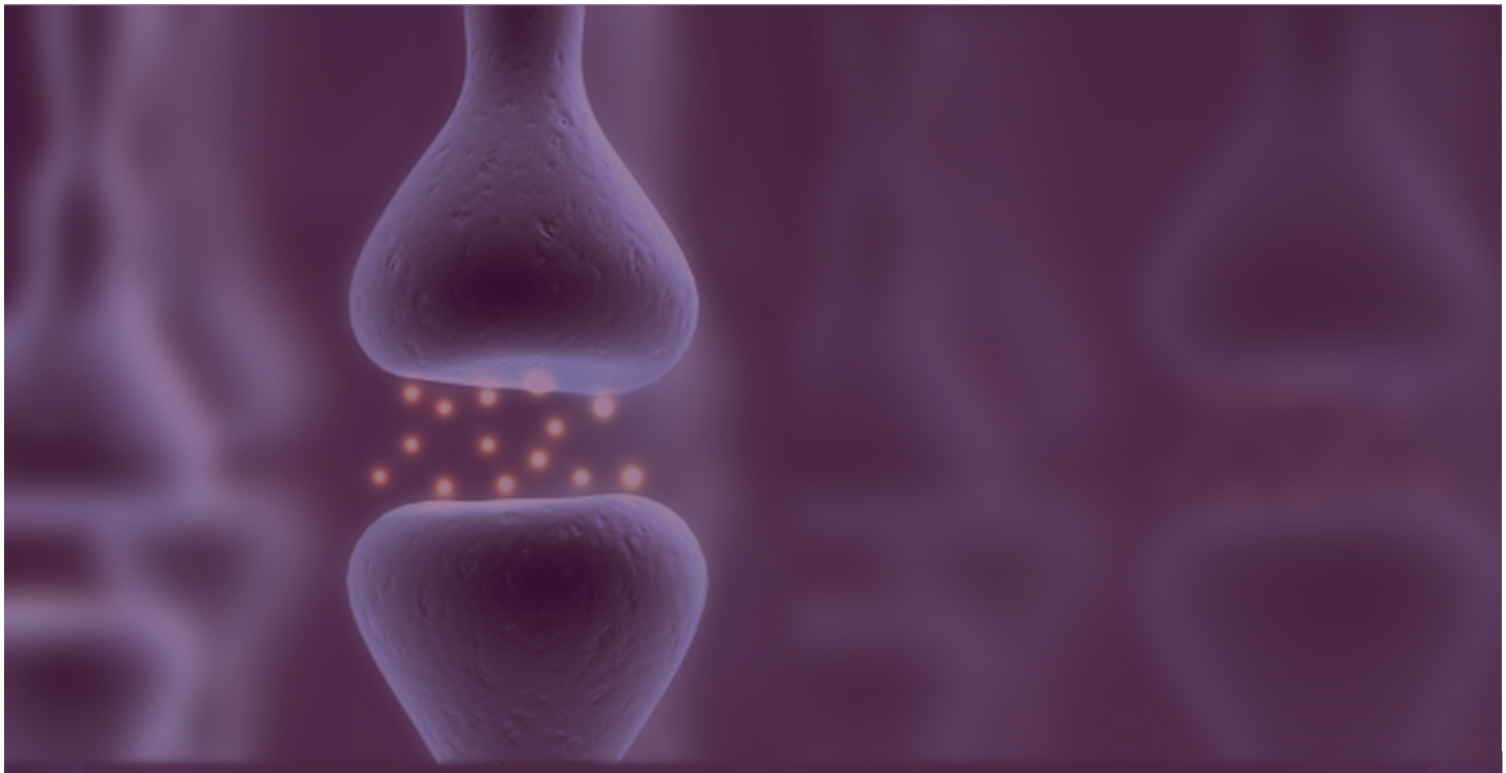

SYNAPSE

A quarterly update on the Pharmaceutical Industry

Vol. IV/Issue I/
January 1, 2020 – March 31, 2020

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SYNAPSE

Dear Readers,

We hope that all of you and your families are safe and healthy at this time.

As we all embrace a new way of life that is governed by a paramount need to observe social distancing and try to stand informed of all that goes around us, we present you with the latest issue of our quarterly Pharmaceutical, Healthcare and Life Sciences practice newsletter- *Synapse*.

2020 started on a very positive note. Things were looking up for the pharma industry. We saw a steady stream of transactions and disputes across the board. There was some regulatory action as well. However, the world was soon faced with the COVID-19 pandemic. The normal changed. As the virus spread across borders from its origins in Wuhan, China, countries across the world scrambled to take action to prevent the spread. Some countries like Italy, the UK and USA are affected very badly. India too has not remained immune to this crisis and despite a slow start and a hard lockdown enforced on the entire country, the number of infections and fatalities continue to rise. The normal has certainly been disrupted.

Given lockdowns or work from home directives that have become global actions, the resultant curbs on daily activity had an unmistakable impact on economic activity and increase in uncertainty in the markets. M&A activity in the pharma sector was also hit. All litigation activity was halted as most courts started minimizing their operations starting from early March and limited their functioning to matters of urgent nature. That said, given the pandemic situation and the resolve of the Government to deal with the same, a lot of regulatory action has been taken. The early part of the quarter saw some long-awaited amendments being brought into the regulatory framework for drugs and medical devices and the later part of the quarter was dominated by the Government's response to the COVID-19 crisis. The priority of the Government, the courts and sectoral watchdogs was clearly to focus on the fight against COVID-19, and this is reflected in actions that have been taken on a daily basis. The real newsmakers at this time have been the Ministry of Health and Family Welfare, the Central Drugs Standard Control Organization (**CDSCO**), the Indian Council of Medical Research and to the National Pharmaceuticals Pricing Authority (**NPPA**).

In this issue, in addition to the routine amendments and notifications, we have also endeavored to highlight some of the most important regulatory developments, with a direct bearing on the pharmaceutical and life sciences sector, which were aimed at fighting the current COVID- 19 crisis, such as restrictions on export of certain essential drugs, price caps on masks and sanitizers, introduction of guidelines on telemedicine and doorstep delivery of drugs and expedited approval processes initiated by the sectoral regulators. The crisis has not passed yet and is a rapidly developing situation.

Cyril Amarchand Mangaldas, India's premier full-service law firm has an industry leading and dedicated Pharmaceutical, Healthcare and Life Sciences

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practice. Our class leading practice specialists are always on top of the latest developments in the sector. In our endeavor to keep you abreast of the latest developments in this dynamic sector, we present to you **Volume IV Issue I** of **Synapse**. While we hope you enjoy reading this newsletter from the safety of your homes, as always, your feedback makes us improve our efforts. 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 tracking development in pharmaceutical and healthcare sector.

Take care and stay safe!

Regards,
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REGULATORY UPDATES

1. Regulatory Response to the COVID-19 Pandemic

In view of the COVID-19 pandemic, the Government and various regulatory authorities have come up with, and notified various rules and regulations to combat this crisis. Some of the most important responses vis-à-vis the pharmaceuticals and healthcare sector are as follows:

(a) Price Control for Masks and Sanitizers

The Department of Consumer Affairs, Ministry of Consumer Affairs, Food and Public Distribution (Consumer Affairs Department), vide Gazette Notification no. SO 1087(E) dated March 13, 2020[1] , notified the ***Essential Commodities Order, 2020.***

In terms of the said order, the Schedule to the Essential Commodities Act, 1955 was amended to include 'masks (2ply & 3ply surgical masks, N95 masks) & hand sanitizers' was included. This notification will remain in force till June 30, 2020.

Further, the department *vide* Gazette Notification no. SO 1169(E) dated March 19, 2020[2], notified the 'Ingredients and Prices of the Ingredients as Raw Materials of Essential Commodities Order, 2020' in order to regulate the production, quality, distribution, prices and other aspects of alcohols used in manufacturing the hand sanitizers for preventing infections due to virus and bacteria. In terms of the said order, the raw material used in manufacturing an essential commodity shall be treated as essential commodity and the prices of the alcohols used in manufacturing the hand sanitizers shall not exceed from those prevailing on March 5, 2020 without concurrence of the Central Government. This notification will also remain in force till June 30, 2020.

Thereafter, the department *vide* Gazette Notification no. SO 1197(E), dated March 21, 2020[3] , notified the 'Fixation of Prices of Masks (2ply & 3ply), Melt Blown non-Woven Fabric and hand Sanitizers Order, 2020' in order to regulate the prices of masks (2ply and 3ply), melt blown non-woven fabric used as raw material in production of masks, masks (2ply and 3ply) and hand sanitizers for preventing infections due to COVID-19 virus. In terms of the said order, retail prices of:

i. melt blown non-woven fabric used in manufacturing masks (2ply and 3ply), shall not be more than the prices prevailing on February 12, 2020;

ii. masks (3ply surgical mask), shall not be more than the prices prevailing on February 12, 2020 or not more than INR 10 (Indian Rupees Ten) per piece whichever is lower;

iii. mask (2ply) shall not be more than INR 8 (Indian Rupees Eight) per piece;

iv. hand sanitizer shall not be more than INR 100 (Indian Rupees One Hundred) per bottle of 200ml, and the prices of other quantities of hand sanitizers shall be fixed in the proportion of these prices.

This notification will also remain in force till June 30, 2020.

The aforementioned order was amended vide Gazette Notification no. SO 1207(E) dated March 24, 2020[4], whereby retail prices of 3ply surgical masks containing a layer of melt blown non-woven fabric has been set to not exceed INR 16 (Indian Rupees Sixteen) per piece. Further, the CDSCO, vide a letter to the Drug Controllers of States and Union Territories[5], requested them to submit the list of manufacturers under their jurisdiction, who were manufacturing hand sanitizers and directed them to intensify regulatory oversight on manufacture and distribution of the

[1] http://www.egazette.nic.in/WriteReadData/2020/218645.pdf
[2] http://www.egazette.nic.in/WriteReadData/2020/218808.pdf
[3] http://www.egazette.nic.in/WriteReadData/2020/218845.pdf
[4] http://www.egazette.nic.in/WriteReadData/2020/218904.pdf
[5] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTc4Nw==

same. The authorities were also requested to expedite the licensing process for manufacture of hand sanitizers.

(b) Prohibition of Export of Ventilators and Sanitizers

The Directorate General of Foreign Trade, Ministry of Commerce and Industry (**DGFT**), *vide* Gazette Notification no. 53/ 2015-2020 dated March 24, 2020[6], amended Schedule 2 of the ITCHS Export Policy, 2018. In terms of this notification, export of 'all ventilators including any artificial respiratory apparatus or oxygen therapy apparatus or any other breathing appliance/ device falling under any ITCHS Code' and 'Sanitizers falling under any ITCHS Code' was prohibited with immediate effect.

(c) Prohibition of Export of '*Hydroxychloroquine*'

The DGFT, *vide* Gazette Notification no. SO 1208(E), dated March 25, 2020[7], amended Schedule 2 of the ITC(HS) Export Policy, 2018. In terms of this notification, export of: (i)'Hydroxychloroquine'; and (ii) formulations made from 'Hydroxychloroquine' was prohibited with immediate effect, except certain circumstances. Thereafter, *vide* Gazette Notification no. SO 1247(E) dated April 4, 2020[8], the circumstances and conditions under which the export of 'Hydrochloroquine' and formulations made from it was allowed, were revoked. The export of Hydroxychloroquine and formulations made from Hydroxychloroquine, therefore, was prohibited, without any exception.

(d) Regulation of Sale of '*Hydroxychloroquine*'

In addition to the prohibition on export of Hydroxychloroquine and formulations made from Hydroxychloroquine, the Department of Health and Family Welfare, Ministry of Health and Family Welfare (**MoHFW**), *vide* Gazette Notification no. GSR 219(E) dated March 26, 2020[9], in exercise of the powers granted under Section 26B of the Drugs and Cosmetics Act, 1940 (**D&C Act**), directed that sale by retail of any preparation containing the drug 'Hydroxychloroquine' shall be in accordance with the conditions for sale of drugs specified in Schedule H1 to the Drugs and Cosmetics Rules, 1945 (**D&C Rules**).

By way of this direction, sale of any preparation containing the drug 'Hydroxychloroquine' would require a valid prescription from a registered medical professional. In terms of this notification, the drug 'Hydroxychloroquine' is essential to meet the requirements of emergency arising due to COVID-19 and in the public interest, it is necessary and expedient to regulate and restrict its sale and distribution and for preventing its misuse.

(e) Restriction on Export of Certain Active Pharmaceutical Ingredients and Formulations

In order to address the concerns related to drug security and acute shortage that may arise due to the lack of imports from China, the Department of Pharmaceuticals (**DoP**) constituted a committee under the chairmanship of Dr. Eshwara Reddy, Joint Drugs Controller, CDSCO (**Reddy Committee**). Based on the recommendations of the Reddy Committee, the DoP issued directions the NPPA to ensure price monitoring to ensure affordable prices in the market and prevent black-marketing. To comply with the same the NPPA has also written to Chief Secretaries of States and Principal Secretaries (Health) and State Drug Controllers, requesting them to closely monitor the production and availability of active pharmaceutical ingredients (**APIs**) and formulations to prevent the black marketing and hoarding in their states and union territories as well as to ensure that there is no violation of provisions of the DPCO with regard to compliance of

[6] http://egazette.nic.in/WriteReadData/2020/218924.pdf
[7] http://egazette.nic.in/WriteReadData/2020/218908.pdf
[8] http://egazette.nic.in/WriteReadData/2020/219012.pdf
[9] http://egazette.nic.in/WriteReadData/2020/218927.pdf

ceiling prices/ permissible increase in prices of scheduled/ non-scheduled formulations respectively.

The Reddy Committee, in its report, has mentioned that the present stock-in hand of the APIs may be sufficient for 2 (two) to 3 (three) months to manufacture formulations and has also given recommendations in this regard.

Furthermore, in furtherance to the recommendations of the Reddy Committee, the DoP had written to DGFT to restrict exports of 13 (thirteen) APIs and formulations made using these APIs. These APIs are primarily made in the Hubei province of China.

The Ministry of Commerce and Industry, vide Gazette Notification no. SO 955(E) dated March 3, 2020[10] , amended the export policy of the following APIs and formulations made therefrom:

i. Paracetamol;
ii. Tinidazole;
iii. Metronidazole;
iv. Acyclovir
v. Vitamin B1;
vi. Vitamin B6;
vii. Vitamin B12;
viii. Progesterone;
ix. Chloramphenicol;
x. Erythromycin Salts;
xi. Neomycin;
xii. Clindamycin Salts; and
xiii. Ornidazole

In terms of this notification, the export of the abovementioned APIs and formulations made from these APIs was 'restricted' with immediate effect and till further orders.

SYPNAPSE FLASH! The abovementioned notification was amended again vide Gazette Notification no. SO 1248(E) dated April 6, 2020[11], whereby, the export status of all the above mentioned APIs and formulations made therefrom (apart from Paracetamol and formulations made therefrom), was again changed to 'free'.

(f) Restriction on Export of Diagnostic Kits

The DGFT, vide Gazette Notification no. SO 1246(E), dated April 4, 2020, amended Schedule 2 of the ITC(HS) Export Policy, 2018. In terms of this notification, export of: 'Diagnostic Kits (Diagnostic or laboratory reagents on a backing, preparation diagnostic or laboratory reagents whether or not on a backing, other than those of heading 3002 or 3006; certified reference materials)' was restricted with immediate effect.

(g) Doorstep Delivery of Drugs

With a view towards regulating the retail sale of drugs by way of doorstep delivery to consumer, the MoHFW, *vide* Gazette Notification no. GSR 220(E) dated March 26, 2020[12], in exercise of the powers conferred by Section 26B of the D&C Act directed that in case any person holding a license in Form 20 or Form 21 under the D&C Rules intends to sell any drug, including the drugs specified in Schedule H except narcotics, psychotropics and controlled substances as defined in the Narcotic Drugs and Psychotropic Substances Act, 1985 and the drugs as specified in Schedule H1 and Schedule X of the D&C Rules, by retail with doorstep delivery of the drug, the licensee can sell such drugs subject to the condition that any such sale of a drug specified in Schedule H shall be based on receipt of prescription physically or through e-mail and such sale of drugs shall further be subject to the following conditions:

[10] http://egazette.nic.in/WriteReadData/2020/216551.pdf
[11] http://www.egazette.nic.in/WriteReadData/2020/219015.pdf
[12] http://egazette.nic.in/WriteReadData/2020/218928.pdf

i. The licensee shall submit an e-mail ID for registration with the licensing authority if prescriptions are to be received through e-mail;

ii. The drugs shall be supplied at the doorstep of the patients located within the same revenue district where the licensee is located;

iii. In case of chronic diseases, the prescription shall be dispensed only if it is presented to the licensee within 30 (thirty) days of its issue and in acute cases, the prescription shall be dispensed only if it is presented to licensee within 7 (seven) days of its issue; and

iv. The bill or cash memo shall be sent by the return e-mail and records of all such transactions shall be maintained by the licensee.

(h) Expedited Regulatory Pathway for Research and Development of Diagnostic Kits, Drugs and Vaccines

The CDSCO, *vide* public notice dated March 19, 2020[13] , clarified that in order to encourage research and development (**R&D**) of in-vitro diagnostic kits for diagnosis of COVID-19, any application submitted to the CDSCO will be processed on high priority and that the CDSCO will also provide guidance on the regulatory pathway on the matter. Similarly, *vide* public notice dated March 19, 2020[14], it was clarified that in order to encourage R&D of drug or vaccine for prevention or treatment of COVID-19, any application submitted to the CDSCO will also be processed on a high priority basis.

In terms of these notices, any firm having an in-vitro diagnostic kit, drug or vaccine under development for COVID-19 can directly approach the Drugs Controller General of India (**DCGI**) through the public relations office for seeking guidance on the regulatory pathway. Firms having already approved diagnostic kits in other countries can also approach the DCGI through the public relations office for expedited review/ accelerated approval for marketing in India. In this regard, the data requirement for clinical performance evaluation may be abbreviated, waived off or deferred on a case to case basis. Any firm or research institute having a protocol for repurposing of existing drugs or vaccines for COVID-19 will also be given priority for review and approval. Applications for clinical trial permissions and applications to import or manufacture drugs or vaccines for sale and distribution would also be processed on priority through the expedited review/ accelerated approval process. Further, any firm having a drug or vaccine which is already approved in other countries can also approach the DCGI through the public relations office for expedited review/ accelerated approval for marketing in India. The data requirement for animal toxicity study, clinical study, stability study etc. may be abbreviated, deferred or waived on a case to case basis.

The applications for manufacture or import of kits for testing, evaluation or further performance evaluation, or a drug or vaccine for test, analysis and further use in bioavailability or bioequivalence studies or clinical trial would be processed on priority within a period of 7 (seven) days. The applications for conducting performance evaluation or import or manufacture test kits for sale and distribution will also be processed on priority through the expedited review/ accelerated approval process. In case of an emergency and subject to approval of the Central Government, import license in Form 10 for drugs and vaccines would be granted without registration certificates.

(i) Guidelines on Telemedicine

The MoHFW, on March 25, 2020, issued the Telemedicine Practice Guidelines

[13] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTc3MA==
[14] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTc2OQ==

(Guidelines) thereby providing registered medical practitioners (RMPs) with the approval to treat patients remotely by using the telemedicine tools at their disposal. Given the current COVID-19 pandemic and the efforts at maintaining social distancing that the country is making, these crucial and long pending guidelines, will serve as an important tool to enable delivery of widespread healthcare services to the general masses of the country. Some salient features of these guidelines are as under:

i. **Definitions**: The Guidelines define terms like 'Telemedicine', 'Telehealth' and 'Registered Medical Practitioner'. Though the definitions of telemedicine and telehealth are borrowed from other sources, the assimilation of the same into the said Guidelines helps establish a much-required scope/ ambit and single point of reference for the same.;

ii. **Scope and Exclusion:** The Guidelines will be published under the Indian Medical Council Act, 1956 (**IMC Act**) and the same will be applicable on RMPs (as defined under the IMC Act) and will act as an aid and tool to enable RMPs to effectively leverage telemedicine.

iii. **Types:** Telemedicine applications have been segregated into four different types, that is, based on - (a) mode of communication, (b) timing of the information transmitted, (c) the purpose of the consultation and (d) the interaction between the individuals involved.

iv. **Professional and Ethical standards:** The Guidelines clearly stipulate that *RMPs using telemedicine shall uphold the same professional and ethical norms and standards as applicable to traditional in-person care, within the intrinsic limitations of telemedicine*[15]. Additionally, it also states that RMPs who intend to practice telemedicine will have to undertake an online course for the same.[16]

v. **Guidelines for telemedicine in India:**

- ***Context:*** an RMP is to exercise his/ her professional judgement and discretion to determine whether the particular case being presented by the patient is appropriate for a telemedicine consultation or whether the same mandates an in-person consultation.
- ***Identification of RMP and Patient:*** it is very crucial to establish the identity of both the RMP and the patient. The RMP has to seek all the information from the patient as may be deemed appropriate to establish the identity of the patient. Furthermore, the RMP shall make available to the patient his/ her credentials and contact details.
- ***Identification of RMP and Patient:*** it is very crucial to establish the identity of both the RMP and the patient. The RMP has to seek all the information from the patient as may be deemed appropriate to establish the identity of the patient. Furthermore, the RMP shall make available to the patient his/ her credentials and contact details.
- ***Mode of Telemedicine:*** with the advent of information technology there are several tools that may be used to cater to telemedicine services. The Guidelines categorize such tools/ modes into three major categories – video, audio or text, and elaborates on the characteristics and drawbacks of each mode of telemedicine.
- ***Patient Consent:*** patient consent is extremely crucial in any telemedicine consultation and the same may be express or implied. If the patient initiates the consultation then the consent is implied and if a health worker, caregiver or RMP initiates the consultation then the express consent of the patient is to be made known.

[15] https://www.mohfw.gov.in/pdf/Telemedicine.pdf.

[16] The said online course will be developed and notified by Board of Governors in supersession of Medical Council of India. The RMPs will need to undertake the said course within three years of the same being notified. Till the time such an online course is being developed, the practice of telemedicine will be guided by the said Guidelines.

- ***Exchange of Information for Patient Evaluation:*** though the guidelines give an indicative framework of the kind of information that is to be sought from a patient, the onus is placed on the RMP to gather sufficient medical information about the patient's condition before making any professional judgment. The RMP is to also maintain records of such patient information.
- ***Types of Consultation:*** the Guidelines segregate the types of consultations into first consultation and follow-up consultation, and also lay down the scope and ambit of such consultations.
- ***Patient Management:*** if the RMP is of the opinion that the condition exhibited by the patient can be adequately managed by telemedicine then he/ she may (a) provide health education, and/ or (b) provide counselling of a particular clinical condition, and/ or (c) prescribe medicines.
- Furthermore, on the issue of prescribing medicines, the Guidelines clearly emphasize that the same is at the professional discretion of the RMP and will entail the same professional accountability as in the traditional in-person consultation. The RMP can only prescribe drugs mentioned in Lists O, A and B and cannot prescribe medicines enlisted in the Prohibited List vide telemedicine consultation.
- Additionally, while issuing the prescription, the RMP is to abide by the provisions of Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 and the D&C Act and D&C Rules.
- The Guidelines also highlight the duties and responsibilities of the RMP regarding medical ethics, data privacy and confidentiality. It also states the penalty provisions upon violation of the said duties and responsibilities.

vi. **Framework for Telemedicine:** The Guidelines provide for an in-detail elaboration of the framework to be followed by the RMP for practicing telemedicine. The five scenarios that have been elaborated upon are – (a) patient to RMP, (b) caregiver to RMP, (c) health worker to RMP, (d) RMP to RMP and (e) emergency situations.

vii. **Guidelines for Technology Platforms Enabling Telemedicine:** The Guidelines also provide for a set of recommendations/ advice to be followed by technology platforms which enable such telemedicine services. These recommendations include due diligence to be carried out by such platforms, to reporting requirements in case of any non-compliance and blacklisting of such technology platforms in case of violation.

viii. **Special Responsibilities of Board of Governors (BoG):** The Guidelines lay down certain powers at the disposal of the BoG in Supersession of the Medical Council of India, such as the power modify any drug list contained in the Guidelines, issue advisories and amend the Guidelines in the larger public interest.

(j) Maintenance of Stock of 'Lopinavir & Ritonavir (200mg + 50mg)'

The NPPA, vide an order dated March 25, 2020[17], in order to deal with the present Covid-19 situation, directed manufacturers of the fixed dose combination drug 'Lopinavir & Ritonavir (200mg + 50mg)' to maintain the stock levels of the said drug at- at least 2,20,00,000 (two crore twenty lakh) tablets at any point of time and to also ensure sufficient availability of the said drug un till further orders. The amount of stock that each identified manufacturer is required to

[17] http://www.nppaindia.nic.in/wp-content/uploads/2020/03/NPPA-Order-dated-25.03.2020.pdf

maintain individually, has also been notified vide this order. This is ostensibly to cater to requirements as there are reports that this drug combination has shown some promise in COVID-19 treatment protocols.

(k) Testing in Private Laboratories

In the early stages of the outbreak of COVID-19, testing was limited to symptomatic patients and was carried out only through designated Government laboratories. However, the Indian Council of Medical Research (**ICMR**) issued a revised strategy for COVID-19 testing in India[18] on March 20, 2020. In terms of this testing strategy, all symptomatic individuals who had undertaken international travel in the last 14 (fourteen) days, all symptomatic contacts of laboratory confirmed cases, all symptomatic health care workers, and all hospitalized patients with Severe Acute Respiratory Illness (fever and cough and/ or shortness of breath) would be tested. Further, asymptomatic direct and high-risk contacts of a confirmed case should be tested once between day 5 (five) and day 14 (fourteen) of coming in his/ her contact.

Thereafter, testing was also expanded to private laboratories which had National Accreditation Board for Testing and Calibration Laboratories accreditation. In this regard, the MoHFW, *vide* an order dated March 21, 2020[19] issued guidelines for COVID-19 testing in private laboratories in India. Salient features of these guidelines are:

i. Appropriate biosafety and biosecurity precautions should be ensured while collecting respiratory samples. Preferable, home collection of samples should be done;

ii. Commercial kits for real time Polymerase Chain Reaction (**PCR**) based diagnosis of COVID-19 should be US FDA approved or European CE certified for in vitro diagnosis of COVID-19 under emergency use;

iii. Laboratory staff involved in COVID-19 testing should be trained in Good Laboratory Practices and performing real time PCR;

iv. All biomedical waste should be disposed according to applicable national guidelines;

v. Government ID to support the current address and contact number of the suspected patient should be collected at the time of sample collection;

vi. Before starting testing activities, the laboratory should ensure real time reporting of test results along with contact details to the ICMR;

vii. Each laboratory will be given a registration number by the ICMR which should be indicated in any advertisement or report;

viii. No laboratory should amplify the virus by culture or sequence the virus from any positive sample[20]. All positive samples will be transported to ICMR-NV, Pune and negative samples should be destroyed within 1 (one) week of collection;

ix. No sample should be shared with any other organisation for any purpose;

x. The recommended maximum cost for testing should not exceed INR 4,500 (Indian Rupees Four Thousand Five Hundred). This may include INR 1,500 (Indian Rupees One Thousand Five Hundred) as screening test for suspect cases and an additional INR 3,000 (Indian Rupees Three Thousand) for confirmation test.

(l) Guidelines and Standard Operating Procedures

The MoHFW issued multiple guidelines and standard operating procedures (**SOP**) to be followed by various stakeholders, such as healthcare professionals, Government

[18] https://www.mohfw.gov.in/pdf/ICMRrevisedtestingstrategyforCOVID.pdf
[19] https://icmr.nic.in/sites/default/files/whats_new/Notification_ICMR_Guidelines_Private_Laboratories.pdf
[20] https://icmr.nic.in/sites/default/files/upload_documents/Addendum_ICMR_guideline_Private_Lab.pdf

departments and citizens to formalize the response to COVID-19 around a well-documented process. Some of the most important guidelines and SOPs that have been issued are as follows:

i. *Revised Guidelines for Management of COVID-19*[21]: This document is intended for clinicians taking care of hospitalised adult and paediatric patients of COVID-19. It aims to provide clinicians with updated guidance on timely, effective, and safe supportive management of patients with COVID-19;

ii. *SOP for Transporting a Suspect/ Confirmed Case of COVID-19*[22] : This SOP is intended to guide and be used for training ambulance drivers and technicians in transporting COVID-19 patients. It also aims to support programme officers in monitoring functionality and infection prevention protocols of the ambulances;

iii. *Guidelines on Disinfection of Common Public Places Including Offices*[23]: These guidelines aim to provide guidance about the environmental cleaning/ decontamination of common public places including offices in areas reporting COVID-19. In terms of these guidelines, public places have been divided into (i) indoor areas; (ii) outdoor areas; and (iii) public toilets. Disinfection strategies and guidelines for each of these 3 (three) areas have been provided in the document;

iv. *Guidelines for Dialysis of COVID-19 Patients*: The MoHFW, on April 1, 2020 issued Guidelines for Dialysis of COVID-19 patients. In terms of these guidelines, chronic kidney disease stage-5 patients on dialysis or continuous ambulatory peritoneal dialysis are vulnerable because of their existing comorbidities, repeated unavoidable exposure to hospital environment and immunosuppressed state. In terms of these guidelines, patients on regular dialysis should adhere to prescribed schedule and not miss their dialysis sessions to avoid any emergency dialysis. In this regard, directions and guidelines have been issued for state and district level health administrations to earmark facilities for haemodialysis and allow movement of patients and suppliers of dialysis consumables. Precautionary and safety guidelines to be followed by the dialysis units and the patients have also been issued.

(m) Essential Technical Features of Ventilators

The Technical Committee of Defence Research and Development Organisation (**DRDO**) was tasked to identify the essential technical features for ventilators for COVID-19. The same was reviewed by the DRDO and the identified technical features of ventilators for COVID-19 are[24]:

i. the machine should be turbine/ compressor based because the installation sites might not have central oxygen lines;

ii. the machine should have invasive, non-invasive and Continuous Positive Airway Pressure features;

iii. 200-600 ML tidal volume, Lung Mechanics Display;

iv. monitoring of Plateau Pressure, Positive End Expiratory Pressure, PS, oxygen concentration, lung mechanics/ inverse ratio (I:E);

v. pressure and volume control and Pressure Support Ventilation; and

vi. continuous working capability for 4 (four) to 5 (five) days.

(n) Rapid Response Regulatory Framework for COVID-19 to Deal with Applications for Development of Vaccines, Diagnostics, Prophylactics, and Therapeutics

The Ministry of Science and Technology,

[21] https://www.mohfw.gov.in/pdf/RevisedNationalClinicalManagementGuidelineforCOVID19310320 20.pdf
[22] https://www.mohfw.gov.in/pdf/StandardOperatingProcedureSOPfortransportingasuspectorconfirmedcaseofCOVID19.pdf
[23] https://www.mohfw.gov.in/pdf/GuidelinesondisinfectionofcommonpublicplacesincludingoffIces.pdf
[24] https://www.mohfw.gov.in/pdf/EssentialTechfeaturesforVentilators.pdf

vide office memorandum dated March 20, 2020[25], notified its decision to fast track the regulatory approval process in relation to applications for development of vaccines, diagnostics, prophylactics and therapeutics for COVID-19 as follows:

i. The Review Committee on Genetic Manipulation (**RCGM**) shall approval applications for import, exchange, and permission for initiating research work fulfilling all criteria within 7 (seven) days of receipt of applications along with recommendation of institutional biosafety committee on the Indian Biosafety Knowledge Portal;

ii. Examination of physico-chemical and molecular characterization data, approval of animal toxicity protocol, and recommendation of RCGM for appropriate stage of clinical trial will be given in 10 (ten) days after submission of required data and information;

iii. Approval in Form 29 (*license to manufacture drugs for purposes of examination, test or analysis*), test license and NOC for manufacture by CDSCO will be given within 10 (ten) days from receipt of the application;

iv. CDSCO shall make a Corona unit to address queries related to development of diagnostics, prophylactics and therapeutics for COVID-19.

(o) Invocation of the Epidemic Diseases Act, 1897

Since the spread of the COVID-19 pandemic, the Epidemic Diseases Act, 1897 (**ED Act**) has gained prominence. On March 11, 2020, the Cabinet Secretary of India, announced that the Centre has decided to invoke the ED Act in order to combat the COVID-19 pandemic in the country and further advised that all States and Union Territories in India should invoke provisions of the Section 2 of the ED Act.[26] After this the governments of majority of the states and union territories have invoked the ED Act by way of a notification and have laid out corresponding regulations to deal with the ensuing crisis. Salient features of the ED Act are as under:

i. In terms of the ED Act, both the Central and State Governments have been given powers to take certain actions for better prevention of the spread of dangerous epidemic diseases. The ED Act is among the shortest acts in India, comprising merely four sections.

ii. Section 2 of the ED Act provides for the powers of the State Governments to take special measures and prescribe regulations during the outbreak of an epidemic diseases. It states that if the State Government "thinks that the ordinary provisions of the law for the time being in force are in sufficient for the purpose, may take, or require or empower any person to take, such measures and, by public notice, prescribe such temporary regulations to be observed by the public or by any person or class of persons" to control the outbreak and spread of such disease.

iii. Section 2A of the ED Act provides the powers of the Central Government to take measures and pass regulations for the inspection of any ship arriving or leaving India and for the detention of any person intending to sail therein if it "is satisfied that Indian or any part thereof is visited by, or threatened with, an outbreak of any dangerous epidemic disease and that the ordinary provisions of the law for the time being in force are insufficient to prevent the outbreak of such disease or the spread thereof".

iv. According to Section 3 of the ED Act, any person who disobeys an order or regulation made by the Government

[25] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTc4Mw==
[26] https://www.thehindubusinessline.com/news/national/centre-invokes-epidemic-act-and-disaster-management-act-to-prevent-spread-of-coronavirus/article31049161.ece

under the ED Act, shall be punished in accordance with Section 188 of the Indian Penal Code, 1860 (**IPC**). Section 188 of the IPC imposes punishment for disobeying an order promulgated by a public servant. Under the said section, disobeying an order passed by a public servant and "if such disobedience causes or tends to cause obstruction, annoyance or injury, or risk of obstruction, annoyance or injury", it shall be punishable with simple imprisonment which may extend up to a month and/or a fine of up to INR 200 (Indian Rupees Two Hundred). However, if this disobedience "causes or trends to cause danger to human life, health or safety, or causes or tends to cause a riot or affray", it shall be punishable with imprisonment extending up to 6 (six) months and/or fine up to INR 1,000 (Indian Rupees One Thousand).

v. Section 4 of the ED Act provides protection to public servants from legal action while acting in good faith under the provisions of the ED Act.

(p) Suo Motu Writ Petition (Civil) No(s) 3/2020 by Supreme Court of India in Cognizance for Extension of Limitation, dated March 23, 2020

On account of the unforeseen challenge faced by the country and the global community in general due to the rapid spread of the novel corona virus, the Supreme Court of India while exercising its powers under Articles 141 and 142 of the Constitution, has taken up *suo-motu* cognizance of the said situation and the consequent implication it has on litigants across the country in filing their petitions/ applications/ suits/ appeals/ all other proceedings within the period of limitation prescribed under the general law of limitation or under Special Laws (both Central and/or State). The Supreme Court has ordered that the period of limitation in all such proceedings (irrespective of the limitation prescribed under the general law or Special Laws whether condonable or not) shall stand extended with effect from March 15, 2020 till further order(s) are passed regarding the same by the said court.

(q) Advisories on Mental Health

The MoHFW has been constantly publishing advisories and recommendations, urging people to take care of their mental health during the crisis. A detailed note on 'Minding our Minds During the COVID-19' [27] was published which inter alia contains guidance on understanding the importance of the lockdown imposed across the country, strategies to handle social isolation, handling emotional problems, recognition of mental health problems, and contact details of the mental health helpline. Specialized guidance documents on taking care of mental health of the elderly[28] and children[29] have also been issued.

2. Introduction of Concept of Marketer in the Drugs and Cosmetics Rules, 1945[30]

The MoHFW, *vide* Gazette Notification no. GSR 101(E) dated February 11, 2020, notified the Drugs and Cosmetics (Amendment) Rules, 2020. In terms of this amendment, the concept of a 'marketer' has been introduced in the D&C Rules. The salient features of this amendment are:

i. 'Marketer' has been defined to mean a person who as an agent or in any other capacity adopts any drug manufactured by another manufacturer under an agreement for marketing of such drug by labelling or affixing his name on the label of the drug with a view for its sale and distribution;

ii. A new Rule 84D has been introduced in the D&C Rules, which provides that no 'marketer' shall adopt any drug manufactured by another manufacturer for marketing of such drug by labelling or affixing his name on the

[27] https://www.mohfw.gov.in/pdf/MindingourmindsduringCoronaeditedat.pdf
[28] https://www.mohfw.gov.in/pdf/mentalhealthelderly.pdf
[29] https://www.mohfw.gov.in/pdf/mentalhealthchildrean.pdf
[30] http://egazette.nic.in/WriteReadData/2020/216113.pdf

label of the drug with a view for its sale and distribution without an agreement;

iii. A new Rule 84E has been introduced in the D&C Rules which provides that any 'marketer' who sells or distributes any drug shall be responsible for quality of that drug as well as other regulatory compliances along with the manufacturer under the D&C Rules;

iv. The name of the 'marketer' of the drug and its address, in case the drug is marketed by a 'marketer' is required to be printed on the label of the drug.

3. Introduction of Concept of Blood Centres in the Drugs and Cosmetics Rules, 1945[31]

The MoHFW, *vide* Gazette Notification no. GSR 166(E) dated March 11, 2020, notified the Drugs and Cosmetics (Second Amendment) Rules, 2020. In terms of the amendment to the D&C Rules, the words 'blood banks' have been replaced with 'blood centres'. The salient features of this amendment are:

i. 'Blood centres' have been defined to mean an authorized premises in an organization or institution as the case may be, for carrying out all or any of the operations including collection, apheresis, processing, storage and distribution of blood drawn from donors or received from another licensed Blood Centre and for preparation, storage and distribution of blood components;

ii. 'Erythrocytapheresis' has been defined to mean selective collection of one or two units of red cells from a donor or patient using a cell separator and re-transfusing the remaining blood into the donor or patient;

iii. The qualifications of the competent technical staff under whose personal supervision operation of 'blood centres' or processing or both of whole human blood for components shall be conducted, have been prescribed;

iv. Amendment have been made in Schedule A, Schedule F and Schedule K of the D&C Rules to reflect the substitution of 'blood banks' with the new concept of 'blood centres'.

4. Medical Devices: All Devices Now Covered as '*drugs*' and Under Price Control.

The MoHFW, *vide* Gazette Notification no. SO 648(E) dated February 11, 2020[32], significantly expanded the definition of the term '*medical devices*'. In terms of this notification, the following devices intended for use in human beings or animals have been notified as drugs with effect from April 1, 2020:

"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 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 or disability;*

iii. *investigation, 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."*

As a direct follow through to the above, the NPPA vide Gazette Notification no. SO 1232(E) dated March 31, 2020[33], clarified that all medical devices shall be governed under the provisions of the Drug (Price Control) Order, 2013 (**DPCO**).

[31] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTc2MQ==
[32] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTU0OA==
[33] http://www.nppaindia.nic.in/wp-content/uploads/2020/04/Order-dt.01.04.2020-for-govt-Mediacl-Devices-under-DPCO-2013.pdf

Henceforth, provisions of the Drugs and Cosmetics Act, 1940 and the Medical Devices Rules, 2017 shall be applicable across the board on all medical devices that fall within the aforesaid definition and are notified as such. It may also be noted that provisions of the Drugs and Cosmetics Rules, 1945 would also apply thereto in so far as licensure requirements for sale of medical devices are concerned.

5. Registration of Medical Devices

The MoHFW, *vide* Gazette Notification no. GSR 102(E) dated February 11, 2020[34], notified the Medical Devices (Amendment) Rules, 2020, which provides for the registration of 'medical devices' in a phased manner, with effect from April 1, 2020. The salient features of this amendment are:

i. A new Chapter IIIA (Registration of Certain Medical Devices) has been introduced in the Medical Devices Rules, 2017 (**MD Rules**);

ii. Chapter IIIA is 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. In this regard, an Annexure to the Eighth Schedule has also been notified vide this notification;

iii. The devices shall be registered with the Central Licensing Authority through an identified online portal;

iv. The registration shall be on voluntary basis for a period of 18 (eighteen) months from the commencement of Chapter IIIA and thereafter, it shall be mandatory;

v. An exemption from the application of the MD Rules has been provided in respect of medical devices other than those specified in the Annexure to the Eighth Schedule, subject to the condition that such medical devices are registered under Chapter IIIA. Further, this exemption shall cease after a period of 30 (thirty) months for Class A and Class B devices and after a period of 42 (forty two) months for Class C and Class D devices, from the date of the notification.

6. Prohibition on Import of Certain Drugs

The MoHFW, *vide* Gazette Notification no. GSR 180(E) dated March 16, 2020[35], in exercise of the powers conferred by section 10A of the D&C Act, prohibited the import of (i) Chenodeoxycholic acid extracted and prepared from porcine sources; and (ii) Ursodeoxycholic acid extracted and prepared from porcine sources. This step was taken as these drugs are likely to involve risk to human beings and animals and it was necessary and expedient to prohibit the import of the said drugs in the public interest.

7. Draft Amendment to the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954

The MoHFW, *vide* a public notice dated February 3, 2020[36], published a draft of the Drugs and Magic Remedies (Objectionable Advertisements) (Amendment) Bill, 2020. The salient features of this Bill are:

i. It proposes to increase the ambit of the term 'advertisement' by defining it to mean any audio or visual publicity, representation, endorsement or pronouncement made by means of light, sound, smoke, gas, print, electronic media, internet or website and includes any notice, circular, label, wrapper, invoice, banner, poster or such other documents (Provided that label or wrapper is an advertisement only if it contains any information or claim other than provided in the rules);

ii. It proposes to make amendments to the schedule appended to the Drugs and Magic Remedies (Objectionable Advertisements) Act,

[34] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTU0OQ==)
[35] http://egazette.nic.in/WriteReadData/2020/218732.pdf
[36] https://main.mohfw.gov.in/sites/default/files/Draft%20of%20the%20Drugs%20and%20Magic%20Remedies.pdf

1954 (**DMROA**), whereby several additions, deletions and modifications to the existing list of diseases, disorders and conditions;

iii. It proposes to amend the provision for penalty in the DMROA, by substituting Section 7 with a provision which provides that whoever contravenes any of the provisions of DMROA or the rules made thereunder shall, on conviction, be punishable, in the case of first conviction, with imprisonment which may extend to 2 (two) years and fine up to INR 10,00,000 (Indian Rupees Ten Lakh); and in the case of a subsequent conviction, with imprisonment which may extend to 5 (five) years and fine up to INR 50,00,000 (Indian Rupees Fifty Lakh).

NEWS UPDATES

1. India and the US Inked Two Bilateral Pacts for Mental and Emotional Wellbeing

During the recent visit of the President of the United States of America (USA), Mr. Donald Trump, India and the US entered into two bilateral pacts[37].

The first memorandum of understanding (**MOU**) that has been entered into between the countries is expected to enable India to learn from the USA's research and experience in treating mental health issues, an emerging trend in India[38]. Furthermore, the MOU also facilitates the use of Indian traditional therapies and medicines to address mental health issues as well as facilitate a greater access to such drugs and therapies to the large USA market.

The second MOU that was entered into between the countries is expected to increase access to Indian generic drugs in the USA. The USA has among the largest market in the world for generics drugs and India is a large producer of generic drugs[39].

The said MOUs are expected to give a boost to the exchange of the concerned health care facilities and knowledge between the two countries.

2. Cabinet Approves Assisted Reproductive Technology (Regulation) Bill

The Union Cabinet, on February 19, 2020, approved the Assisted Reproductive Technology (Regulation) Bill (**ART Bill**) which aims at establishing a national registry and registration authority for all clinics and medical professionals serving in the field. Furthermore, the said ART Bill also proposes to impose stringent punishment for practicing sex selection and sale of human embryos or gametes[40].

With the aim to heighten privacy, the said ART Bill proposes to ensure the confidentiality of the commissioning couples, women and donors.

A national and state board has been proposed under the aegis of the ART Bill which will ensure the implementation and enforcement of the legal framework that has been proposed by the said bill. The same will be set up within three months of the ART Bill being notified. The state board shall have the responsibility to follow the policies and plans laid by the national board for clinics and banks in the state.[41] Moreover, a central database of clinics and concerned banks will be established.[42] For more information on the ART Bill, you may refer to our blog post on the subject matter which can be accessed here.

3. Cabinet Approves Amendments in Homeopathy Bill

The Union Cabinet, on January 29, 2020,

[37] https://health.economictimes.indiatimes.com/news/industry/india-and-the-us-inked-two-bilateral-pacts-for-mental-and-emotional-wellbeing/74310042
[38] https://theindianpractitioner.com/2020/02/26/india-us-inks-two-bilateral-pacts-for-mental-and-emotional-wellbeing/
[39] https://overallhealth.in/2020/02/29/india-and-the-us-inked-two-bilateral-pacts-for-mental-and-emotional-wellbeing/
[40] https://health.economictimes.indiatimes.com/news/policy/cabinet-approves-assisted-reproductive-technology-regulation-bill/74217971
[41] https://thewire.in/health/assisted-reproductive-technology-regulation-bill
[42] https://www.thehindu.com/news/national/cabinet-approves-assisted-reproductive-technology-regulation-bill/article30860498.ece

approved amendments that have been proposed in the National Commission for Homeopathy Bill, 2019, (Bill) for amending the Homeopathy Central Council Act, 1973 (**HCC Act**)[43]. The Bill proposes to make necessary amendments to ensure:

i. necessary regulatory reforms in the field of homoeopathy education.

ii. enable transparency and accountability for protecting the interest of the general public. The National Commission will promote availability of affordable healthcare services in all parts of the country.[44]

We see that the HCC Act was enacted for constitution of a central council of homoeopathy for the regulation of education and practice of homoeopathy and further for maintenance of a central register of homoeopathy and for matters connected therewith. The said act provides broad functions, constitution, regulation making powers which are identical to those of the Medical Council of India.

Over the years there have been several issues in relation to the functioning of the central council of homeopathy. This has resulted in a detrimental impact on the study and delivery of quality homeopathy services to the country. With an aim to resolve the same, the current amendments have been proposed in the Bill. The Bill is pending in the Rajya Sabha.[45]

4. Cabinet Approves Raising of Upper Limit for Permitting Abortions to 24 weeks

The Union Cabinet, on January 29, 2020, approved the proposal presented before it in the Medical Termination of Pregnancy (Amendment) Bill, 2020 (Bill) to extend the upper limit for permitting abortions from 20 (twenty) weeks (as it is currently) to 24 (twenty four) weeks[46].

The said Bill once passed will amend the Medical Termination of Pregnancy Act, 1971.

The rationale behind the said proposal is to ensure safe termination of pregnancies and also give women reproductive rights over their bodies. Furthermore, the extension to 24 (twenty four) weeks will also help victims of rape, girls with disabilities as well as minors, who may not realize they are pregnant until later.[47] The said Bill will be placed before the Parliament in its upcoming session.

CASES

1. National Company Law Tribunal (NCLT) Rejects Sun Pharmaceutical Industries Limited's Plan to Demerge Overseas Subsidiary

Sun Pharmaceutical Industries Limited (**Company**) faced a barrier in its plan to consolidate its subsidiaries after the same has been rejected by the Ahmedabad Bench of the NCLT. The Company intended to demerge its overseas subsidiary.

The Company had approached the Ahmedabad bench of NCLT for an approval to transfer investment undertakings from the Company to its Netherlands-based wholly-owned subsidiary. The Company now has the option to challenge the NCLT ruling in higher courts.

In the order that was passed by the Ahmedabad bench of NCLT, the court was called up to adjudicate whether a demerger and transfer of specified business undertaking to another overseas company can be made. The NCLT rejected the said application.

The court in its order reasoned that Section 234 of the Companies Act, 2013 uses the words *merger* and/ *or amalgamation* and does not specifically provide for a *compromise* and/ *or arrangement* and/ *or demerger*. Thus, the same cannot be construed. Further, the procedures and

[43] https://health.economictimes.indiatimes.com/news/industry/cabinet-approves-amendments-in-homeopathy-bill/73731434
[44] https://medicaldialogues.in/ayush/homeopathy/news/national-commission-for-homoeopathy-bill-2019-amendments-approved-by-union-cabinet-62722
[45] https://www.business-standard.com/article/news-ani/cabinet-approves-official-amendments-to-national-commission-for-homoeopathy-bill-2019-120012901173_1.html
[46] https://health.economictimes.indiatimes.com/news/policy/cabinet-approves-raising-of-upper-limit-for-permitting-abortions-to-24-weeks/73733171
[47] https://www.thehindu.com/news/national/cabinet-approves-raising-of-upper-limit-for-permitting-abortions-to-24-weeks/article30683013.ece

requirements related to cross-border mergers also does not prescribe any procedure in relation to demergers. Thus, the same was not allowed by the court and the application was rejected.

We see that the Company in recent times has been consolidating its businesses. In December 2018, the Company completed the demerger of the specified business of Sun Pharma Global FZE and its merger into the Company. The merger has had a significant impact on the standalone Ind-AS financial statements of the Company, including revenue, profit, tax, reserves and comparative numbers. We also note that this was done pursuant to an order of the Ahmedabad Bench of the NCLT passed on October 31, 2018 – the said order being in conflict with the order currently passed by the same bench of the NCLT.

IMPORTANT DEALS

1. Glenmark Sells Gynaecology Business for INR 115 crore

Glenmark Pharma has sold its gynaecology business to Intergrace Pharma. The sale comes two years after Glenmark sold its orthopaedic business to Integrace Pharma[48]. Integrace Pharma will pay INR 1,15,00,00,000 (Indian Rupees One Hundred and Fifteen Crore) for four products of the portfolio that includes products like Dubagest, Mumfer and Fenza. These three products currently have sales of INR 60,00,00,000 (Indian Rupees Sixty Crore) and are growing by 15% (fifteen percent).[49]

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[48] https://indianpharma.in/industry/Glenmark-sells-gynac-business-for-Rs-115-crore

[49] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/glenmark-sells-gynac-business-for-rs-115-crore/articleshow/73494790.cms?from=mdr

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