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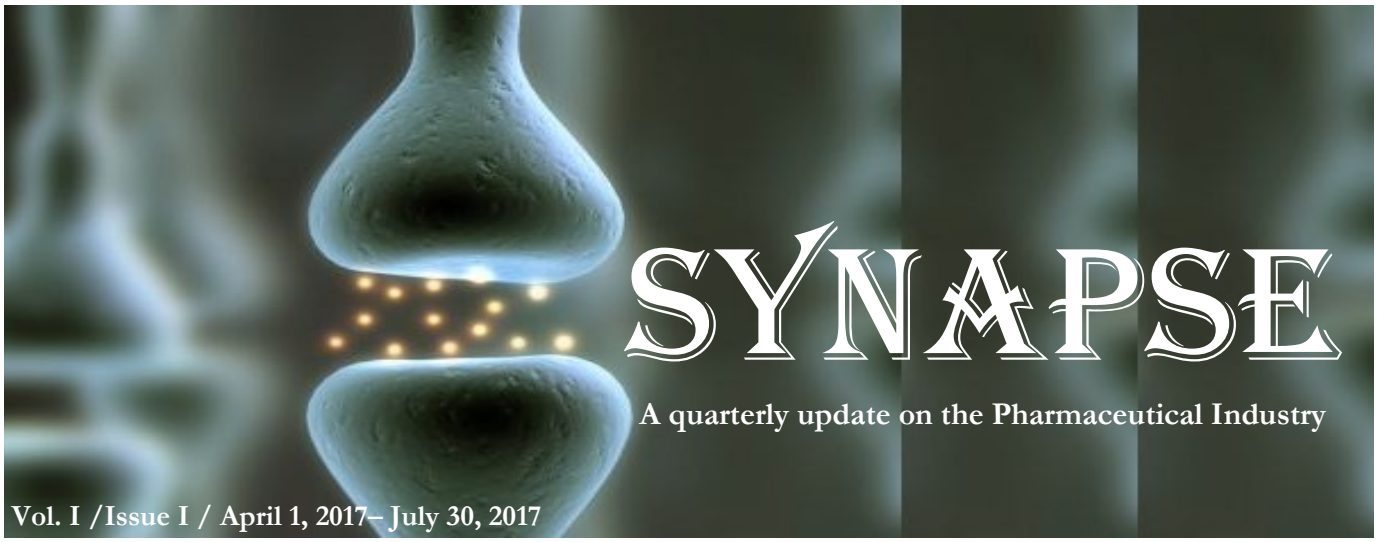

Dear Readers,

We are pleased to present before you the inaugural issue of '***Synapse*** - *a quarterly update on the pharmaceutical industry'*.

Over the past few years, the industry has witnessed increased regulatory scrutiny by the regulator. Manufacturing, sale, marketing, research and development activities are key areas where increased regulatory scrutiny is changing how the business of the industry is conducted.

With the release of the National Health Policy, the government has demonstrated its resolve to ensure quality and affordable healthcare for the public at large. This outlook has seen some interesting developments such as banning of irrational combination drugs, price fixation of drugs and medical devices and most importantly, a move towards increased regulation of the industry.

Some steps taken by the government have been applauded by the industry while some have been opposed and while these interactions continue, the regulator continues to issue additional guidance's and notices/ circulars which impact the business of the industry.

Cyril Amarchand Mangaldas, India's premier full service law firm has a dedicated Pharmaceutical, Healthcare and Life Sciences practice, which has subject matter specialist as part of its team. With this in mind, we present to you our Pharmaceutical and Life Sciences Newsletter *Synapse*. The purpose of this newsletter is to provide a birds eye view of the latest developments in the sector with a view towards keeping the reader well informed of the latest developments in this rapidly developing sector.

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 UPDATES

Revision in the ceiling price of coronary stents

Within a few months following the inclusion of coronary stents in the National List of Essential Medicines[1], the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers ("**DoP**"), *vide* its notification dated April 1, 2017, bearing reference number S.O. 10410 (E) revised the ceiling prices for notified coronary stents as follows: (a) for bare metal stents - from Rs. 7,260 (Rupees Seven Thousand Two Hundred and Sixty only) to Rs. 7,400 (Rupees Seven Thousand Four Hundred only); and (b) for drug eluting stents – from Rs. 29,600 (Rupees Twenty Nine Thousand Six Hundred only) to Rs. 30, 180 (Rupees Thirty Thousand One Hundred and Eighty only). The revised ceiling price of the coronary stents is applicable from April 1, 2017.

Ministry changes its stance in relation to sale and distribution of dextroproxyphene and formulation containing dextroproxyphene

The Ministry of Health and Family Welfare ("**MoHFW**"), *vide* its notification dated April 13, 2017, bearing reference number GSR 367 (E) rescinded its earlier notification dated May 23, 2013, bearing reference number GSR 332 (E). As per the new notification manufacturing, selling and distributing of dextroproxyphene and formulations containing dextroproxyphene is subject to following conditions: (a) manufacture shall indicate the following on the package-insert, promotional literature and containers of dextroproxyphene and formulation containing Dextroproxyphene: "*(i) Use of drug for cancer pain only; and (ii) daily administration dose shall not exceed 300 mg per day*"; and (b) the manufacturer shall advise the registered medical practitioner to administer or prescribe the said drug and its formulation for use in patients with cancer pain only. The said notification is in force from April 13, 2017.

By way of the said notification, the Government has changed its stand on the said drug and its formulations, as it was earlier labelled as unfit for human consumption and now been permitted for sale. The sale of the drug and its formulations is currently strictly regulated by the authority.

Medical Practitioners to face action failing to prescribe generic drugs

The Medical Council of India ("**MCI**") is the regulatory authority that regulates the practice of medicine by healthcare professionals. The MCI *vide* its circular dated April 21, 2017, bearing reference number MCI-2112(2) (gen.)/ 2017 Ethics/ 104728 directed all the registered medical practitioners to strictly comply with the Clause 1.5 of the Indian Medical Council (Professional Conduct, Etiquette an Ethics) Regulations, 2002. According to Clause 1.5 every physician is required to prescribe drugs using its generic name legibly and preferably in capital letters and further, he/she should also ensure that there is a rational prescription and use of such drug. The MCI has furthermore informed that appropriate disciplinary action shall be taken for any non- compliance, in this regard.

New Health Policy

The Union Cabinet, chaired by The Hon'ble Prime Minister Shri Narendra Modi in its meeting on March 15, 2017 approved the National Health Policy, 2017.

The Policy intends to inform, clarify, strengthen and prioritize the role of the Government in shaping India's health system in all its dimensions i.e. (a) investment in the healthcare sector; (b) organization of healthcare services; (c) prevention of diseases; (d) promotion of good health through cross sectoral actions; (e) access to technologies; (f) developing human resources; (g) encouraging medical pluralism; (h) building knowledge base; (i) developing better financial protection strategies; and (j) strengthening regulations and health assurance.

The Policy has been re-introduced after a gap of 15 years since the issuance of the last National Health Policy, which was notified in the year 2002.

Price approval of new drug

The National Pharmaceutical Pricing Authority ("**NPPA**") *vide* its office memorandum dated May 17,

[1]DoP *vide* its notification dated December 21, 2016, bearing reference number SO 4100 (E) included coronary stents in the National List of Essential Medicines to regulate its prices.

2017, bearing reference number F.No.37(1)/2016/Div-III/NPPA, directed all pharmaceutical companies, who are engaged in the activity of manufacturing/ importing 'new drug' (in accordance with Para 2 (u) of the Drugs (Price Control) Order, 2013 ("**DPCO, 2013**"), to furnish batch wise production and sale details along with corresponding maximum retail price (duly certified by a chartered accountant), from the date of launch of the product till date, in Form-I in order to get their prices approved from the Government.

The Drugs Controller General of India ("**DCGI**") by way of a letter dated May 16, 2017, bearing reference number DCGI/MISC/2017(51) directed Drug Controllers of all state, union territories that if the state government or union territories grant licenses for manufacture of new drugs including fixed dose combination, without prior approval of DCGI, the same shall be considered as illegal and not in conformity with the law. Further, the same may call for cancellation of licenses and penalty as provided under Para 15(5) of DPCO, 2013 read with Section 7 of Essential Commodities Act, 1955 ("**EC Act**").

Monitoring price movement of notified medical devices

The NPPA *vide* its office memorandum dated May 12, 2017, bearing reference number F.No. 20(8)/2013/Div-III/NPPA, directed all medical device associations/ manufacturers/importers/marketers to submit price related data in Form V (in accordance with Para 25 of DPCO, 2013), in respect of all notified medical devices, irrespective of their classification, to the NPPA by way of an 'online submission' through the Ingredient Pharmaceutical Data Base Management System. Contravention to said compliance, would attract penalty as envisaged under Para 15 (5) of the DPCO, 2013 read with Section 7 of the Essential Commodities Act.

Extension of time for affixing sticker indicating date of manufacture and date of expiry on medical devices

According to international labelling requirements for medical devices, the expiry date is given in the same month as that of manufacturing month; and the same is observed to not be in line with labeling provisions as envisaged under Rule 109A (e) read with Rule 96 of the Drugs and Cosmetics Rules, 1945 ("**D&C Rules**")[2].

The Central Drugs Standard Control Organization ("**CDSCO**") had in a similar matter previously provided a relaxation clause, according to which the importers were allowed to affix stickers indicating the manufacturing date and expiry date as per the provisions under D&C Rules till May 25, 2017.

The CDSCO, *vide* its office memorandum dated May 4, 2017, bearing reference number 29/Misc/3/2016-DC (288) has directed that the requirement for affixing sticker on the label indicating the date of manufacture and expiry with respect to medical devices stands extended till December 31, 2017. This has been done keeping in mind the practical difficulties faced by the manufacturer/importer/marketer to accommodate the required changes. Representations made by the industry were considered in this regard.

Examination of safety and efficacy of fixed dose combinations ("FDCs") licensed for manufacture/sale in the country without due approval from the DCGI

The DCGI *vide* its notice dated June 5, 2017, bearing reference number F.No.04-01/2013-DC (Misc.13-PSC) requested concerned stakeholders to submit phase IV trial protocols (in line with Schedule Y of the D&C Rules), based on the recommendations of expert committee.

The said request has been made by the DCGI for the purpose of ascertaining whether the FDCs in question are safe and rational. This exercise arises out of the report submitted by the Kokate Committee back in February 2016 wherein a large number of FDCs' were identified as irrational, sans any therapeutic justification and requiring further investigation.

Procedural requirement for subsequent applicants in respect of FDCs declared as rational by Kokate Committee and approved by DCGI

The DCGI *vide* its notice dated June 5, 2017, bearing reference number File No. 4-01/2013-DC (Misc. 13-PSC) has directed manufacturers who are already

[2]In accordance with Rule 109A (e) read with Rule 96 of the D&C Rules the manufacturer/ importer/ marketer of the medical devices is required to print in indelible ink the date of manufacture and date of expiry or the shelf life the product.

holding licenses from state licensing authorities for FDC's which were declared rational by the Kokate Committee, but have not obtained NOC from DCGI, to submit their application in Form 44 in a manner prescribed in the said notice before the DCGI within a period of 4 months from the date the said notice. The DCGI has further intimated that if the manufacturer fails to comply with the said requirements then their application will not be considered and further, their licenses will also be considered as invalid.

Limited compliance Medical Devices Rules, 2017

The CDSCO *vide* its notice dated June 29, 2017, bearing reference number DCG(I/Misc./2017 (68)) has requested importers, manufacturers, distributors and supply chain personnel to submit data on safety, performance and quality aspects as provided under the Medical Devices Rules, 2017 for the purpose of creating a proper eco-system for its effective management.

The Medical Devices Rules, 2017 have already been notified and will come into force with effect from January 1, 2018.

Labelling of pharmaceutical products as per Goods and Service Tax ("GST")

The CDSCO *vide* its notice dated July 10, 2017 bearing reference number F. No. 4-01/2017-DC (Misc 78) has given its no objection to manufacturers to alter their product label as per the provisions of the D&C Rules and Legal Metrology Act, 2009 read with Legal Metrology (Packaged Commodities) Rules, 2011, if required for implementation of GST.

B. AMENDMENT TO STATUTES

Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Amendment Rules, 2017

The MoHFW *vide* its notification dated June 19, 2017, bearing reference number GSR 599 (E) amended the Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996 ("**PCPNDT Rules**") by adding a proviso to Rule 5(1). The said proviso exempts government institutions that provide health and medical services from paying the prescribed application fee for registration and renewal.

Legal Metrology (Packaged Commodities) Amendment Rules, 2017

The Ministry of Consumer Affairs, Food and Public Distribution *vide* its notification dated June 23, 2017, bearing reference number GSR 629(E) has amended the Legal Metrology (Packaged Commodities) Rules, 2011 aiming at enhanced consumer protection and maintaining a balance with the requirement of ease of doing business.

The said amendment apart from aiming at harmonizing the declaration and labelling requirements for goods displayed on e-commerce platforms also: (a) synchronizes labelling requirements under the Food Safety and Standards Act, 2006 regarding the declaration on food products; and (b) directs that all important declarations other than MRP that are required to be displayed on the notified medical devices, to fall under the purview of the Legal Metrology (Packaged Commodities) Rules, 2011.

The said amendment rules will be in force with effect from January 1, 2018.

C. PROPOSED AMENDMENTS

Draft Drugs and Cosmetics Amendment Rules, 2017

The MoHFW *vide* its notification dated May 2, 2017, bearing gazette notification number GSR 429 (E), published draft rules to bring out amendment in the D&C Rules.

By way of such amendment, the Ministry suggested replacement of the word "*patent or proprietary medicines*" with "*drugs*" in the following rules: (a) Rule 71(6); (b) Rule 71-B; (c) Rule 76(7); and (d) Rule 76A of the D&C Rules. In addition to this substitution, the draft amendment rules also suggest changes in Schedule D, against item 1, under the column 'class of drugs' to substitute the entry with: "*substance not intended for medical use excluding those intended to be used as drugs after further purification or rendering them sterile*".

The said draft amendment rules will be taken into consideration on or after a period of 30 days from the date on which copies of the gazette of India containing these draft amendment rules are made available to the public and during such period, affected parties are free to raise their objections or provide suggestions on these draft amendment rules and the same shall be duly considered by the Central Government.

Draft Food Safety and Standards (Organic Foods) Regulations, 2017

The MoHFW *vide* its notification dated June 19, 2017, bearing reference number F.No. CPB/03/Standards/ FSSAI/2016 published the Food Safety and Standards (Organic Foods) Regulations, 2017. By way of the said Rules, the Government has made an attempt to regularize the following: (a) labelling requirements and certifications of organic foods; (b) import and reciprocity of organic foods; (c) constitution of accreditation body.

The said draft regulation will be taken into consideration on or after a period of 30 days from the date on which copies of the gazette of India containing these draft amendment rules are made available to the public and during such period affected parties are free to raise their objections or provide suggestions on these draft amendment rules and the same shall be duly considered by the Central Government.

Addendum on revised guidelines regarding discontinuation of scheduled formulation under Para 21(2) of the DPCO, 2013.

DoP *vide* its office memorandum approved the addendum to the revised guidelines regarding discontinuation of scheduled formulations by postulating that Paras 4.1 to 4.5 of the DPCO, 2013 are applicable to scheduled formulations only and all Form-IV applications for discontinuation of notified medical devices are required to be put up before the appropriate authority and such cases shall be examined on a case to case basis.

Draft guidance document on essential principles for safety and performance of medical devices as per Medical Devices, Rules, 2017

DCGI vide its notice bearing reference number File No.:29/Misc/3/217-DC (179)[3] published a guidance document on 'essential principles for safety and performance of medical devices' under the provisions of Rule 6 of the Medical Devices Rules, 2017[4].

The guidance document provides binding guidance to manufacturers of medical devices in relation to medical devices that are intended to be sold in India. The said document further provides for an overview on meeting the essential principles for safety and performance of medical devices.

The DCGI has requested all stakeholders to give their comments/ suggestions on the said guidance document within a period of 3 weeks.

[3]The guidance document was uploaded on the official website of CDSCO on July 25, 2017.
[4]The Medical Devices Rules, 2017 has already been published which is to be implemented with effect from January 01, 2018.

D. FDC BAN

Update in FDC ban matter

The matter pertaining to challenges mounted by pharmaceutical companies against the notifications banning 344 (Three Hundred and Forty Four) FDC's back in March, 2016 was finally decided by the Hon'ble High Court of Delhi in December, 2016. The Hon'ble Ld. single judge upheld the contentions of Petitioners and quashed the said ban notifications. The Government subsequently moved a series of Transfer Petitions before the Hon'ble Supreme Court of India seeking a transfer of all cases across the country to the Supreme Court for final adjudication as they involve similar challenges and questions of law. The Government has also filed a series of SLPs' assailing the judgment of the Ld. single judge. The matter has been mired in a lot of procedural lapses on part of the Government (SLPs' not correctly filed, parties not included, no service to parties etc.). The Hon'ble Supreme Court of India has directed the Government to take steps to bring all matters before the Apex court for a final and proper adjudication.

While the Government has at every stage tried to pray for a stay of the judgment of the Ld. Single judge, the same has been vehemently objected to and the Hon'ble Apex Court has refused to stay the same.

The matter will now come up for arguments on September 19, 2017.

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