Pharma & Healthcare Update

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PHARMA YEARLY WRAP

INTRODUCTION

Looking back, 2016 was both exciting and challenging for the pharmaceutical industry. The government, with its Digital India, Make in India and Startup India campaigns showed that it is invested and committed to ensuring ease of doing business in India. The pharmaceutical industry regulators also appeared to be serious about taking steps to streamline and relax the regulatory process. But doing business wasn't always easy, and the industry had to bear some rude shocks. One fine morning, the industry woke up staring at a potential loss[1] owing a sudden ban on sale of combination drugs. On another day, the Industry witnessed import duty exemption being suddenly withdrawn from some critical drugs.

In this wrap, we have sought to summarize the major regulatory events for pharmaceutical industry that took place over the course of 2016. We hope you enjoy reading it.

DELHI HIGH COURT SETS ASIDE GOVERNMENT'S MEGA DRUG BAN

The Delhi High Court ("**Court**") on 1st December set aside the notification ("**Impugned Notification**") issued by the Ministry of Health and Family Welfare ("**MoHFW**") banning the manufacture, sale and distribution of 344 Fixed Dose Combinations ("**FDCs**") in India[2]. While hearing Pfizer India ("**Petitioners**") and 453 connected petitions instituted by affected pharmaceutical companies, the Court ruled against the Union of India and the MoHFW ("**Respondents**"), stating that due procedure was not followed in issuing the ban. The judgment, delivered by a single judge bench of the Court, came as a relief to numerous pharmaceutical manufacturers after a long and dramatic court battle that spanned the better part of the year. It remains to be seen whether the government will now move the Supreme Court of India by way of an appeal, considering that it had earlier approached the Supreme Court to club all pending petitions across the country in order for the issue to be decided quickly.[3] The facts and circumstances leading to the case are summarized in the paragraph below.

FDCs are a combination of two or more active pharmaceutical ingredients or compounds formulated as a single medicine. Such drugs are considered "new drugs" under the Drugs and Cosmetics Act, 1940 ("**D&C Act**") and Rules, 1945 ("**D&C Rules**"). The safety and efficacy of new drugs are required to be proved through clinical trials before permission is granted for it to be manufactured, sold or distributed in India. Approval for new drugs is granted by the central licensing authority, i.e., the Central Drugs Standard Control Organisation ("**CDSCO**"), while the license to manufacture, sell and distribute a drug is granted by the state licensing authority, i.e., the State Food and Drug Administration ("**FDA**"). Till some time ago, manufacturing licenses for new drugs were being issued by State FDAs without inquiring whether the FDC had the approval of CDSCO or not. In other words, the State FDAs were issuing manufacturing license to FDCs without checking whether they were safe and efficacious. In order to weed out unsafe FDCs, the MoHFW initiated a process for all such manufacturers to submit data in this regard. The MoHFW further constituted an expert committee under the chairmanship of Professor C.K Kokate, to look into the submitted data and determine the safety and efficacy of the FDCs. The first assessment report of the Kokate committee was submitted to the MoHFW in April 2015, after examining data submitted for nearly 1100 FDCs. On the basis of the report, in 2016, the MoHFW on the 10th of March banned 344 FDCs from being manufactured, distributed or sold in India. The ban notification was passed in exercise of power under Section 26A of the D&C Act which empowers the MoHFW to prohibit the manufacture or sale of any drug if it deems that it is in the public interest to do so. In one sweep, nearly 1,670 drug brands including popular brands such as Corex (Pifzer), Phensedyl (Abbott Laboratories), Vicks Action 500 (Proctor & Gamble) and Crocin (GlaxoSmithKline) were required to be removed from the market.

The judgment comes as a relief to numerous pharmaceutical manufacturers who were taken by surprise with the Government's ban. This is, however, not the first time that such a sudden move was taken. In 2007, the government had banned 294 FDCs but the industry was able to obtain a stay on the ban before Madras High Court. Interestingly, this time, the Madras High Court had refused to admit the plea of the Federation of South Indian Pharmaceutical Manufacturers Association in March for interim stay on the Impugned Notification. Chief Justice Kaul and Justice Sundresh disagreed with the view of the Delhi High Court, stating that the "mere fact of the sale of medicines for the last so many years ipso facto cannot call for the sale to continue when an expert body has gone into this issue".

PROPOSAL TO EXTEND NEW DRUG PERIOD FROM 4 TO 10 YEARS

A proposal to extend the 'new drug' period from four to ten years is reportedly being deliberated by a committee[4] comprising of secretaries of various departments including the Industrial Policy and Promotion, health and pharmaceuticals, as well as the CEO of Niti Aayog and a joint secretary of the Prime Minister's Office.

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Self Declaration Certificate For Ads: Decoding The Complexities Of Ad Regulations

Rule 122E of the Drugs and Cosmetics Rules, 1945 ("**D&C Rules**") deals with the definition of a 'new drug', which is a drug that does not have a history of safe and effective use in the country, or is an existing drug proposed to be marketed with different indications, route of administration or dosage. Currently, new drug would be considered as such for a period of four years from the date of first approval. In the duration that a drug is considered 'new', all importers and manufacturers intending to market that drug are required to furnish clinical data to prove the safety and efficacy of the drug as a precondition to marketing. Generation of clinical data involves undertaking a clinical trial, which is an expensive process. However, once this period is over, the drug may be imported or manufactured without furnishing the clinical data. Therefore, generic drug manufacturers usually wait for the four year period to lapse before manufacturing such products, in order to avoid incurring costs associated with clinical trials for new drugs.

The reason for the proposed extension of the new drug period is reportedly to increase the safety and efficacy data of new drugs, which would lead to better monitoring for side-effects. However, some generic manufacturers have reportedly dismissed the move on the ground that the amendment would constitute a concealed form of data exclusivity being introduced on behalf of financially sound innovator drug companies.

ONLINE PHARMACY SAGA

The e-pharmacy space has been seeing a lot of activity since 2015, with industry associations, regulators and brick-and-mortar players pushing for regulations for the emerging sector. One of the first actions seen was the raid on 27 online pharmacies by the Maharashtra Food and Drug Administration ("**FDA**") and a First Information Report being filed against top management of a popular e-commerce website[5]. Separately, a Public Interest Litigation ("**PIL**") was also filed before the Bombay High Court by a college lecturer, expressing concerns over the sale of prescription medicines by online pharmacies without the requisite licenses to do so. The Bombay High Court had directed the Maharashtra FDA to take measures to curb such sales.

The causes of concern surrounding e-pharmacies are two-fold. Firstly, there is a greater potential for abuse of medicines given the fact that the purchaser places the order for medicines remotely. Secondly, the law requires the sale of prescription medicine to be done under a duly signed prescription from a registered medical practitioner. However, e-pharmacies have to rely on scan of prescription to process customer orders. This raises a legal issue which is whether a scan of a prescription can be equated to the original prescription. To read our interpretation on the legality of a scan of prescription, you may refer to our research paper on e-health in India available here.

The All India Organisation of Chemists and Druggists ("**AIOCD**"), which represents interest of brick and mortar pharmacy stores, had called for a nationwide strike back in October 2015, which saw 8.5 lakh chemists from all across the country shut shop for the entire day, demanding action from the government. A similar strike was proposed in November 2016 but was cancelled.

A few e-pharmacies have joined hands to form the Indian Internet Pharmacy Association ("**IIPA**")[6] to introduce self-regulation to the sector and build credibility. IIPA has already published a code of conduct for the e-Pharmacy sector in November 2016 together with the Federation of Indian Chambers of Commerce and Industry ("**FICCI**"), which lays down guidelines to be followed by e-pharmacies. Some of the noteworthy ones are that e-pharmacies shall refrain from the sale of narcotic drugs, put in place recall procedures and have a grievance redressal mechanism.

The Government had then constituted a sub-committee under the chairmanship of Maharashtra FDA Commissioner Harshdeep Kamble to look into the issues regarding online pharmacies. In the interim, the Drugs Controller General of India ("**DCGI**") directed all state drug authorities to keep a close eye on online pharmacies operating in the state, and take necessary action if there is a contravention of the D&C Act or Rules.

The sub-committee has reportedly submitted its recommendations to the DCGI, which has been reviewed and further recommendations have been submitted by the DCGI to the MoHFW. The Central Drug Standards Control Organization ("**CDSCO**") is also reportedly planning to launch a centralised online system which will help make use of new technologies to deliver medicines effectively and in a regulated manner[7].

However, till date, the government has not clarified its position on e-pharmacies. 2017 may see amendments to the D&C Rules or a new set of rules in order to facilitate and regulate online pharmacies in India. This would be a welcome change, considering that most players are facing difficulties operating their business in the current uncertain regulatory framework.

FOREIGN DIRECT INVESTMENT IN EXISTING PHARMACEUTICAL COMPANIES RELAXED

The Department of Industrial Policy and Promotion ("**DIPP**") issued a press note in June[8] amending the current Foreign Direct Investment ("**FDI**") policy, allowing foreign investment in brownfield pharmaceutical companies up to 74% under the automatic route. Before the amendment, the FDI policy allowed investment in both greenfield (new) and brownfield (existing) companies up to 100% of the capital of the company. However, any investment in brownfield pharmaceutical companies were subject to the approval of the Foreign Investment Promotion Board ("**FIPB**"). The amendment to the policy now allows investment in brownfield projects up to 74% without FIPB approval. Above 74%, investments can only be made after approval is received. Certain additional conditions are also required to be complied with in the case of brownfield investments. These include production and supply levels of National List of Essential Medicines ("**NLEM**") drugs as well as Research & Development expenses being maintained at an absolute quantitative level for five years from when the investment is made. The decision to relax these norms was taken with the objective of promoting the development of the sector. While the press note regarding the change in the FDI Policy was issued in June, the amendment to the Foreign Exchange Management (Transfer or Issue of Security by a Person Outside India) Regulations, 2000, which is necessary to give effect to the change, was issued only in December, reportedly causing investment proposals to be held up until the amendment was issued.

PHARMA LICENSES TO BE MADE PERPETUAL

In an ongoing effort to streamline and bring in ease of doing business in the pharmaceutical sector, the Central Drugs Standard Control Organisation ("**CDSCO**") is proposing[9] to make the validity of various licenses and approvals under the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945 ("D&C Act and Rules") perpetual, unless otherwise canceled by the authority. The Drugs Technical Advisory Board has also approved of the proposal,

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with the condition that the licenses could be revoked after inspection, if required. The licenses would include licenses for the manufacture, sale and distribution of drugs and medical devices covered under the D&C Act and Rules. Currently, licenses under the D&C Act and Rules are typically valid for a period of five years, unless revoked by the authority. The proposed change comes with the condition that there should be an assessment of compliance with the conditions of the license or approval at least once every 10 years. The draft medical device rules released earlier this year by the Health Ministry also contained provisions in line with the proposal, with the addition of the payment of a 'license retention fee[10]' every year. The move would benefit pharmaceutical companies, who currently have to ensure that certain renewal applications are made six months prior to its expiry so that the license continues to remain in force while the application is being processed.

REVISED NATIONAL LIST OF ESSENTIAL MEDICINES RELEASED

On 23rd December, 2015, the Ministry of Health and Family Welfare notified the National List of Essential Medicines 2015 ("**NLEM 2015**"). The NLEM 2015 replaced the National List of Essential Medicines 2011.

The NLEM is based on the World Health Organization Model Essential Medicines List, which contains a list of medicines that aim to satisfy the basic health care needs of the population. The NLEM 2015 adds 106 medicines and removes 70 from NLEM 2011. Certain medicines from the previous list that were counted twice are now been counted as one.

Once a drug is added to NLEM, it is automatically brought under price control and considered for inclusion in the schedule to Drug Price Control Order, 2013 ("**DPCO**"), which is the law for price control of drugs. A notification is issued by the Government prior to inclusion of the new additions in the schedule of DPCO. The DPCO was amended on March 10, 2015 and NLEM 2015 was included in it in place of NLEM 2011. On the 29th of March, 2016, the NPPA published two notifications[11] that fixed price ceiling of the 106 medicines which were new additions to the NLEM 2015.

The timing of revision of NLEM, however, led to some confusion. The National Pharmaceutical Pricing Authority ("**NPPA**"), which administers DPCO, usually notifies a revision of ceiling prices of NLEM drugs in accordance with wholesale price index once a year. This year, the ceiling prices were notified on March 2 and were to take effect on April 1. The concerned manufacturers and importers revised their prices accordingly. However, the NLEM 2015 was included in the DPCO around the same time. The DPCO gives NPPA the power to fix ceiling prices of drugs as and when NLEM is revised. Using the power, the NPPA fixed ceiling prices of essential drugs again in accordance with the data on moving annual turnover. This created confusion as the NPPA had, unprecedentedly, revised ceiling prices of the essential drugs twice with a matter of few months.

NPPA MAY CHOOSE ONE-TIME SETTLEMENT FOR PENDING OVERCHARGING CASES

The NPPA may reportedly choose to go in for a one-time settlement with drug manufacturers alleged to have overcharged their medicines. The dues that have accumulated over two decades with respect to this have reportedly reached Rs. 4,551 crores ($683 million). Since most of the companies that have been accused of overcharging have challenged the penalties levied on them, most of this amount is tied up in litigation, and will continue to be so unless the matter is decided or settled between the parties. The proposal to reach a settlement is reportedly being reviewed by senior officials within the Department of Pharmaceuticals and must also be cleared with the ministry of finance and the departments of corporate and legal affairs, before it can be taken forward.[12]

CUSTOMS DUTY EXEMPTION FOR 76 LIFESAVING DRUGS WITHDRAWN

On 28th January, 2016[13], the Central Board of Excise and Customs ("**CBEC**") – the agency responsible for customs, central excise and service tax in India - issued a notification which withdrew customs duty concessions for 76 drugs, stating that it was in the public interest to do so. The drugs for which the concession was withdrawn reportedly include those that were being used in the treatment of diseases and illnesses such as kidney stones, heart rhythm disorders and diabetes. The import of these drugs would now be subject to more tax, a decision reportedly taken to encourage domestic production of these lifesaving drugs and level the playing field. This move would lead to increase in the prices of these drugs as the burden of paying these taxes ultimately rests with the consumer.

However, a further notification was issued by the CBEC on the 17th of February, 2016, which restored exemptions for 3 of the 76 drugs, namely Octreotide, Somatropin and Anti- Haemophilic Factor Concentrate (VIII and IX).[14]

NATIONAL PHARMACEUTICAL PRICING AUTHORITY ("NPPA") MAY BE DISBANDED

The NPPA, the apex authority that determines the prices of essential medicines in India, is reportedly set to be disbanded, with the functions of the authority being transferred to the Department of Pharmaceuticals with a new mandate. Along with this move, there is also a proposal for delinking of the Drugs (Price Control) Order ("**DPCO**") from the National List of Essential Medicines ("**NLEM**").[15] In its current form, the DPCO gives the NPPA the power to fix the prices of all medicines listed under its schedule. The schedule to the DPCO is based on the NLEM that is released by the Ministry of Health and Family Welfare from time to time, which is derived from the World Health Organization's List of Essential Medicines. The latest version of the NLEM was issued at the end of 2015, and the DPCO was amended accordingly to reflect the new list. The new form of price control is reportedly proposed to be on a case to case basis as and when required, rather than having all medicines under the NLEM being subject to price control.

The proposed disbanding of the NPPA is reportedly to bring in ease of doing business in India as well as encouraging investments in the pharmaceutical sector. However, the move may lead to an increase in prices of many medicines that are currently under price control, which amounts to over 450. Medical devices such as coronary stents were also recently added to the NLEM, with a view to bring the sector under price control as well. The disbanding of the NPPA in its current form and delinking of the DPCO from the NLEM may lead to an increase in the prices of medicines for which prices were earlier capped. However, at the same time, the move would incentivize both local as well as foreign drug manufacturers to invest more into the research and development of medicines that can be used to cure diseases that are more specific to the country, as they would now be able to receive a higher return on investment made in the production of the drug.

REVISED DRAFT GUIDELINES FOR BIOSIMILAR DRUGS RELEASED

The Union Health Ministry has issued draft of guidelines on regulatory approval of similar biologics prepared by CDSCO and DBT[16]. These draft guidelines are applicable to similar biologics that contain well characterized proteins as their active substance, derived through methods such as use of recombinant DNA technology. The demonstration of similarity depends upon detailed and comprehensive product characterization, preclinical and clinical studies carried out in comparison with a reference biologic. The draft guidelines lays down a regulatory pathway for market authorization in India and provides a guideline for applicants so they can understand and comply with the regulatory requirements for the authorization of similar biologics in India. The new draft guidelines are set to replace the earlier one that was released in 2012. There was a need to revise the guidelines as the previous guideline reportedly lacked rigorous standards needed to establish the safety and efficacy of biosimilars.

COMPETITION COMMISSION OF INDIA (CCI) IMPOSES INR 72.96 CRORE PENALTY FOR ANTI-COMPETITIVE PRACTICES

The CCI, the apex anti-trust regulator in India, passed an order levying penalty against the Karnataka Chemists & Drugs Association (KCDA), its president and Lupin Ltd. (Lupin)[17], finding KCDA and Lupin along with its office bearers to be indulging in anti-competitive practices. The order was passed on the basis of information received from M/s Maruti & Co., Bangalore (Informant), who had earlier been appointed as a stockist for the Diabetes Care Division of Lupin. Lupin had refused to supply drugs to the informant until it received a No Objection Certificate (NOC) from KCDA.

Based on the investigation report submitted by the Director General – an officer appointed to look into anti-competitive practices on the request of the CCI – the CCI found both KCDA and Lupin to be indulging in anti-competitive practices by insisting on a NOC being issued by KCDA before pharmaceutical companies supply drugs to new stockists.

The CCI in its order observed that anti-competitive practices, including the practice of mandating NOC before appointment of new stockists was being followed by various state and regional chemists and druggists associations, despite several orders passed in this regard.

In addition to penalizing KCDA for the default, the CCI imposed a penalty at the rate of 10% of its income (calculated based on the average income received in the previous two financial years), with a view to create a deterrent effect and prevent future contraventions by the associations.

While determining the penalty to be imposed on Lupin, the CCI took into consideration the fact that the refusal to supply the Informant was brief and that the company had 'mended its ways'. Taking this as a mitigating factor, the CCI imposed a penalty at the rate of 1% of Lupin's turnover (calculated based on financial statements submitted by the company), which amounts to INR 72.96 crores.[18]

HOST OF RELAXATIONS TO BENEFIT STARTUPS

The government in January released the 'Startup India: Action Plan[19]', which provides for certain relaxations, funding support and incentives for startups in India. Notably, the government has decided to bear the statutory costs and set up a panel of facilitators who would provide general advisory on intellectual property, as well as appear for hearings and contest oppositions until the final disposal of the application. The move is aimed at incentivizing startups to engage in innovation and for the protection of the intellectual property. Along with such incentives, the action plan also provides for relaxed norms in relation to public procurement, faster exit in case of insolvency or bankruptcy, tax exemptions on capital gains and investments, and a compliance regime based on self-certification for labour laws. With India seeing a lot of startups focusing on the healthcare and medical device sectors, the startup action plan would greatly help such entities and encourage the formation of more startups, creating an atmosphere for innovation in India.

CONCLUSION

While the pharmaceutical industry has had its fair share of ups and downs this year, 2017 promises to be nothing short of exciting at the moment. At this time next year, the industry may see a separate ministry to govern the industry, more relaxations in licensing and regulatory procedures, a new National Medical Commission as well as much needed changes in the legislation in form a new price control regulation, mandatory code for promotion and advertisement and guidelines for biosimilars. However, it remains to be seen if the momentum that picked up in 2016 will spill over to the New Year as well.

– Darren Punnen, Anay Shukla & Dr. Milind Antani
You can direct your queries or comments to the authors

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