

Pharma & Healthcare Update

December 31, 2019

PHARMA YEAR-END WRAP: SIGNS OF EXCITING TIMES AHEAD?

INTRODUCTION

The last quarter of 2019 has been more about beginnings rather than endings. The hot button issue of e-pharmacy regulation has made a comeback to the forefront of regulatory discourse while a new issue on the regulation of e-cigarettes is simmering on the backburner. The government has also taken some laudatory steps by requiring manufacturers to use brand names for drugs that are not similar to other brand names or trade names of drugs already in existence as a condition for obtaining the manufacturing license. Given all the collective developments that have taken place in 2019, 2020 should be filled exciting times for the pharma industry. In case you missed it, do also read our pharma round up covering updates from January to July [here](#).

DRUG REGULATOR ISSUES LETTER TO STATE DRUG CONTROLLERS TO ENFORCE COURT ORDER PROHIBITING E-PHARMACIES FROM OPERATING WITHOUT A LICENSE.

The DCGI issued an office letter on November 28, 2019 requiring all drug controllers to enforce an order passed by the Delhi High Court in December 2018 in the case of *Zaheer Ahmed v. Union of India W.P.(C) 11711/2018* ("Delhi HC Order") which prohibited the online sales of medicines without a valid license ("Office Letter").¹ The Delhi HC Order is based on a previous order issued by the Madras High Court² banning the online sales of medicine altogether. However, even though the Madras High Court Order was subsequently reversed in appeal, the Delhi HC Order continues to remain in force.³

The Office Letter is the latest development in a series of events surrounding e-pharmacy regulation. e-Pharmacies have been at the center of controversy in India since 2015, with regulators being asked to keep a strict watch on all players in the market until the expert committee, headed by ex-Maharashtra Food and Drug Commissioner Harshdeep Kamble examined the issues in the sector.⁴ The committee had later submitted its recommendations to the Drugs Controller General of India ("DCGI") - India's apex drug regulator – who had reportedly examined the report and forwarded his recommendations to the the Ministry of Health and Family Welfare ("Health Ministry"). Subsequently, in August 2018, the Health Ministry released draft rules proposing to regulate e-pharmacies under the ambit of D&C Act ("E-pharmacy Rules").⁵ However, soon after the E-pharmacy Rules were published the aforementioned orders were passed by the Delhi High Court and Madras High Court.

E-pharmacy regulation regulatory hot button issue for over a year now. The Office Letter appears to only be a continuation and reaffirmation of the current position i.e. online sale of medicines should not be done by pharmacies who are not licensed for the same.

HEALTH MINISTRY AMENDS DRUG REGULATION TO PREVENT MANUFACTURERS FROM USING SIMILAR BRAND NAMES

The Health Ministry has amended the Drugs and Cosmetics Rules, 1945 ("D&C Rules") – rules framed under the Drugs and Cosmetics Act, 1940 ("D&C Act"), India's primary drug control legislation – to require manufacturers to use brand names that are not similar to other brand names or trade names of drugs already in existence as a condition for obtaining the manufacturing license ("Amendment").⁶ The Amendment also requires manufacturers to provide an undertaking to the relevant authority to the effect that the manufacturer has already undertaken a search of the proposed brand name in the trademarks registry, the central database maintained by the drug regulator, literature and reference books on drug formulations as well as the internet and is not aware of the existence of any drug with the same or similar proposed brand name.

The Amendment comes on the heels of another circular issued by the DCGI directing all drug controllers in India to take strict action against manufacturers who change the underlying formulation of a drug without changing the brand name of the drug, to prevent patients from being confused about the composition of a drug marketed under a brand name.⁷

GOVERNMENT BANS ELECTRONIC NICOTINE DELIVERY SYSTEMS SUCH AS E-CIGARETTES

The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019 ("END Act") received Presidential Assent on December 05, 2019⁸ and has come into effect retrospectively from September 18, 2019. The END Act was based on and has replaced an ordinance promulgated earlier in the year ("Ordinance").⁹ The END Act prohibits the production, manufacture, import, export, transport, sale, distribution, storage and advertisement of electronic nicotine delivery systems such as e-cigarettes ("END"). Contravention of the END Act is punishable with imprisonment up to one year or with fine which up to INR 100,000. A repeat offence is punishable with imprisonment of up to three years and with fine up to INR 500,000.

The Health Ministry has been in the process of regulating ENDS for over a year now. In August 2018, the Health

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Ministry issued an advisory to all Indian States and Union Territories to ensure that ENDs were not sold in their territory (through brick-and-mortar stores or online), except in accordance with the provisions of the D&C Act ("Advisory").¹⁰ Since then, the Central Board of Indirect Taxes and Customs has also issued a circular to India's customs authorities asking such authorities to ensure the Advisory is implemented ("Circular")¹¹ as well as sending an internal communication to all state drug controllers requiring them to ensure that ENDs are sold in accordance with the D&C Act ("Communication").¹² However, the validity of the Circular and Communication were challenged in the Delhi High Court, where it has been stayed.¹³ The Delhi High Court, while ruling on the interim stay, held that ENDs do not appear to be drugs on the face of it. The Bombay High Court, in the case of *Godfrey Philips India Ltd. & Anr. V. The State of Maharashtra and Ors.*¹⁴ relating to the Advisory, placed reliance upon the decision of the Delhi High Court and passed an interim order directing the Maharashtra Food & Drug Authority to not take any action against the petitioner who is a manufacturer of e-cigarettes.¹⁵

Currently, the Ordinance has been challenged before the Calcutta High Court by an importer of e-cigarettes ("Petitioners").¹⁶ The Petitioners before the Calcutta High Court have contended that e-cigarettes should be treated as any other Nicotine Replacement Therapy and are currently being unfairly and arbitrarily singled out. The Petitioners are also expected to place evidence before the Calcutta High Court to demonstrate that e-cigarettes pose fewer health risks as compared to combustible cigarettes and cigars.¹⁷ However, the status of these matters is unclear now that the END Act has been passed.

CONCLUSION

A lot of issues have been left open ended at the end of 2019. We expect that the END saga is likely to come into its own as the highlight of the 2020. However, all eyes are on seeing a resolution to the e-pharmacy debate, with the expectation that a final set of rules would be released on how e-pharmacies should be properly regulated. All in all, the progress made over the course of 2019 has paved the way for a very exciting 2020!

– Shreya Shenolikar, Darren Punnen & Dr.Milind Antani

You can direct your queries or comments to the authors

¹ News article on 'Necessity of a license for online sale of medicines', available at: <https://timesofindia.indiatimes.com/business/india-business/e-pharmas-come-to-a-halt-as-regulator-makes-licence-must/articleshow/72357270.cms> (last accessed December 26, 2019).

² The Tamil Nadu Chemists and Druggists Association v. Union of India and Ors., High Court of Judicature at Madras, W.P. No. 28716/2018, dated 17.12.2018.

³ News article on 'Different opinions of two High Courts on online sale of medicine', available at: <https://www.thehindu.com/news/cities/Delhi/two-high-courts-two-different-views-on-online-drugs-sale/article26045505.ece> (last accessed December 26, 2019).

⁴ Report of the 48th Meeting of the Drugs Consultative Committee held on 24th July, 2015. New Delhi. Available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=ODEw (last accessed December 26, 2019).

⁵ Notification dated August 28, 2018 by Ministry of Health and Family Welfare, available at: <http://egazette.nic.in/WriteReadData/2018/189043.pdf> (last accessed December 26, 2019).

⁶ Amendment by Ministry of Health of Welfare dated November 6, 2019, available at: <http://egazette.nic.in/WriteReadData/2019/213740.pdf> (last accessed December 26, 2019).

⁷ News article on 'Circular issued by Drugs Controller General of India', available at: <http://pharmabiz.com/ArticleDetails.aspx?aid=119266&sid=1> (last accessed December 26, 2019).

⁸ The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019 (42 of 2019), available at: <http://egazette.nic.in/WriteReadData/2019/214523.pdf> (last accessed December 26, 2019).

⁹ The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Ordinance, 2019 (14 of 2019) available at: <http://egazette.nic.in/WriteReadData/2019/212582.pdf> (last accessed December 26, 2019).

¹⁰ Advisory notification on Electronic Nicotine Delivery Systems (ENDS), available at: <https://mohfw.gov.in/newshighlights/advisory-electronic-nicotine-delivery-systems-ends-including-e-cigarettes-heat-not> (last accessed December 26, 2019).

¹¹ Advisory on Electronic Nicotine Delivery Systems (ENDS) including e-cigarettes, Heat Not Burn Devices, Vape, e-Sheesha, e-Nicotine Flavored Hookah, and the like Products – reg. Ministry of Finance, Department of Revenue, available at: <http://www.cbic.gov.in/resources/htdcs-cbec/customs/cs-circulars/cs-circulars-2018/Circular-46-2018-Customs.pdf;jsessionid=9FC34600D43298D09E3D1C265319ACC6> (last accessed December 26, 2019).

¹² News article dated December 28, 2018 on Govt restricts import of e-cigarettes available at: <https://www.thehindubusinessline.com/economy/policy/govt-restricts-import-of-e-cigarettes/article25850299.ece>. (last accessed December 26, 2019).

¹³ News article on 'Delhi High Court Decision', available at: https://www.business-standard.com/article/news-ians/delhi-hc-extends-stay-on-circular-banning-e-cigarettes-119051701264_1.html (last accessed December 26, 2019).

¹⁴ W.P. 3690/2019.

¹⁵ Order dated July 25, 2019 by Bombay High Court in *Godfrey Philips India Ltd. & Anr. V. The State of Maharashtra and Ors.*, W.P. 3690/2019.

¹⁶ M/s. Plume Vapour Private Limited & Anr. v. Union of India, A.S.T. 40 of 2019.

¹⁷ Order dated September 26, 2019 by Calcutta High Court in *M/s. Plume Vapour Private Limited & Anr. v. Union of India*, A.S.T. 40 of 2019.

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