness.com/health-care/northbrook-based-pharma-firm-buys-east-coast-biotech-company>.

<sup>24</sup> <https://www.chicagobusiness.com/health-care/northbrook-based-pharma-firm-buys-east-coast-biotech-company>.

<sup>25</sup> <https://inc42.com/buzz/online-pharma-netmeds-raises-35-mn-series-c-funding-onboards-second-cambodian-investor/>.



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