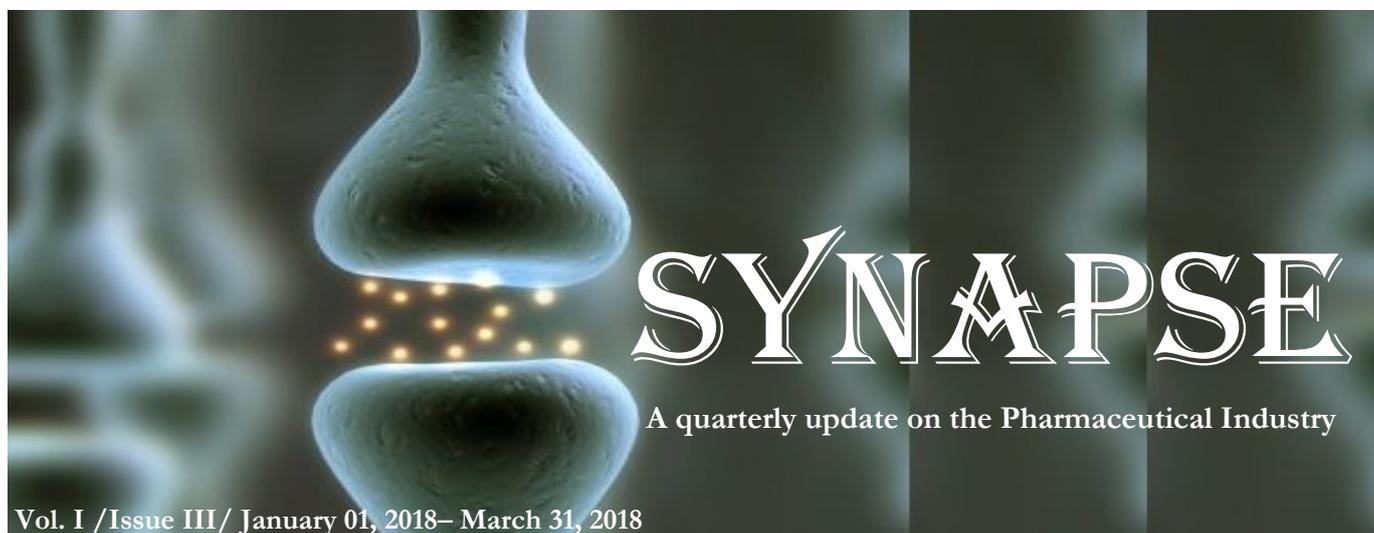




cyril amarchand mangaldas
advocates & solicitors



Dear Readers,

It gives us immense pleasure to bring to you the third issue of our pharma newsletter 'Synapse - a quarterly update on the pharmaceutical industry'. Synapse had been conceptualized to cater to the desire of our esteemed readers to remain updated with the latest happenings in this altogether specialized and niche sector which has lately seen a marked increase in regulatory scrutiny by the regulator in the past few years. Cyril Amarchand Mangaldas, India's premier full service law firm has a dedicated Pharmaceutical, Healthcare and Life Sciences practice, which has subject matter specialists in this sector that are well tuned to the latest sector specific developments and endeavor to share the same in a concise and easy to read format by way of this newsletter.

As a general summary, this edition sheds light on some recent developments relating to issues of price fixation of cardiac stents and drugs, ban of FDC drugs, changes to rules pertaining to medical devices and also summarizes some key M&A transactions in the sector.

With the above in mind, we present to you Volume I Issue III of our Pharmaceutical and Life Sciences Newsletter *Synapse*. We hope that you enjoy reading this newsletter as much as we have enjoyed creating it and find the information contained therein useful.

Please feel free to send your comments, feedback and suggestions to synapse@cyrilshroff.com.

From all of us at CAM, we wish you a prosperous year ahead!

Regards,

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A. RECENT NEWS

FDC Ban Matter- Submission of information to DTAB/DTAB Sub-Committee for reconsideration.

The FDC ban matter was decided in finality by the Supreme Court of India. The Court whilst upholding the power of the government to ban drugs under Section 26A of the Drugs and Cosmetics Act 1940 (“Act”), directed that all FDC’s in question be reviewed afresh by the Drugs Technical Advisory Board (“DTAB”) and further prescribed parameters of such review.

The Central Drugs Standard Control Organization (“CDSCO”) vide notification no. F. No.-4-01/2013-DC (Misc.13-Part1) dated March 12, 2018, directed all concerned parties (FDC manufacturers) to submit information in a prescribed format to the DTAB Sub Committee¹ which has been formed under the chairmanship of Dr. Nilima Khirsagar, Chair, Clinical Pharmacology, ICMR. The sub-committee has been formed to evaluate all 349 FDC’s and deliberate on the safety, efficacy, therapeutic value and other parameters as set out in section 26A of the Act.

The review conducted by the DTAB/ Sub-Committee would be within the parameters as set by the apex court in its judgement. In that the DTAB/Sub-Committee has been directed to:

1. Satisfy itself that the FDC in question is likely to involve any one of the ingredients specified in Section 26A namely that the:
 - (a) FDC is likely to involve any risk to human beings or animals; or
 - (b) FDC did not have the requisite therapeutic value claimed or purported to be claimed for them; or
 - (c) FDC contains ingredients in such quantity for which there is no therapeutic justification.
2. Apply its mind as to whether it is necessary or expedient, in the larger public interest, to regulate, restrict, or prohibit the manufacture, sale, or distribution of such FDCs.
3. Clearly indicate in its report as to why:
 - (a) Any one of the three factors as mentioned above are attracted;

- (b) Is it, post such satisfaction and in the larger public interest, necessary or expedient to (a) regulate, (b) restrict, or (c) prohibit the manufacture, sale or distribution of such FDCs.

4. Indicate in its report as to why, in case it prohibits a particular FDC, restriction or regulation is not sufficient to control the manufacture and use of the FDC in question.
5. Afford a hearing to the Petitioners (manufactures) as well as patient groups such as AIDAN (who had filed cross SLP’s challenging the Delhi High Court Judgement).
6. Complete the entire exercise of sending a consolidated report within a period of six months from the date on which the judgment was received by the DTAB.

All concerned appellants/petitioners were required to submit the information in the prescribed format in hard copy as well as soft copy on/before April 07, 2018.

Ceiling prices of Coronary Stents re-fixed by NPPA.

The National Pharmaceutical Pricing Policy (“NPPA”) vide order bearing SO 412(E) dated February 13, 2017 fixed prices of: (a) Bare Metal Stents (“BMS”) at INR 7260 (Rupees Seven Thousand Two Hundred and Sixty only); and (b) Drug Eluting Stents (“DES”) including metallic DES and Bioresorbable Vascular Scaffold (“BVS”)/ Biodegradable Stents at INR 29,600 (Rupees Twenty Nine Thousand Six Hundred only) respectively². These prices were revised on April 1, 2017 and the NPPA vide order S.O. 10410 (E) increased ceiling prices for these notified coronary stents as follows: (a) BMS - from Rs. 7,260 (Rupees Seven Thousand Two Hundred and Sixty only) to Rs. 7,400 (Rupees Seven Thousand Four Hundred only); and (b) DES – from Rs. 29,600 (Rupees Twenty Nine Thousand Six Hundred only) to Rs. 30, 180 (Rupees Thirty Thousand One Hundred and Eighty only).

Having previously revised prices, the NPPA vide order S.O. 639(E) dated February 12, 2018, further revised prices and fixed the price of: (a) BMS at INR 7660 (Rupees Seven Thousand Six Hundred and Sixty only); and (b) DES including metallic DES and BVS/ Biodegradable Stents at INR 27890 (Rupees Twenty Seven Thousand Eight Hundred Ninety only)³. The revised ceiling price is applicable from February 13, 2018 till March 31, 2019, unless revised by a notification.

¹ <http://www.cdscop.nic.in/writereaddata/Notice%20344%20FDCs.pdf>

² <http://nppaindia.nic.in/ceiling/press13Feb2017/so412e-13-02-17.pdf>

³ [http://www.nppaindia.nic.in/order/revised_prices\(Coronary-stents\).pdf](http://www.nppaindia.nic.in/order/revised_prices(Coronary-stents).pdf)

Additionally, as per the Order, NPPA directed all the manufacturers to ensure all brands of coronary stents are available in the market without any disruption. For the purpose of this order, importers are considered as manufacturers. The order also states that as per section 21(2) of the DPCO 2013, any manufacturer who intend to discontinue production or import of any Coronary Stents shall furnish information to NPPA in Form-IV of the Schedule II of the DPCO 2013 at least six months prior to the intended date of discontinuation. In the meantime, manufacturers are required to oblige with the ceiling price and ensure that all brands of coronary stents are available in the market without any disruption. However, as per section 21(2) of the DPCO 2013, the Government may, in public interest, direct the manufacturer to continue with required level of production or import for a period not exceeding one year, from the date of receipt of intimation.

NPPA issues office memorandum regarding discontinuation of sale of coronary stents in India

The NPPA after extending the period of price caps on coronary stents vide its notification of 12th February, 2018 has issued another notification F.No.20 (8)/2018/Div-III/NPPA dated 21st February, 2018 whereby it has stated that the NPPA has in principle decided not to disallow any application submitted for withdrawal of coronary stents from the market by manufacturers/importers⁴.

Any manufacturer intending to discontinue production or import of any coronary stent is required to furnish information in relation such intention to discontinue the production/ import thereof to the NPPA at least six months prior to the intended date of discontinuation as prescribed under paragraph 21(2) of the DPCO 2013 and follow the ceiling price till such time as has been prescribed by the government.

Price fixation of Scheduled drugs

The NPPA *vide* order dated 02.04.2018 fixed the ceiling prices (exclusive of goods and services tax) of 841 scheduled formulations in schedule-I under DPCO 2013⁵. The price revision is done as per the Annual Wholesale Price Index (“WPI”), which stands at 3.43812%. The NPPA also revised the prices of 18 additional scheduled formulations in Schedule-I under DPCO 2013⁶. Manufacturers of other scheduled formulations for which price ceiling is not fixed are required to approach NPPA with relevant market data for fixation of ceiling price. The ceiling prices are applicable w.e.f. April 01, 2018.

All manufacturers, selling the branded or generic versions of scheduled formulations, are required to revise the prices of all such formulations downwards with immediate effect. Further, the Memorandum directed all retailers and dealers of the scheduled formulations to display the price list and the supplementary price list (if any) on a conspicuous part of the premises where the business is carried and which is accessible to any person wishing to consult the same.

Grouping guidelines for medical devices applications

The Ministry of Health and Family Welfare on March 16, 2018 in pursuance of Rule 5 of the Medical Devices Rules, 2017 (“MD Rules”), laid down guidelines for grouping of medical devices⁷. These guidelines shall be applicable to any person making an application for license to import, manufacture, sale or distribution of such medical devices.

This grouping is done as per similar intended use or commonality of technology. Applicants can submit a single application for obtaining the license for each group of devices. The grouping categories mentioned are Single, Family, In-vitro diagnostics test kit, System, In-vitro diagnostics cluster & Groups. All the applications are required to be made in the manner laid down in the MD Rules.



No NOC required for Export of Drugs & Cosmetics.

The Central Drugs Standard Control Organization (“CDSCO”) in a notice dated March 23, 2018 has struck off the provision of acquiring a “no-objection” certificate with a view to ease the regulations of export to all the countries⁸. Initially export without an NOC was only permitted for countries like Canada, Japan, the US and European Union. With this notification, export without NOC is permitted for all countries.

⁴ [http://www.nppaindia.nic.in/order/coronarystent_discontinuation\(21022018\).pdf](http://www.nppaindia.nic.in/order/coronarystent_discontinuation(21022018).pdf)

⁵ [http://www.nppaindia.nic.in/ceiling/press02April18/Formulation_Prices\(841\).pdf](http://www.nppaindia.nic.in/ceiling/press02April18/Formulation_Prices(841).pdf)

⁶ [http://www.nppaindia.nic.in/ceiling/press02April18/Formulation_Prices\(18\).pdf](http://www.nppaindia.nic.in/ceiling/press02April18/Formulation_Prices(18).pdf)

⁷ http://cdsco.nic.in/writereaddata/Guidelines%20on%20Grouping%20of%20Medical%20Device%20and%20IVD_1.pdf

⁸ http://www.cdsco.nic.in/writereaddata/order21_3_2018.pdf

This regulation aims to cut down unnecessary delay, paper work and will provide smooth exports to other countries. All stakeholders are required to strictly comply with the administrative prerequisites of the importing countries as per their particular needs.

Health Ministry and Tata Memorial Centre launch first Digital Online Oncology Tutorial

On January 04, 2018, Secretary of the Ministry of Health and Family Welfare (“MoHFW”) launched the country’s first digital Online Oncology Tutorial Series designed by the Tata Memorial Centre in collaboration with the Health Ministry⁹. This is a part of a national program that will be rolled out across the country by Tata Memorial Centre in collaboration with state governments. The overall course is designed for 7 weeks with different modules based on various sites and sub-sites of Cancer. It comprises of 14 hours of comprehensive e-learning through more than 40 video lectures, case studies, assessment questionnaires and periodic interactive Webinar sessions with respective consultants of Tata Memorial Hospital. The oncology tutorial series aim to train doctors across the country to educate them in early detection, prevention, palliation, rehabilitation and treatment of various cancers.

Mandatory warning labels on fast food

On January 02, 2018, the Food Safety and Standards Authority of India (“FSSAI”) has clarified that fast food has not been separately defined under the Food Safety and Standards Act, 2006 and Rules and Regulations made thereunder¹⁰. In order to address the issue of high fat, sugar and salt in food and associated health risks, FSSAI constituted an expert group, which provided its recommendations. FSSAI has decided to revise its labelling regulations to include mandatory declaration of total fat, added sugar, salt, trans fat and energy per serving along with its contribution to Recommended Dietary Allowance on front of pack label.

Improving healthcare services across the country with tele-medicine system

The Ministry of Health and Family Welfare has taken steps to strengthen healthcare services across the country with a proposed tele-medicine system¹¹. The facilitation provided is as follows:

1. National Medical College Network (“NMCN”): With the purpose of providing e- education and e-healthcare delivery, 50 government medical colleges have been selected to interconnect, riding

on a National Knowledge Network (high speed bandwidth connectivity).

2. State Telemedicine Network (“STN”): Ten States/ UTs have been supported under National Health Mission (“NHM”) under Program Implementation Plan (“PIP”) for strengthening State Telemedicine initiatives under STN & to create reliable, ubiquitous and high speed network backbone, all available and future network.
3. Tele-Medicine Nodes at Pilgrim places: The ministry in collaboration with the Department of Space has setup Telemedicine nodes for health awareness, screening of non-communicable disease and for providing specialty consultation to the devotees visiting certain pilgrims.
4. Tele-Evidence: The tele-evidence facility streamlines the process of doctors appearing in courts in response to summons and saving their time not only for patient care but also for medical education and research.

Operational guidelines for implementation of the scheme for creation/expansion for food processing & preservation capacities revised.

The Ministry of Food Processing Industries has, by notification number F. No. MFPI/14-CEFPPC dated December 13, 2017, released revised operational guidelines for the implementation of the scheme for Creation/Expansion for Food Processing & Preservation Capacities (“CEFPPC”) ¹².

These guidelines have been revised to leverage the benefits of the CEFPPC scheme to those who propose to set up units in mega food parks, agro cluster units and in designated food parts as notified by the Ministry from time to time.

This will provide a wider scope for setting up modern food processing units along with the established supply chain.

This scheme was originally launched under the Central Sector Scheme- ‘Pradhan Mantri Kisan Sampada Yojna’.

AYUSH vertical created at CDSCO

A vertical structure of AYUSH has been created within the CDSCO for regulation of Ayurvedic, Siddha, Unani and Homoeopathic (“AYUSH”) drugs under provisions

⁹ <http://pib.nic.in/PressReleaseDetail.aspx?PRID=1515449>

¹⁰ <http://pib.nic.in/PressReleaseDetail.aspx?PRID=1514962>

¹¹ <http://pib.nic.in/PressReleaseDetail.aspx?PRID=1513822>

¹² <http://www.mofpi.nic.in/sites/default/files/20171213154905.pdf>

of the Drugs and Cosmetics Act, 1940 and allied Rules in so far as they apply to AYUSH drugs.¹³

B. SOME IMPORTANT TRANSACTIONS

1. TPG's Healthium Medtech sold to Apax.

On April 6, 2018 Apax acquired Healthium Medtech ("HMPL") from TPG. Texas Pacific Group ("TPG") an American investment company which is one of the largest private equity investment firms in the world. This is the second major merger for TPG within the recent weeks. Apax is a private equity company working in different sectors like telecom, healthcare etc., with an investment of \$2 billion, in India over the last 11 years acquired HMPL to strengthen its networking in India and globally. HMPL owned by TPG is one of the largest medical consumables and surgical stitch company. It has a strong all India distribution providing services to more than 10,000 hospitals under the Sutures India. It owns several companies like UK based Clini Supplies and Quality Needles, which were acquired in 2015 & 2017 respectively.

2. Abbott sells two brands to Corona Remedies

Abbott India & Corona Remedies are popular brands in providing prescribed medication for diabetes and hyperthyroid. Corona remedies focuses on cardio metabolic & nutraceutical segments and has acquired two brands Obimet & Thyrocab brands comprising of 14 product line extensions from Abbott. This is the

second purchase of the Corona Remedies after the acquisition of four products from GlaxoSmithKline in the previous year. Corona Remedies currently, has a manufacturing unit at Himachal Pradesh manufacturing 100 crore tablets, 6 crore capsules and one crore liquid bottles per year and announced the opening of another project on April 02, 2018¹⁴ in Bavla, Gujarat, targeting the production of 200 crore tablets, 60 crore capsules and 3 crore liquid bottles by 2019.

3. Glenmark to market Helsinn's chemo-induced nausea drug in India, Nepal.

On April 06, 2018, Helsinn, a Swiss pharmaceutical group that largely markets cancer care products, has entered into an exclusive agreement with Glenmark Pharmaceuticals to introduce Akynzeo an oral fixed dose combination of Netupitant 300mg & Palonosetron 0.5mg in a capsule intended to prevent chemotherapy-induced nausea and vomiting (CINV)¹⁵. Akynzeo was developed by Helsinn and is currently sold in the US and European Union. Under the agreement, Glenmark would hold exclusive rights for marketing the drug in India and Nepal. It has been reported to have obtained marketing approval from The Central Drugs Standard Control Organization ("CDSCO").

The drug is envisaged to help Indian patients undergoing chemotherapy and struggling to manage CINV issue efficiently. This is the first ever collaboration of Helsinn with any Indian company.

¹³ <http://www.cdsc.nic.in/writereaddata/ayush%20regarding.pdf>

¹⁴ <https://health.economictimes.indiatimes.com/news/pharma/corona-remedies-acquires-two-brands-from-abbott/63581987>

¹⁵ <https://health.economictimes.indiatimes.com/news/pharma/glenmark-to-market-helsinns-chemo-induced-nausea-drug-in-india-nepal/63611684>

DISCLAIMER

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