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Dear Readers,

At the outset, we wish all our readers and their families a very healthy, happy and prosperous New Year.

We thank each and every one of you for making the first issue of Synapse a resounding success. We received a lot of positive feedback on the content and how the same was presented in a succinct and easy to read manner. True to our endeavor to keep our clients and readers updated on all the latest happenings in this rapidly developing sector, it gives us immense pleasure to bring to you the second issue of our pharma/ healthcare and life-sciences newsletter which has been created bearing in mind the increasing need of clients and industry members to be updated with the changing landscape of the Pharmaceutical and Life Sciences industry and the increase in regulatory scrutiny by the government in the past few years.

The past year has seen a lot of action both in terms of increasing regulatory action on part of the government and has also seen some big ticket litigation between the industry on one hand and the government on the other. From the highly talked about FDC drug ban matter, to price control of orthopedic implants and stents, to increasing regulatory action against healthcare institutions and major transactions in the sector, the industry has been busy.

With this in mind, we present to you Volume I Issue II of our Pharmaceutical and Life Sciences Newsletter *Synapse*. We hope you would enjoy reading this newsletter as much as we have enjoyed creating it.

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

Regards,

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100 YEARS OF VALUES

A. RECENT NEWS AND LEGAL AMENDMENTS

FDC Ban Matter - Supreme Court Passes Final Judgment on December 15, 2017. Part Loss Part Win.

The Fixed Dose Combination ("FDC") ban matter regarding banning of 344 FDC's by the Government back in March 2016, was heard at length by the Hon'ble Supreme Court in the last few months of 2017 (the Government had appealed against the order of the Single Judge of the Hon'ble Delhi High Court which resulted in the quashing of the ban notifications). The court heard the government on one side and the industry on the other. A final judgment was pronounced in the matter on December 15, 2017.

Issues before the court:

The issues that the court ruled and issued directions upon are twofold.

1. Whether the government needs to consult the Drugs Technical Advisory Board (DTAB) before issuing any notification/ taking action under Section 26A of the Drugs and Cosmetics Act, 1940 (D&C Act)?

2. In-case the court rules in favour of the Government on the above, what were to become of the banned FDC's given apparent perversities in the Kokate Committee Report.

Opinion:

(a) The Court held that Section 26A is an additional power with the Central Government which must be governed by its own terms, as it is without prejudice to the other provisions in the D&C Act. (Para 15). The court also held that the expressions '"is satisfied" and "without prejudice to" in Section 26A were enough to deem it an additional power and the provision did not require a separate non-obstante clause (Para 23).

(b) On this issue of whether a consultation with DTAB is necessary, the Court held that so long as the Central Government's satisfaction can be said to be based on relevant material, Section 26A is satisfied. The court gave the example of an FDC which is banned in 50 countries based on expert committee reports in those respective nations, citing a significant risk to human health. The Central government can take this as relevant material in order to reach its 'satisfaction' in order to prohibit, regulate or restrict such a drug without consulting DTAB (Para 17). The court observed that even though it would be desirable for the Central Government to take such advice on technical matters arising out of the administration of the D&C Act, this does not lead to the conclusion that if such advice is not taken, power under Section 26A cannot be exercised (Para 20).

(c) With regard to the argument of the industry that DTAB alone can constitute sub-committees, the Court held that the Central Government did in-fact have power to constitute sub-committees with non-members of the DTAB while the power of DTAB under S. 5(5) of the D&C Act was for a separate purpose and was different from the Central government's power (Para 20).

(d) On the issue of whether Section 26A is arbitrary, the Court held that there are sufficient indicators in the Section 26A to eschew any ground of arbitrariness. If the power was exercised by Central Government on the basis of irrelevant or no material, then such 'satisfaction' could not be said to be reached in the first place (Para 25).

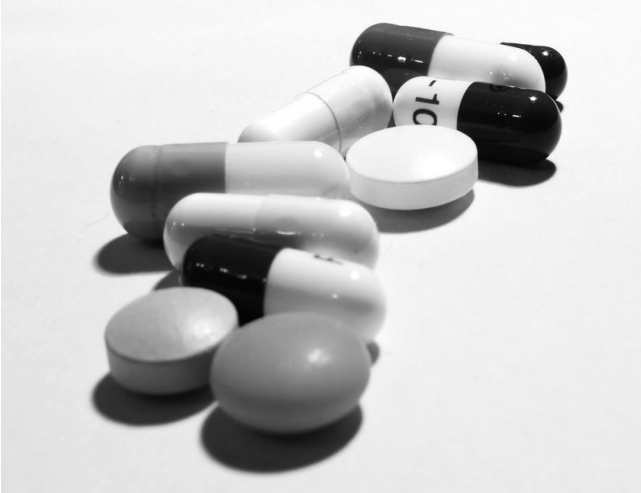
(e) The Court also rejected the argument as made by the industry that words must be read into Section 26A to give it a harmonious construction as words can only be added if the literal interpretation of the Section leads to an absurd result, which was not the case with Section 26A as per the Court (Para 27).

(f) For the foregoing key reasons, the court reversed the order of the Ld. Single Judge.

Apparent Perversities in the Expert Committee Report:

It was argued by the industry that the Kokate Committee – the Expert Committee which reviewed the FDC's in question, had acted in a mechanical manner. In that the report suffered from glaring discrepancies which the court termed as "*apparent perversities*". For example, in case of

our client- the relevant scientific article that was relied upon by the said committee to term our client's FDC as lacking therapeutic justification actually supported the use of FDC's to treat the condition in question. This fact was demonstrated to the Court (along with other similar instances) basis which the Court was of the view that the report suffered from apparent perversities and therefore directed all parties to point out the same in addition to pointing out which FDC's were prior to 1988. A detailed list outlining discrepancies and perversities in the report was submitted to the court.



The Court eventually took note of submissions on the aspect of apparent perversity as made by all parties and notwithstanding reversal of the High Court Judgment, issued directions with respect to the further course to be adopted in the matter as under:

(i) Reasons for committee conclusions not clear. Why prohibit instead of restricting/ regulating as per Section 26 A.

The Court noted that even though the Kokate Committee deliberated on the 344 FDCs (plus 5 FDCs) to conclude that the aforesaid FDCs be banned, the reasons for such conclusions were not clear, and whether it was necessary in the public interest to take the extreme step of prohibiting such FDCs, instead of restricting or regulating their manufacture and supply.

(ii) FDC's to be sent to DTAB for reconsideration.

The 344 FDCs (plus another 5 FDCs) that have been banned, i.e. 349 FDCs, pursuant to the Kokate Committee report, by notifications of the Central Government under Section 26A, shall be sent to the DTAB and/or a Sub-Committee formed by the DTAB. The DTAB/ Sub-Committee, after examining the peculiar facts of each of these cases, shall send a consolidated report to the Central Government within 6 months. 15 FDCs that are pre September 21, 1988 will not be sent to the DTAB and the notifications qua these FDC's will be set aside.

(iii) Parties to be heard.

The DTAB/Sub-Committee will also hear submissions by the Petitioners/ Respondents and the All India Drug Action Network (AIDAN). AIDAN had also filed an SLP in the matter.

(iv) Parameters and purview. DTAB review and report.

The DTAB/Sub-Committee will make its report along the following parameters**:**

(1) Why according to it, any one of the three factors mentioned in Section 26A is attracted (risk, to humans/animals, no therapeutic justification, no therapeutic justification for quantity of ingredients);

(2) Post such satisfaction, that in the larger public interest, that it is necessary or expedient to (i) regulate, (ii) restrict, or (iii) prohibit the manufacture, sale or distribution of such FDCs.

(v) Reasons to be recorded.

As an additional measure, the DTAB/Sub-Committee must also 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.

(vi) Action by the Central Government based on above review.

The Central Government, thereafter, must have due regard to the report of the DTAB/Sub-Committee and to any other relevant information, and ultimately apply its mind to the parameters contained in Section 26A of the D&C Act and, accordingly, either maintain the

notifications already issued, or modify/ substitute them or withdraw them.

(vii) FDC's outside purview of review. Notifications set aside.

With regard to drugs manufactured pre-September 21, 1988, the notifications banning these drugs have been set aside by the Court subject to a fresh inquiry by the Central Government, since these drugs were not meant to be sent to the Kokate Committee in the first place.

(viii) Status quo as on date of judgement.

Status quo with respect to stay orders in all cases, is to be maintained, until the Central Government issues fresh notifications in this behalf. The FDC's can be sold in the market.

(ix) 294 FDC's banned previously. The Madras matter. Report from DTAB accepted.

With regard to certain petitions transferred from the Madras High Court where a ban was imposed on 294 FDCs under Section 33 of the D&C Act, a similar exercise to the one proposed by this judgement had already been done and the DTAB had accordingly prepared a report regarding 294 FDCs, which was taken on record by this court and the aforesaid petitions were disposed off accordingly.

Ceiling prices of Orthopedic Knee Implants fixed by NPPA.

The National Pharmaceutical Pricing Policy ("NPPA") *vide* Order bearing reference number S.O. 2668(E) dated August 16, 2017 invoked emergency powers under Para 19 of the Drugs (Price Control) Order, 2013 ("DPCO, 2013") to reduce prices of knee implants by up to 69 per cent.

Paragraph 19 of the DPCO, 2013 *interalia* authorizes the Government, in extraordinary circumstances, if it considers necessary so to do in public interest, to fix the ceiling price or retail price of any drug (i.e. notified devices) for such period, as it deems fit.

The Notification also refers to Supreme Court pronouncements on the issue. The Supreme Court's decision in *Union of India vs. K.S. Gopinath & Ors* (SLP no. 3668/2003) directed the Government to ensure that lifesaving drugs do not fall out of price control. In the case of *Glaxo India Limited vs. UOI* (2014) 2 SCC 753, the Supreme Court dealt with the issue of implementation of price fixation measures by the manufacturers. This case referred to the landmark case of *Union of India vs. Cynamide India Limited* (1987) 2 SCC 722 which held that the menace of profiteering in essential commodities and lifesaving drugs has to be curbed in India.

Orthopedic implants were notified as 'medical devices' under Section 3(b)(iv) of the D&C Act by notification bearing reference number S.O. 1468 dated October 6, 2005 by Ministry of Health and Family Welfare ('MoHFW').

Price fixation of Orthopedic Knee Implants. Bone Cements and instruments included.

The NPPA *vide* its Office Memorandum bearing reference number F.No.20 (8)/2013/Div-III/NPPA/ Part-3/Vol. III dated August 25, 2017, clarified that the ceiling price, mentioned in column number 6 of the table under para 9 of the Order passed by NPPA on August 16, 2017 bearing no. SO 2668 (E), is inclusive of the *bone cement* component of the orthopedic implant as well as the *cost of instruments*.

Further, the Memorandum directed all manufacturers/importers/distributors/stockists of orthopedic knee implants and hospitals/ nursing homes/ clinics to display on the 'home page' of their website, the maximum retail price ("MRP") or price of the knee implant system at which it is being charged/billed to the patients.

Cardiac Stents. Pricing. Request for discontinuation of "Absorb" and "Absorb GT1" brands of cardiac stents by Abbot.

The NPPA *vide* Office Memorandum bearing reference no. 31(A)/Stent/2017/Div.III/NPPA, dated September 21, 2017 disposed of an application made by M/s Abbott Healthcare Pvt. Ltd. to allow the discontinuation of the production of Absorb and Absorb GT1 brands of stents manufactured by them. The application was on the grounds of unsustainable production and low commercial uptake of the cardiac stent in view of the price fixation notification issued by the NPPA dated February 13, 2017 in respect of cardiac stents. The NPPA directed Abbot to follow the

procedure for discontinuation of drugs under Para 21 of DPCO, 2013. Para 21(2) which requires any manufacturer of scheduled formulation, intending to discontinue any scheduled formulation from the market to issue a public notice and also intimate the Government.

Cardiac Stents. NPPA clarifies the definition of 'manufacturer' for implementation of ceiling price for coronary stents.

The NPPA *vide* its addendum bearing reference number F.No.8 (47)/2017/DP/NPPA/Div.II dated August 3, 2017 clarified the meaning of manufacturer and dealer under the DPCO, 2013. This addendum is in continuation of an earlier order passed by NPPA dated February 13, 2017, wherein the NPPA had fixed the ceiling price of coronary stents including bare metal stents and more advanced stents.

Cardiac Stents. Price fixation. Pricing of Cardiac Stents being revisited by NPPA.

The NPPA had fixed prices of Cardiac Stents vide Notification No. S.O 412E dated February 13, 2017. The said Notification was valid for a period of 1 year. The NPPA has now vide Office Memorandum dated November 9, 2017 indicated that this decision needs to be revisited in the month of January- February 2018. Based on this, the NPPA has called upon all domestic stent manufacturers and importers to submit representations on the said issue by December 31, 2017.

Through the aforesaid addendum dated August 3, 2017, the NPPA clarified that "manufacturer" means any person who manufactures or imports or markets drugs for distribution or sale in the country. Accordingly, any person who imports stents directly without having registration certificate ("RC") in Form 41 issued under D&C Act and D&C Rules in his/her own name and does it under a license issued under Form 10 shall be construed as 'distributor'. Further, in case a trade margin in excess of 8 percent is charged in the transactions between such distributors and any other 'person/institution/hospitals', such amount will be liable to be deposited, jointly or severally, by the concerned persons along with interest payable from the date of transaction.

Medical Device Rules 2017. Classification of devices.

The Drugs Controller General of India ("DCGI") *vide* notice bearing reference no. 29/Misc.l3/2017-DC(292) dated November 1, 2017, has classified all medical devices and in-vitro diagnostic medical devices under the provisions of the Medical Devices Rules, 2017. Prior to this, the Central Government had notified the Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated January 31, 2017 for the regulation of medical devices with regard to their import, manufacture, clinical investigation, sale and distribution. These Rules are to commence from January 1, 2018 onwards.

In connection with the aforesaid Rules, the Government on November 1, 2017 classified the medical devices and in-vitro diagnostic medical devices under Rule 4 of the Medical Device Rules, 2017 in order to ensure smooth implementation of the Rules in the industry. This classification is based on the intended use of the device, risk associated with the device and other parameters specified in the First Schedule of the aforesaid Rules. The classification of these devices is as follows.

- Class A (low risk). Examples include Surgical dressing, Alcohol swabs.
- Class B (low to moderate risk). Examples include Hypodermic syringe, Needle kits.
- Class C (moderate to high risk). Examples include Ablation device, Orthopedic Implants.
- Class D (high risk). Examples include Catheters, Cardiac Stents.

Draft Mental Healthcare Rules, 2017 released by MoHFW.

The MoHFW *vide* notice bearing reference no. V.15011/09/2017-PH-1 dated September 20, 2017 has notified the draft Mental Healthcare Rules, 2017 under the Mental Healthcare Act, 2017 ('MH Act'), which recently received the Presidential assent. The MH Act decriminalizes the attempt to suicide and the Rules thereunder focus on protecting the rights of people living with mental illnesses. The MH Act further bans the use of electric shock on children and does not allow separating mothers from their children unless absolutely necessary.

The Rules framed thereunder provide for setting up of Central and State Authorities by respective state governments, registration and regulation of mental health establishments, establishing a mental health review board on district level and lists in detail the other rights of persons with mental illnesses.

Drugs and Cosmetics Rules, 1945: Application for renewal no longer required in case of license to manufacture, sell.

The MoHFW *vide* notification bearing reference no. G.S.R 1337(E), dated October 27, 2017 brought in the Drugs & Cosmetics (Tenth Amendment) Rules, 2017 to amend the D&C Rules. The amendment is mainly regarding provisions regarding renewal of manufacturing and selling licenses for pharma companies. Earlier, the license to manufacture and license to sell drugs was granted for a period of 5 (Five) years and for renewal, a separate application was required to be made before the expiry of this period.

By this amendment, the process of application for renewal has been substituted by a *license retention fee* which is to be submitted before the expiry of the license. Thus a license obtained under Rule 68A is now *valid in perpetuity*. This is subject to inspection for verification of conditions of license at least once in 3 (Three) years or as needed under the newly inserted Sections 65B and 73AB in the D&C Act. Prior to this, the inspection requirement was only prior to the grant of license.

Definition of 'manufacturing' in case of medical devices expanded: To include coating, assembling as well as sterilization of medical devices.

The Central Drugs Standard Control Organization ("CDSCO") *vide* its circular dated August 9, 2017 bearing reference number 29/Misc./03/2017-DC (08) clarified that processes like coating, assembling of components, sterilization of devices would now be encompassed in the definition of "manufacture" under Section 3(f) of D&C Act.

This comes in the wake of manufacturers facing difficulties in obtaining licenses to establish facilities to carry out processes, or a part of processes such as making, altering, ornamenting, finishing, packing, labelling, breaking-up or treating or adopting any drug (or device) with a view to its sale. Therefore, for conducting these processes, persons and firms now require a 'manufacturing' license under the D&C Act and the D&C Rules made thereunder.

National patient safety implementation framework by Ministry of Health and Family Welfare.

The MoHFW released the draft National Patient Safety Implementation Framework on September 15, 2017 to bring about a uniform patient safety framework in India. Patient safety is a fundamental aspect of healthcare and the goal of these guidelines is to improve patient safety at all levels of healthcare including prevention, diagnosis, treatment and follow-up treatment, with an eventual progression towards Universal health coverage ('UHC'). It applies at national and sub-national level to public as well private sectors. The major objectives of this framework include building structural systems along with a Quality Assurance ('QA') program, promoting research for healthcare, assessing the nature and scale of adverse events in healthcare, establishing systematic reporting in healthcare and preparing a capable and sensitized workforce in healthcare.

Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011: New segment of non-carbonated and non-alcoholic water based beverages covered.

The FSSAI *vide* notification bearing reference no. No. Stds/SP(Water & Beverages)/Notif (1)/FSSAI-2016 dated September 15, 2017 has notified the

Food Safety and Standards (Food Products Standards and Food Additives) Tenth Amendment Regulations, 2017 to the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 ("Food Safety Regulations 2011"). The principal regulations included standards for alcoholic and non-alcoholic-carbonated beverages, but, through this amendment, the scope of these regulations has been enlarged to cover a whole new segment of non-carbonated non-alcoholic water based beverages such as flavoured water, herbal water etc. being introduced into the Indian market.

Certain salient features of these regulations include:

1. The amendment specifies separate general and microbiological standards for specific non-carbonated, non-alcoholic water based beverages. It covers a range of new and novel beverages including flavoured water and herbal water.

2. Allowing use of fruits and vegetables extractives, herbs, spices, salts and salt substitutes in addition to sugar and non-sugar sweeteners, such as honey, dextrose monohydrates to widen the scope of standards and encourage *innovation.*

3. Allowing use of herbs other than those specified in Food Safety and Standards (Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical Purpose, Functional Foods and Novel Food) Regulations, 2016. However, manufacturers are mandated to provide toxicological data before use of any herbs in such beverages not specified in the Food Safety Regulations 2011 to ensure the safety of such beverages.

Food Safety Regulations 2011: FSSAI amends Regulations for provision of additional additives, enzymes and processing aid in beverages.

MoHFW *vide* notification bearing reference number F. No. 1/Additives/Stds/14.2/Notification/ FSSAI/2016, dated July 31, 2017 has amended the Food Safety Regulations 2011. This amendment prescribes a list of permitted additives/processing aids and enzymes for use in beverages, excluding dairy products. These will be in addition to the additives already mentioned in the Appendix A of the Food Safety Regulations 2011, with respect to grape wine, aromatic alcoholic beverages, and distilled spirituous beverages containing more than 15 (Fifteen) percent alcohol.

Draft Guidelines under the Bio-medical Waste Management Rules, 2016.

The Ministry of Environment, Forests and Climate Change ("MoEF&CC") released draft guidelines on September 7, 2017 for developing a Bar-code system under The Bio-medical Waste Management Rules ("**BMW Rules**"), 2016. The BMW Rules, 2016 were earlier notified on March 28, 2016 under Rule 4 of the Environment (Protection) Act, 1986. Rule 4 and 5 of the BMW Rules, stipulate that it is the duty of every *occupier* as well as *operator* to establish a Bar code system for handling of Bio-medical Waste in their premises. An *occupier* is a person who has administrative control over a premises which generates bio-medical waste. An *operator* is a person who owns or controls a common bio-medical waste treatment facility for the collection, treatment, disposal or any other form of handling of bio-medical waste.

These guidelines have been prepared for ensuring effective enforcement of the BMW Rules, 2016 and to simplify the handling of bio-medical waste by tracking it from source to final disposal and treatment.

Submission of safety data for non-patent and propriety medicines.

The DCGI *vide* notification bearing reference number F.No. DCG(I)/MISC/2017(93) dated August 18, 2017 directed all the manufacturers to submit stability data of non-patent and propriety medicines at the time of submission of application for manufacture. A condition for grant of manufacturing license is to show that the medicine or drug is stable under conditions of storage. Manufacturers were asked to submit such data with regards to non-patent and proprietary medicines as well, in order to ensure that such medicines have the quality and stability required of drugs under the conditions of storage.

B. SOME IMPORTANT TRANSACTIONS

Sun Pharma Invests in US-Based Krystal Biotech.

In August 2017**,** India's biggest drug maker Sun Pharmaceutical Industries Ltd. ("Sun Pharma") invested $7 million to buy a 15.9 percent stake in thr US based bio-pharmaceutical company Krystal Biotech ("Krystal"). As part of its continuous expansion plans, in July 2017, Sun Pharma invested Rs. 85.5 crore in Hyderabad based Zenotech Laboratories Ltd., and earlier this year, it had acquired Canadian pharmaceuticals firm Thallion Pharmaceuticals for USD 2 million.

Plasmagen Raises Rs. 160 Crore From Private Equity Investors.

In August, 2017**,** Bengaluru based Biopharmaceutical Company Plasma Gen BioSciences Pvt. Ltd ("Plasma Gen") raised USD 25 million (Rs 160.4 crore) from investors led by private equity ("PE") firm Eight Roads Ventures India.[1] The investment will help PlasmaGen expand its product portfolio, deepen market penetration, strengthen its product supply chain. It develops and makes blood plasma-derived products which are administered across various therapeutic areas such as neurology, hematology, oncology, immunology, pediatrics and rheumatology.

Temasek buys significant stake In Manipal Health Enterprises Pvt. Ltd.

In September 2017, Temasek Holdings Pvt. Ltd, ("Temasek") a Singapore based investment company, agreed to acquire a 16 percent stake in Bengaluru based Manipal Health Enterprises Pvt. Ltd ("MHEPL") worth Rs 1,000 crore from True North (formerly called India Value Fund Advisors).

MHEPL is India's third-largest hospital chain which runs a multi-specialty hospital which has a network of 15 hospitals in 5 states offering approximately 4,900 beds and catering to 2 million patients from India and around the world. The deal values MHEPL at $1 billion, or Rs 6,500 crore.[2]

Novartis divests anti-infective brands to Samara capital.

In October, 2017, Swiss-based Global Pharma Novartis AG divested some of its anti-infective brands catering largely to women's healthcare and gynecology to PE firm Samara Capital for an undisclosed sum. These include the rights to the trademarks *Cofvector, Monkezin* and *Glyred* along with an exclusive license to the trademarks *Curam, Foristal* and *Gretacal,* for use in India.[3]

Drug maker Eris Lifesciences Ltd. Has Acquired Nutraceuticals Maker UTH Healthcare Ltd.

In October, 2017, Indian based drug maker Eris Lifesciences Ltd ("Eric Lifesciences") acquired nutraceuticals maker UTH Healthcare Ltd ("UTH") for Rs 12.85 crore ($1.96 million).[4]

UTH offers products for obesity, diabetes, maternal nutrition and cardiovascular diseases. Eris Lifesciences offers products in chronic therapy segments such as cardiovascular and anti-diabetes, and specialty segments like vitamins, gastroenterology, women's health and bone health. Thus, his acquisition provides Eris Lifesciences

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1 https://www.vccircle.com/plasmagen-biosciences-raises-25-mn-from-eight-roads-ventures-f-prime/.
2 https://timesofindia.indiatimes.com/business/india-business/temasek-buys-rs-1k-cr-manipal-stake/articleshow/60724907.cms.
3 https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/novartis-divests-anti-infectives-brands-to-samara-capital/articleshow/60960289.cms.
4 https://www.vccircle.com/eris-lifesciences-acquires-nutraceuticals-maker-uth-healthcare/ ; https://health.economictimes.indiatimes.com/news/pharma/eris-lifesciences-acquires-uth-healthcare/60939512.
5 https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/fosun-pharma-acquires-74-stake-in-gland-pharma-for-1-09-billion/articleshow/60941486.cms.

with a wider portfolio of products and complement its offerings.

The UTH Healthcare deal is the first acquisition by Eris Lifesciences since its initial public offering ("IPO") in June 2017.

China's Fosun acquires 74 percent stake in Hyderabad based drug maker Gland Pharma Ltd.

In October, 2017, China based Fosun Pharmaceuticals Group Co. Ltd. ("Fosun") bought a majority stake in Gland Pharma from its founders and PE Investors and the deal is valued at around USD 1.09 billion.[5] In the regulatory filing, Fosun mentioned that Gland Pharma has become an indirect non-wholly owned subsidiary of Fosun Pharma and Fosun International.

Fosun was initially looking to buy a larger stake in Gland Pharma which it later trimmed to 74 percent, since the Indian Government's Cabinet Committee of Economic Affairs ("CCEA") was reluctant to approve this plan in light of the border stand-off between Indian and China. Therefore, Fosun agreed to acquire 74 percent stake which does not require CCEA's prior approval as FDI up to 74 percent in existing pharmaceutical companies would fall in the automatic route which does not require prior permission.

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