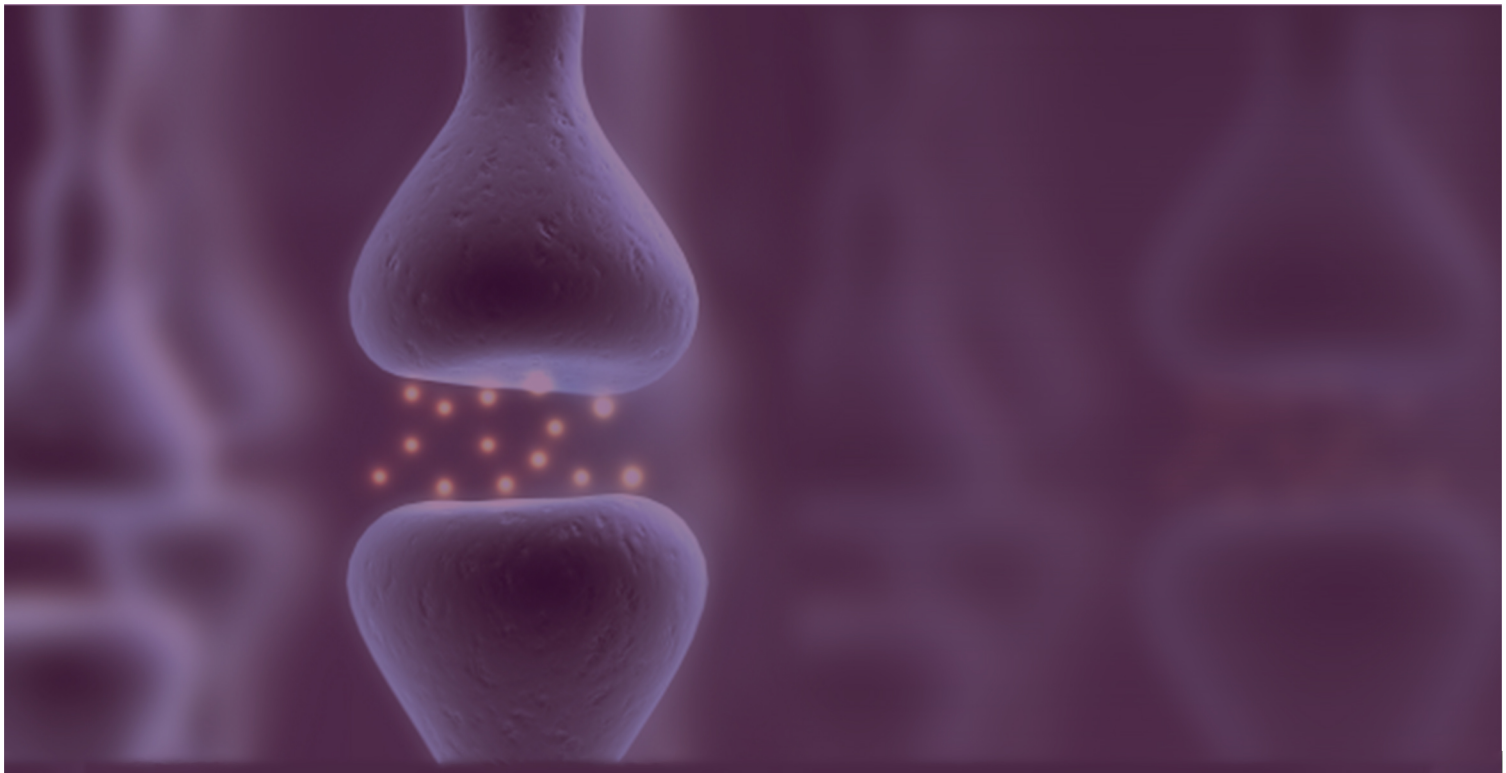

SYNAPSE

A Quarterly update on the Pharmaceutical Industry

Vol. III/Issue IV/
October 01, 2019 – December 31, 2019

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SYNAPSE

Dear Readers,

We wish you a happy and prosperous new year. We hope that the new year, the new decade is a good one for all of you.

Cyril Amarchand Mangaldas, India's premier full-service law firm has an industry leading and dedicated Pharmaceutical, Healthcare and Life Sciences practice. Our class leading practice specialists are always on top of the latest developments in the sector. With this background, it gives us immense pleasure to bring forth the latest issue of our quarterly Pharmaceutical, Healthcare and Life Sciences practice newsletter- Synapse.

In this issue, we have compiled some important events and regulatory developments that took place during the last quarter of 2019. As the year ended, it witnessed yet another round of interesting developments especially on the regulatory front, all of which have been captured in the present issue.

One of the key highlights of the quarter was the passing of the Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019, prohibiting the manufacture, sale, import etc. of e-cigarettes thereby bringing an end to the issue surrounding regulation of e-cigarettes in India.

Another highlight of the quarter was related to medical devices and the issuance of draft amendments to the law that aim to bring 'all' 'medical devices' within the ambit of regulatory control. A confirmation of the fact that the Government is moving ahead with the decision to regulate all medical devices as opposed to only certain notified categories of medical devices.

We also witnessed some interesting M&A activity in the quarter, all of which have been reported in this issue.

It is our endeavor to keep our readers abreast of the latest developments in this dynamic sector through our quarterly newsletter. With this in mind, we present to you Volume III Issue IV of Synapse. We hope you enjoy reading this newsletter as much as we have enjoyed 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 IV/
October 01, 2019 –
December 31, 2019

REGULATORY UPDATES

1. Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019[1]("ENDS Act")

The ENDS Act has been notified by the Ministry of Law and Justice, vide Gazette Notification bearing reference no. 66, dated December 5, 2019 and has come into force with effect from September 18, 2019. This Act replaces the Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Ordinance, 2019 ("**ENDS Ordinance**"). The stated objective of the ENDS Act is to prohibit the production, manufacture, import, export, transport, sale, distribution, storage and advertisement of electronic cigarettes in the interest of public health.

The provisions of the ENDS Act are *pari-materia* to the ENDS Ordinance. Some of the salient features of the ENDS Act are enumerated below:

(i) 'Electronic Cigarette' Definition:

The term 'Electronic Cigarette' is defined to mean an "*electronic device that heats a substance, with or without nicotine and flavours, to create an aerosol for inhalation and includes all forms of electronic nicotine delivery systems, heat not burn products, e-hookah and the like devices, by whatever name called and whatever shape, size or form it may have, but does not include any product licensed under the Drugs and Cosmetics Act, 1940*";

(ii) Prohibited Activities:

The activities of production, manufacture, import, export, transport, sale, distribution, storage and advertisement of Electronic Cigarettes is prohibited;

(iii) Storage of Electronic Cigarette:

No person, being the owner of a place, can permit the place to be used for storage of Electronic Cigarettes and the stock thereof is required to be surrendered to the authorities; and

(iii) Punishment for Non-Compliance:

Punishments for contravention of the provisions of the ENDS Act include monetary penalty, imprisonment or both.

2. Notification of Drugs and Cosmetics (Thirteenth Amendment) Rules, 2019

The Ministry of Health and Family Welfare ("**MoHFW**"), *vide* Gazette Notification bearing reference no. GSR 828 (E), dated November 6, 2019[2], has notified the Drugs and Cosmetics (Thirteenth Amendment) Rules, 2019. This amendment has introduced new sub rules in Rule nos. 71, 71A, 71B, 76 and 76A of the Drugs and Cosmetics Rules, 1945 ("**D&C Rules**").

The aforementioned rules *(i.e. Rule nos. 71, 71A, 71B, 76 and 76A)* provide for inter alia the terms and conditions of various licenses for manufacture of 'drugs' (*as defined under the Drugs and Cosmetics Act, 1940 ("***D&C Act***"))*. Through this notification, an additional condition for grant of the manufacturing licenses has been introduced, which will be applicable in case the applicant intends to market a 'drug' under a brand name or a trade name. In such a situation, the applicant will henceforth be required to furnish an undertaking to the licensing authority to the effect that: (a) to the best of his knowledge, and (b) based on search in: (i) trade-marks registry, (ii) central data base for brand name, or (iii) trade name of drugs maintained by the Central Drugs Standard Control Organisation ("**CDSCO**"), (iv) literature and reference books on details of drug formulations in India, and (v) general internet search, such or similar brand name or trade name; is not already in existence with

[1] http://www.egazette.nic.in/writereaddata/2019/214523.pdf

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

respect to any drug in the country and that the proposed brand name or trade name will not lead to any confusion or deception in the market.

The abovementioned undertaking will be required to made to the licensing authority in the newly introduced 'Form 51' (*"Form of undertaking to the licensing authority for marketing a drug under a brand name or trade name"*).

3. Notification of Ultrasound Equipment as 'Drugs'

The MoHFW has, *vide* Gazette Notification bearing reference no. SO 3721(E), dated October 16, 2019[3], notified 'ultrasound equipment' as 'drugs' within the meaning of Section 3(b) of the D&C Act, with effect from November 1, 2020. Accordingly, 'ultrasound equipment' will be regulated as 'medical devices' under the Medical Devices Rules, 2017 ("**MD Rules**"), with effect from November 1, 2020.

4. Draft Amendment to the Drugs and Cosmetics Rules, 1945[4]

The MoHFW, *vide* Gazette Notification bearing reference no. GSR 827 (E), dated November 6, 2019, has notified a draft for amendment of the D&C Rules. The objective of this draft amendment is to substitute the entry at serial no. 23 of Schedule K of the D&C Rules *(which currently reads- "Drugs supplied by: (i) Multipurpose Workers attached to Primary Health Centres/ Sub-Centres, (ii) Community Health Volunteers under the Rural Health Scheme and (iii) Nurses, Auxiliary Nurse, Midwives and Lady Health Visitors attached to Urban Family Welfare Centres/ Primary Health Centre/ Sub Centres and Anganwadi Workers".)*, with the following entry:

"*Drugs supplied by: (i) Health Functionaries including Community Health Officers, Nurses, Auxiliary Nurse Midwives and Lady Health Visitors attached to Primary Health Centres/ Sub-Centres/ Health & Wellness Centres in rural and urban areas, (ii) Community Health Volunteers such as Accredited Social Health Activists (ASHAs) under the National Health Mission, and (iii) Anganwadi Workers*"

The MoHFW had invited objections and suggestions in relation to this draft amendment which could be communicated to it by any affected person within a period of 45 (forty five) days from the date of the Gazette Notification (*i.e. November 6, 2019*).

5. Draft Amendment to the Medical Devices Rules, 2017

The MoHFW, *vide* Gazette Notification bearing reference no. GSR 797(E), dated October 18, 2019[5], has published a draft of certain proposed amendments to the MD Rules. The objective of this draft amendment is to insert a new 'Chapter IIIA' in the MD Rules, after the existing 'Chapter III', which would be applicable to all devices notified under Section 3(b) of the D&C Act, except the medical devices and devices specified in the Annexure of Eighth Schedule of the MD Rules (*this Annexure is also currently a part of the draft amendment*).

In terms of this draft amendment, all such medical devices will required to be registered with the Central Licensing Authority through an identified online portal established by the CDSCO. It has been further provided that such registration shall be on a voluntary basis for a period of 18 (eighteen) months from the commencement of Chapter IIIA and thereafter, the registration shall become mandatory.

The medical devices which shall be exempt from the requirement of registration under the proposed Chapter IIIA have been specified in the Annexure attached in the aforementioned draft amendment. This Annexure includes all medical devices which have been notified till date. Therefore, it appears that this amendment has been published in pursuance of the Government's plan to regulate all medical devices. This has already been the subject matter of discussion in meetings of the Drugs Technical Advisory Board.

The MoHFW had invited objections and suggestions in relation to this draft amendment which could be communicated within a

[3] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTE3NA
[4] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTE5OA
[5] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTE4MQ

period of 30 (thirty) days from the date of the Gazette Notification (*i.e. October 18, 2019*).

6. Draft Notification to Notify all 'Medical Devices' as 'Drugs'

The MoHFW, *vide* Notice bearing reference no. F.No. X.11035/281/2018-DRS, dated October 18, 2019[6], has published a draft notification to notify all 'medical devices' within the meaning of 'drugs' under Section 3(b) of the D&C Act. The draft envisages the notification of the following devices as drugs':

"All devices including an instrument, apparatus, appliance, implant, material or other article; whether used alone or in combination, including a software or an accessory, intended to be used by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of –

(i) Diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;

(ii) Diagnosis, monitoring treatment, alleviation or assistance for, any injury, disability;

(iii) Investment, replacement, or modification or support of the anatomy or of a physiological process;

(iv) Supporting or sustaining life;

(v) Disinfection of medical devices; and

(vi) Control of conception."

This aforementioned draft notification, upon implementation, would widen the ambit of 'medical devices' which are currently regulated under the D&C Act and the MD Rules.

7. Draft of Frequently Asked Question Regarding Import and Registration of Drugs

The CDSCO, *vide* Notice bearing reference no. Import/Misc./29/2019-DC, dated October 7, 2019 , has published a draft of frequently asked questions ("**FAQ**"), to streamline the regulatory process for import and registration of 'drugs' into India. The said draft FAQs contain responses to and guidance on some of the most basic questions which an importer of drugs may have, such as:

(i) Which division of CDSCO (HQ) is responsible for registration/ import of drugs (for human use) in India?

(ii) What are the requirements for import of drugs into India

(iii) What is the procedure for obtaining registration certificate?

(iv) What is the procedure for obtaining Import License?

(v) How to register additional drugs in already approved/ valid registration certificate?

The CDSCO had invited all the affected stakeholders to submit their feedback and suggestions in relation to this draft FAQ which could be communicated within a period of 7 (seven) days from the date of the publication of these FAQ (*i.e. October 7, 2019*).

8. Strengthening of Materiovigilance Programme of India ("MvPI")

The MvPI aims to improve patient safety and welfare by monitoring medical device safety. In this regard, the Indian Pharmacopoeia Commission has been entrusted with the responsibility of operating the MvPI. The CDSCO has opined that materiovigilance and medical device adverse event reporting among healthcare professions is in need of scaling up by developing educational

[6] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTE3OA
[7] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTA5OQ

and promotional interventions such as continuous medical education, awareness programs, workshops, conferences on materiovigilance etc.

The CDSCO, vide a Letter bearing reference no. F. No. 29/Misc/03/2017-DC (48), dated November 26, 2019[8], has requested all States' Drug Controllers/ authorities to initiate steps for sensitizing and advising all clinicians and other healthcare professionals to mandatorily adopt reporting of medical device adverse events to MvPI.

9. Setting up of Public Relations Offices ("PRO") at Zonal and Sub-Zonal Offices of CDSCO[9]

The CDSCO, *vide* its Office Order bearing reference no. A.32029/01/2018-D, dated December 12, 2019, has notified its decision to set up PROs at all zonal and sub-zonal offices of the CDSCO in order to make regulatory guidance more accessible to all stakeholders across the country. These PROs will also act as a 'single window' for disposal of all grievances of stakeholders and will provide information to innovators regarding regulatory requirements for developing and commercialization of their products.

The manner in which these PROs will function and maintain records, will be guided by the procedure adopted by the PRO at the CDSCO headquarters. A process flow chart for handling applications and queries at zonal and sub-zonal PROs has also been published for guidance.

10. Regulation of Products such as 'Adhesives for Fixing Wigs on Scalp or Hair' etc.

The CDSCO, *vide* a Notice bearing reference no. F.No. COS/MISC-101/19, dated November 4, 2019[10], has clarified that products such as 'adhesives for fixing wigs on scalp or hair', 'products for cleansing scalp' and 'artificial nail systems' are covered under the definition of 'cosmetics' under the D&C Act. It is to be noted that 'Products for Temporary Hairs' are already mentioned in the Guidelines for Import of Cosmetics[11]. With regard to artificial nails, the CDSCO has decided to incorporate a new category named 'Artificial Nails' in the Guidelines for Import of Cosmetics in order to follow the requirements of Bureau of Indian Standards (BIS) IS 4707.

The CDSCO had invited comments in relation to this clarification which could be communicated within a period of 30 (thirty) days from the date of the publication of this Notice (*i.e. November 4, 2019*).

11. Compensation in Cases of Faulty Medical Devices.

The CDSCO, *vide* Office Memorandum bearing reference no. File No: Import/Misc/129/2019-Dc, dated October 18, 2019[12], has decided that if the manufacturer itself is importing dual use Active Pharmaceutical Ingredients ("**API**") for their end use (*other than medicinal use*), a 1 (one) time dual use- no objection certificate may be granted for 1 (one) year to such manufacturers. The 1 (one) year period may be relaxed if the data submitted and the operations carried out by the operators prove that it is for self-consumption and further manufacturing.

However, all zonal and sub-zonal offices of the CDSCO have been directed to strictly monitor the end use of dual use APIs and communicate the action taken in this regard to the office of the Drugs Controller General of India ("**DCGI**").

12. Regulation of 'Digital Thermometer' and 'Blood Pressure Monitoring

'Nebulizer', 'Blood Pressure Monitoring Devices', 'Digital Thermometers', and 'Glucometers' were notified as 'drugs' under Section 3(b) of the D&C Act (*with effect from January 1, 2020*) in the Gazette Notification bearing reference no. SO 5980(E), dated December 3, 2018[13].

However, the CDSCO, *vide* Notice bearing reference no. 29/MISC/3/2018-DC (165),

[8] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTMxMw
[9] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTM3Mg
[10] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTE5Nw
[11] https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/cosmetics/Guidelines_on_Registration_of_Import_of_Cosmetics.pdf
[12] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTE4MA
[13] https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadGazette_NotificationsFiles/so5980e.pdf

dated November 13, 2019[14], has clarified that only those 'Digital Thermometers' and 'Blood Pressure Monitoring Devices' whose primary intended purpose is 'temperature monitoring and blood pressure monitoring', will be considered under the purview of regulation from January 1, 2020 onwards. Those machines, whose primary intended purpose is composite and not individual/ unit monitoring of the parameters mentioned above, will note be considered at this stage as falling within the purview of regulation.

13. Re-registration and Renewal of Registration of Ethics Committees

The CDSCO, *vide* Notice bearing reference no. File No. ECR/Misc./16/Validity-Notice/2019, dated October 18, 2019[15], has clarified that if the applications for renewal of registration or registration of Ethics Committees (*as defined under the New Drugs and Clinical Trials Rules, 2019*) have been submitted within the timelines specified in the New Drugs and Clinical Trials Rules, 2019, the same shall remain valid till an order is passed by the CDSCO on such applications otherwise.

14. Draft of Food Safety and Standards (Safe Food and Healthy Diets for School Children) Regulations 2019 ("Safe Food Regulation")

The MoHFW, *vide* Gazette Notification bearing reference no. F. No. 15 (1) 2016/School Children Regulation/Enf/FSSAI, dated October 30, 2019[16], has published a draft of Safe Food Regulations.

Some of the salient features of the Safe Food Regulations are as follows:

i. Definition of certain terms:

(a) 'Healthy Diet': The term 'healthy diet' has been defined to mean: "*a diet which provides all the nutrients including the essential micro nutrients in required amounts and proper proportions*";

(b) 'Schools': The term 'schools' has been defined to mean: "*all types of schools whether pre-primary, primary, elementary, secondary, day care/ crèche, or boarding run by private entities, local bodies, government or aided by government*";

(c) 'School Meals': The term 'school meals' has been defined to mean: "*all foods and beverages sold or supplied on the school campus through canteens/ school mess/ hostel kitchens/ vending machines or any other method and include all meals served through mid-day meal kitchens and catered for students by the school*";

ii. Registration as a Food Business Operator: Every school authority selling or catering school meals by itself in the school campus will be required to get registered registration as a Food Business Operator ("**FBO**") under the Food Safety and Standards Act, 2006;

iii. Compliance with Food Safety Standards (Licensing and Registration of Food Businesses) Regulations, 2011: FBOs selling or catering food on school campus will be required to comply with the requirements of sanitary and hygienic practices to the food service establishments under the Food Safety Standards (Licensing and Registration of Food Businesses) Regulations, 2011;

iv. Role of School Authorities: School authorities shall ensure that no person shall offer or expose for sale of pre-packaged foods which are referred to as foods high in fat, salt and sugar as per the Food Safety and Standards (Labeling and Display) Regulations, 2019 to school children in school canteens/ mess premises/ hostel kitchens or within 50 (fifty) meters of the school campus; and

v. The school authorities and the Food Authority will be required to promote safe and healthy foods in and around the school premises.

[14] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTIyOQ
[15] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTE3Nw
[16] https://fssai.gov.in/upload/uploadfiles/files/Draft_Notification_School_Children_04_11_2019.pdf

The MoHFW had invited the affected stakeholders to submit their comments and objections in relation to this draft regulation, which could be communicated within a period of 30 (thirty) days from the date of the publication of the draft Safe Food Regulations (*i.e. October 30, 2019*) to the 'Chief Executive Officer, Food Safety and Standards Authority of India'.

15. Draft Guidelines on 'Working With Private Sector'

The Food Safety and Standards Authority of India ("**FSSAI**"), vide Notice bearing reference File No. 13(36)2019/Guidelines on Pvt. Companies/RCD/FSSAI, dated October 4, 2019[17], has published a draft of the proposed guidelines on 'Working With Private Sector' ("**Pvt. Sector Guidelines"**).

The Pvt. Sector Guidelines specify the standards and requirements which the FSSAI would be expected to follow while working with the private sector entities. These guidelines are based on the realization that food safety is a shared responsibility of the regulators, food businesses and the consumers, and that the FSSAI regularly works with all stakeholders including private sector entities to achieve the objectives of self-compliance and ensuring food safety. This leads to a need for accountability, transparency and addressing potential conflicts of interests on the part of FSSAI whenever it deals with private entities.

Some of the salient features of the Pvt. Sector Guidelines are as follows:

i. To avoid any potential conflict of interest in the composition and day to day working of the Food Authority and Central Advisory Council, a declaration regarding any conflict of interest to be obtained before any meeting of the Food Authority and the Central Advisory Committee along with a provision for a member to recuse himself from the meeting in case of conflict of interest;

ii. The constitution of the Scientific Committee, Scientific Panel and Working Groups to be done in such manner to ensure 'independent' scientific experts, and any candidate who is employed, working with or associated with any private food business or their research centre to not be considered for appointment. Candidates with prior association to private entities to be allowed after obtaining a declaration and undertaking to that effect;

iii. Inclusion of representatives from reputed consumer rights and civil society organisations in Standards Review Groups;

iv. In respect of food testing laboratories, while the FSSAI encourages laboratories under the public private partnership framework, care to be taken to ensure that the framework agreements are designed in a manner that prevent any risk of conflict of interest;

v. For training of laboratory staff, the private sector may be associated with, provided that it does not promote a proprietary technology or product;

vi. While associating with specialized centres established by the private sector, the FSSAI to ensure that the centre does not promote a particular business or brand and that there is no potential conflict of interest; and

vii. Principles of neutrality and non-profit to be ensured when the FSSAI utilizes the private sector for awareness and outreach activities such as promotion of 'Eat Right India' initiative;

16. Changed Timelines For Regulation of Certain Medical Devices

The MoHFW, *vide* Gazzette Notification bearing reference no. SO 4672(E), dated

[17] https://fssai.gov.in/upload/uploadfiles/files/Notice_Draft_Guidelines_Private_Sector_04_10_2019.pdf

December 27, 2019[18], has changed the date of coming into force of Gazette Notification no. SO 775(E)[19] to April 1, 2021 instead of April 1, 2020. Accordingly, the medical devices which had been notified in terms of the Gazette Notification no. SO 775 (E) (*i.e. All implantable medical devices, CT scan Equipment, MRI Equipment, Defibrillators, Dialysis Machine, PET Equipment, X-Ray Machine, and Bone marrow cell separator*) will now be regulated under the D&C Act and MD Rules starting from April 1, 2021, instead of April 1, 2020.

Further, the MoHFW, *vide* Gazzette Notification bearing reference no. SO 4671(E), dated December 27, 2019[20], has changed the date of coming into force of Gazette Notification no. SO 5980(E)[21] to January 1, 2021 instead of January 1, 2020. Accordingly, the medical devices which had been notified in terms of the Gazette Notification no. SO 5980 (E) (*i.e. Nebulizer, Blood Pressure Monitoring Devices, Digital Thermometer, and Glucometer*) will now be regulated under the D&C Act and MD Rules starting from January 1, 2021, instead of January 1, 2020.

RECENT NEWS

1. NATHEALTH Inks Pact with Roche Diagnostics India

NATHEALTH (*a forum that facilitates the coordination and cohesive functioning between healthcare stakeholders and policy makers*), on October 24, 2019, signed a memorandum of understanding ("**MoU**") with Roche Diagnostics India ("**Roche**") to improve access to quality diagnostics in the country[22] . It is for the first time that NATHEALTH has released a roadmap to enable healthcare access amongst people and patients, with a special focus on diagnostics and preventive medicine. The MoU with Roche highlights and encapsulates the aim to drive awareness, access and acceptance of digitalization for quality screening, diagnosis and monitoring solutions to reach people across India.[23]

2. High Court of Delhi Cautions the Delhi Government Over the Misuse of the 'Farishtey Dilli Ke' Scheme

The 'Farishtey Dilli Ke' scheme was launched by the Delhi Government in October, 2019. The said scheme is targeted towards road accident victims in Delhi and the salient features of the same are enumerated herein-below[24] :

i. Encouraging Common People: The primary objective of the scheme is to encourage common people to come forth and help accident victims. Their timely action will save the lives of many people, who require medical attention after an accident;

ii. Free Medical Treatment: The accident victims, who are admitted to the hospitals, will get free of cost treatment. The medical bills will be paid by the Delhi Government;

iii. Monetary Reward: If any individual helps a road accident victim and admits him/ her to the nearest hospital, then the Delhi Government will commend his/ her deeds by offering a financial reward of INR 2,000 (Indian Rupees Two Thousand);

iv. Certificate from the State Authority: Apart from the financial reward, the citizens who help road accident victims will also get a certificate from the Delhi Government. The certificate will highlight their deed and prove that they are good citizens of Delhi who are eager to assist others in need;

[18] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTM4Nw
[19] hhttps://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTM4Nw
[20] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTM5Mw
[21] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MjM1NA
[22] https://health.economictimes.indiatimes.com/news/diagnostics/nathealth-inks-pact-with-roche-diagnostics-india/71742061
[23] https://www.nathealthindia.org/pdf/newsletter/2019/oct/NATHEALTH%20Weekly%20Newsletter%20(23rd%20October%20-%2028th%20October).pdf
[24] https://pmjandhanyojana.co.in/farishte-dilli-ke-scheme-delhi/

v. No Legal Hassles: The scheme clearly states that such citizens will not be harassed or questioned by the police authorities in case of a road accident.

However, it is to be noted that the High Court of Delhi, on October 30, 2019, (bench of Justices G. S. Sistani and A. J. Bhambhani) remarked that it seemed the scheme had been misused by touts, and stressed that a balance needs to be struck to ensure real accidents victims benefitted from the said scheme[25] . They observed that, "The common citizen will not be able to avail the scheme. The Delhi government needs to take strict action against such misuse…". [26]

3. Urge to Enforce Ban on Gutka, Khaini and Pan Masala in West Bengal

A routine notification was issued on October 25, 2019 by Commissioner of Food Safety Tapan Kanti Rudra of Health and Family Welfare Department, banning 'gutkha', 'khaini' and 'pan masala' across the State of West Bengal[27]. The said notification is the annual notification which is issued by the FSSAI, to ban the manufacture, storage, distribution and sale of articles of food in which tobacco and nicotine are used as ingredients. The said ban has been prevailing in the State of West Bengal on paper, since 2013. However, the notification issued on October 25, 2019 went viral in the social media with a demand for stringent implementation. The public opinion has now forced the Government to think of its enforcement. Though the ban is routinely notified around this time for a period of 1 (one) year, it is violated openly. But ever since the ban was issued this year, citizens are questioning the relevance of such notification, especially when it is being violated every day[28].

4. MoHFW Requests Medical Council of India, Board of Governors ("MCI BoG") to Draft Guidelines for Fess Structure at Private Medical Colleges

Since the setting up of the National Medical Commission ("**NMC**") may take time, the MoHFW has asked the MCI BoG to prepare draft guidelines for the fee structure in private medical colleges and 'deemed to be' universities from the next academic session[29]. We note that once the NMC comes into being, the MCI will automatically get abolished. Furthermore, after the dissolution of the MCI in 2018, a BoG was appointed to perform its functions. The MCI BoG, which is vested with the powers of the MCI, has now initiated consultations with States and sought their suggestions for framing draft guidelines for the fee structure[30].

We note that National Medical Commission, under Section 10(1)(1) of the National Medical Commission Act, 2019 ("NMC Act"), is empowered to frame guidelines for determination of fees and all other charges in respect of 50% (fifty percent) of seats in private medical institutions and 'deemed to be' universities. As the NMC is yet to come into being the MoHFW has requested the MCI BoG to prepare said draft guidelines so that the NMC, on its constitution, may utilise the same and so that it can be enforced from the next academic session (2020-21) onwards for both under graduate and post graduate medical admissions.[31]

5. Initiatives of Punjab Government for Buprenorphine-Naloxone

In a step that came after the strong crack down on the private de-addiction centres in Punjab, the Punjab Government has requested the National Pharmaceutical Pricing Authority ("**NPPA**") to put a cap on price of detoxification medicine, 'buprenorphine-naloxone', under the Essential

[25] https://timesofindia.indiatimes.com/city/delhi/ensure-only-real-accident-victims-benefit-from-scheme-delhi-high-court/articleshow/71845978.cms.
[26] https://indianexpress.com/article/cities/delhi/high-court-cautions-delhi-govt-over-farishte-scheme-misuse-accident-victims-hospitals-treatment-6095196/
[27] https://health.economictimes.indiatimes.com/news/industry/enforce-ban-on-gutkha-health-experts-urge-west-bengal-government/71870892
[28] https://timesofindia.indiatimes.com/city/kolkata/enforce-ban-on-gutkha-health-experts-urge-west-bengal-government/articleshow/71860939.cms
[29] https://health.economictimes.indiatimes.com/news/policy/health-ministry-asks-mci-bog-to-draft-guidelines-for-fess-structure-at-private-medical-colleges/71938651
[30] https://www.indiatoday.in/education-today/news/story/health-ministry-asks-mci-bog-to-draft-guidelines-for-fee-structure-at-private-medical-colleges-1616474-2019-11-07
[31] Ibid.

Commodities Act, 1955.[32]

The Punjab Government, informed the NPPA that the combination of 'buprenorphine-naloxone' is available at private drug de-addiction centres at exorbitant rates.[33] The Punjab Government has asserted that the private centres were dispensing the medicine at high rates, thus depriving treatment to large number of patients (*belonging to socio-economic backward class*) due to the steep price of the drug.

Additionally, the Punjab Government will impose Punjab State Cancer and Drug Addiction Treatment Infrastructure Fund Act, 2013 ("**CADA**") cess on supply of buprenorphine to private drug de-addiction centres. The decision has been taken to remove the roadblocks in the implementation of the ambitious initiative of the Punjab Government to provide detoxification medicine at controlled rates to private centres [34].

According to the rules framed by the Punjab Government, the funds collected by imposing CADA cess are to be used for creating and upgrading infrastructure, including buildings, machinery and equipment for treatment and rehabilitation of cancer patients, along with those there for de-addiction. The authorities can use the fund for creating awareness about ill-effects of drugs, drug addiction and welfare of patients afflicted with cancer and drug abuse in the State. CADA funds will also be used for strengthening the enforcement capabilities for combating illicit drug trafficking[35].

6. Central Government Approves 4 (Four) Medical Device Parks

The Central Government has given its approval for setting up of 4 (four) medical device parks with a view to support the "Make in India" initiative and provide world-class products at affordable prices. The 4 (four) parks will be set up in Andhra Pradesh, Telangana, Tamil Nadu and Kerala. Furthermore, the States of Uttarakhand and Gujarat have also been approached by the Central Government for building such medical device parks.

These parks will provide necessary infrastructure, and as a consequence, will not only reduce the import of medical devices but also help in easy access to standard testing facilities and reduce cost of production.[36]

7. Lincoln Pharma Gets Indian Patent for Diclofenac Rectal Spray

Lincoln Pharmaceuticals, on October 22, 2019, received an Indian patent for its diclofenac rectal spray, which is used for alleviating pain from various causes. The patent has been awarded for "*a novel liquid rectal spray dosage form containing diclofenac and its pharmaceutically active salts*"[37]. The said liquid rectal spray dosage offers faster and better absorption of the drug resulting in quick relief and speedy recovery to patients compared to the existing therapeutic options.

Furthermore, Lincoln Pharmaceuticals has clarified that it has the necessary approvals from the DCGI and is planning to launch it in the Indian market by January, 2020[38].

8. Government Refers Surrogacy (Regulation) Bill, 2019 to Select Committee of Rajya Sabha

The Government, on November 21, 2019 sent the Surrogacy (Regulation) Bill, 2019 ("**Surrogacy Bill**"), to a select committee of the Rajya Sabha for review. The Surrogacy Bill seeks to ban commercial surrogacy in India.

We have previously written on this subject matter through our blog posts which can be accessed here.

[32] https://health.economictimes.indiatimes.com/news/pharma/punjab-asks-centre-to-regulate-price-of-buprenorphine-under-essential-commodities-act/72000155
[33] https://health.economictimes.indiatimes.com/news/pharma/punjab-asks-centre-to-regulate-price-of-buprenorphine-under-essential-commodities-act/72000155
[34] https://www.medicalbuyer.co.in/punjab-private-centres-to-be-charged-cada-cess-on-buprenorphine/
[35] https://health.economictimes.indiatimes.com/news/industry/punjab-private-centres-to-be-charged-cada-cess-on-buprenorphine/72177088
[36] https://health.economictimes.indiatimes.com/news/medical-devices/govts-go-ahead-for-4-medical-device-parks/71995708
[37] https://health.economictimes.indiatimes.com/news/pharma/lincoln-pharma-gets-indian-patent-for-diclofenac-rectal-spray/71704211
[38] http://pharmabiz.com/NewsDetails.aspx?aid=118901&sid=2

9. DCGI has Ordered E-Pharmacies to Halt Sales

The DCGI, vide an order dated November 28, 2019, directed all States and Union Territories to prohibit sale of medicines through unlicensed online platforms till draft rules to regulate e-pharmacies are finalized and put in place[39].

The said Order has been passed in response to the public interest litigation filed by petitioner 'Dr. Zaheer Ahmed' which came up for hearing before the High Court of Delhi as W.P.(C) 11711/ 2018. It was contended before the Court that there was no statutory control over the sale of medicines and this is in violation of the D&C Act. On December 12, 2018, the Court injuncted the Respondents- Union of India from allowing online sale of medicines without license and they were directed to ensure that the same is prohibited until any further orders. The Court held:

"Shri Arvind Nigam, learned senior counsel appearing for the petitioner submits that online sale of drugs is prohibited in law. There is no control and the sale is being done in total violation of the statutory provisions, namely, the Drugs and Cosmetics Act, 1940. That apart, he invites our attention to the draft rules prepared and circulated wherein online dispensation of drugs is prohibited. He also invites our attention to an interim order passed by the Madras High Court in W.P.No.28716/2018 and W.M.P.No.33542/2018 on 31.10.2018 wherein taking note of all these factors and the seriousness of the issue and the public cause involved, interim injunction has been granted with regard to online sale of medicines without licence and the competent authority has been directed to stall such online sales forthwith. We see no reasons as why similar directions be not issued in the present case… Respondents are injuncted from online sale of medicines without licence and the respondents are directed to ensure that the same is prohibited forthwith until further orders."

This interim stay was further renewed by the High Court of Delhi vide order dated January 8, 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 August 28, 2018 vide Gazette Notification bearing reference no. G.S.R. 817(E).

10. Draft Guidelines on 'Working With Private Sector'

The NITI Aayog has proposed to bring all medical devices under a separate regulatory regime which will be administered by a dedicated Medical Devices Administration ("**MDA**"). In this regard, the NITI Aayog has already drafted a draft legislation which is currently under discussion with various stakeholders[40]. However, there were reports that the MoHFW was not amenable to this proposal, and had asked the NITI Aayog to have wider consultations with the relevant stakeholders[41]. Some of the important salient features of the legislation proposed by the NITI Aayog are as follows:

i. Setting up of a National Register of Medical Devices: All medical devices will be required to be registered in the National Register of Medical Devices;

ii. Establishment of MDA: The MDA will be in the nature of a body corporate and will have functions which include *inter alia* protection of persons using medical devices, providing risk based classification for medical devices, designating standards in addition to those framed by the Bureau of Indian Standards, etc.;

[39] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/states-told-to-restrain-unlicenced-e-pharmacies/article-show/72358177.cms?from=mdr

[40] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/niti-aayog-proposes-separate-regulator-for-medical-devices/article-show/71798635.cms?from=mdr

[41] https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/ministry-niti-aayog-at-odds-over-regulation-of-medical-devices/article-show/72135095.cms?from=mdr

iii. Placing Devices in Market: Specific procedure for placing devices on the market have been laid down. These include inter alia compliance will standards set by the MDA, provisional registration of the device etc.

iv. Compensation: Persons who have suffered any harm or injury as a result of the violation of any provisions of the Act will be entitled to seek compensation from the manufacturer of the device.

MAJOR TRANSACTIONS/ DEALS

1. TA Associates, Warburg Pincus, ChrysCap Shortlisted to Buy Stake in SRL Ltd

Three leading private equity firms, namely- TA Associates, Warburg Pincus and ChrysCapital, have been shortlisted from a group of 5 (five) suitors for acquiring up to 44% (forty four percent) equity stake in SRL Ltd., the diagnostics arm of Fortis Healthcare.

2. Online Medical Supplies Platform Medikabazaar Raises INR 1,12,00,00,000 in Series B Funding

Medikabazaar, India's largest online business-to-business (B2B) platform for medical supplies, has secured INR 1,12,00,00,000 (Indian Rupees One Hundred and Twelve Crores) during a Series B funding round. Founded in 2015, Medikabazaar is now targeting India's tier-2, tier-3 and rural markets, and is now also planning to diversify into other categories such as devices for vascular surgery, ENT, laser devices for varicose veins, gynaecology, interventional radiology and OT environment safety.[42]

This Series B funding round was led by healthcare-centric venture capital fund HealthQuad, Belgium-based diversified group Ackermans & Van Haaren, investment firm Rebright Partners and Japan's Toppan Printing Co Limited.[43]

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[42] https://health.economictimes.indiatimes.com/news/industry/b2b-online-marketplace-medikabazaar-raises-rs-112-crore/72101543
[43] https://www.moneycontrol.com/news/business/companies/online-medical-supplies-platform-medikabazaar-raises-rs-112-cr-in-series-b-funding-4649531.html

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