

Online Pharmacies: Conundrum On Legality

written by Sindhuja Kashyap | December 24, 2018

"It is easy to get a thousand prescriptions, but hard to get one single remedy" so goes a popular Chinese proverb which succinctly summaries

the pharmacy market in India and the debate surrounding e-pharmacies.

Overview of the legislative

framework

In India, the sale of prescribed

medications is controlled by the Drugs and Cosmetics Act, 1940 ("DCA"), Drugs and Cosmetics Rules, 1945, Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, Indian Medical Act, 1956 and Code of Ethics Regulations, 2002. Given the time that these laws were enacted, they are arguably silent on the issue of e-pharmacies and do not regulate direct online

selling of professionally prescribed medications. Due to the advancement of technology, access of drugs through Internet is sought for by users and this corresponds directly to the numbers of internet users in India which has steadily been on the rise. It is estimated that there are over 3,500 sites dealing with online medicines across the country and given that e-pharmacies are largely unregulated there are concerns that the goods may be fake, expired,

contaminated, unapproved and dangerous to patients and may put their health at

risk. The Drugs and Cosmetics Act, 1940 does not distinguish between online and

offline pharmacies.

On August 28, 2018, the Central

Government vide notification vide its notification G.S.R. 817 (E) dated 28th August, 2018 proposed ePharmacy draft rules under Drugs and Cosmetics Act 1945

with an aim to regulate online sale of medicines across India and provide patients accessibility to genuine drugs from authentic online portals.

Amongst

others, the ePharmacy draft rules^[1]

stated that no person will distribute or sell, stock, exhibit or offer for sale

of drugs through e-pharmacy portal unless registered. Any person who intends to

conduct business of e-pharmacy shall apply for the grant of registration to the

Central Licensing Authority in Form 18AA through the online portal of the Central Government. The e-pharmacy draft rules contemplates that premises from

where the e-pharmacy business is conducted shall be inspected, every two years,

by a team of officers authorised by the Central Licensing Authority, with or without the experts in the relevant field or the officers authorised by the concerned State Licensing Authority. It has been proposed that those who want to do online pharmacy will have to register with the Central Drugs Standard Control Organization (CDSCO).

Present Situation

While the Government is yet to act and provide a legislation, most large online pharmacies are operating based on self-regulation[2] and the industry as such has no standards to follow. The growth of online pharmacies has however had an impact on offline players' business and several bodies including the All India Organisation of Chemists and Druggists (AI OCD) and other similar trade bodies have voiced their opposition the unregulated growth of e-pharmacies.

These frictions resulted in several litigations the first among which was dealt by the High Court of Judicature of Madras in the case of N Ruthyramoorthy v Union of India & Ors[3]

and The Tamil Nadu Chemists and Druggists Association vs Union of India & Ors[4].

In this case, a Writ petition was filed to direct the respondents to ban all such websites from selling Schedule-H, H1 and X medicines in violation of Rule

65 and 97 of Drugs & Cosmetics Rules, 1945 ("Rules") till the license were granted

to sell medicines through the online medium and further recommend measures in order to ban all such websites.

The High Court of Madras, on December 20, 2016 stated in its order that a sub-committee has been constituted by the Drugs Consultative Committee ("DCC") to examine the issues relating to the sale of drugs over the

internet and this report has been duly submitted to DCC. DCC has further submitted the report to Ministry of Health and Family Welfare for consideration. However, no further direction on stay or injunction on present sale of medicines was provided.

On August 28, 2018, Ministry of Health and Family Welfare ("Ministry"), in consonance to the report submitted by DCC, issued a draft on "Sale of Drugs by E-Pharmacy"[5]

for suggestions from public under Drugs and Cosmetic Amendment Rules, 2018 ("Rules 2018").

In absence of any interim measures available to curtail the sale of unregulated medicine through online medium, another case by the Tamil Nadu Chemists and Druggists Association vs Union of India & Ors[6] was filed before the High Court of Judicature of Madras for obtaining interim relief in the matter.

Background of the Case

Petitioner had earlier approached the Court to block the link of all such websites from India who are selling Schedule H and Schedule X

medicines in violation of Rule 65 and 97 of the Rules till the grant of licenses for online sale. However, the Court stated that new rules on the matter were being considered by the Ministry thereby providing no actionable directions on these websites. While a draft regulating online sale of medicine

was welcomed, the Petitioner sought the leave of the Court seeking directions to block the link and sale of all such websites selling drugs online till legislation is enacted and the licenses are granted accordingly.

Issues at hand

- Whether the sale of prescribed medicines through online platform without license is legal?
- Whether online pharmacies are acting as intermediaries or pharmacy stores requiring license?

Contention

According

to the learned senior counsel for the petitioner, online sellers are not following the procedure before selling drugs as per DCA. They are also selling

the drugs included in Schedule H, H1 & X, which are only permitted to be sold with a valid prescription and under the supervision of a registered pharmacist, having licence. The learned senior counsel for the petitioner further submitted that subsequent to the order of this Court in W.P.No.28325 of

2016, the first respondent has issued the draft rules on 28.08.2018, legitimising the whole E-commerce sale of drugs. However, the Central Government

has given 45 days' time to record and consider objections. While the matter is

pending, online sale of the above mentioned drugs are still in existence without obtaining proper licences.

Delhi and Madras High

Courts ban online sale of medicines

The Madras High Court, in view of

the seriousness of the issue and public cause granted interim injunction against the online sale of medicines without licence and directed the first respondent or the competent authority to stall such online sales forthwith. Further,

on December 17, 2018 the Madras High Court referred to the Rules 2018 and stated that *"Though there is a statute,*

the regulatory rules are yet to be notified, in the wake of advancement of technology. Unless the legislation keeps pace with the technology, the commerce

based on technology has to lag behind".

The Madras High Court in absence

of notified draft Rules 2018 directed the online traders to not proceed with their online business in drugs and cosmetics unless the same is notified.

Further, the Madras High Court

directed the Central and State Government to notify the proposed Rules 2018 at

the earliest, no later than January 31, 2019 and the concerned stakeholders were directed to obtain licenses under the notified rules within two months from the date of notification in order to proceed with the online trade of drugs and cosmetics. However, an order was passed by the Madras High Court in furtherance of its judgement dated December 17, 2018 wherein Justice Pushpa Sathyanarayana had suspended the ban till 10:30 a.m. of December 20, 2018^[7].

On December 20, 2018, following a

request for extension of suspension Justice M Sathyanarayanan and P Rajamanickam passed an order stating that the order of suspension shall continue till the Court provides a final verdict in these miscellaneous petitions. The judgement seems to have been arrived on at after the contentions

that there was no express law prohibiting such mode of business was brought in.

The Madras High Court also clarified that the continuance of this order shall not create any equitable rights in favour of the appellants i.e the stakeholders.

It is pertinent to note that

Madras High Court judgement on ban seemed to have arrived at this conclusion after the Delhi High Court Judgment in this regard. On December 12, 2018, a division bench of the Delhi High Court comprising of Chief Justice Rajendra Menon and Justice V Kameswar Rao in a PIL filed by Dr Zaheer Ahmed[8] opined that there is no provision to sell drugs online and therefore, same shall be prohibited unless the draft Rules 2018 are notified by the Government.

Further, on December 20, 2018 division bench of Delhi High Court extended the ban till January 08, 2019.

Analysis

The above cases highlight several important issues and more importantly the lack of governance in public healthcare. We are highlighting key issues surrounding the legality of online pharmacies given the present legal and regulatory quagmire.

Present License Requirements

At the outset, section 18[9]

of the DCA, restricts sale and exhibit or offer for sale of any drugs and cosmetics without obtaining license for the same. Therefore, it is crystal clear that the law permits sales of medicines only by a person who has obtained

license under the DCA.

We have reviewed a number of online platform selling medicines and their business model can broadly be classified into two categories, first are those working as marketplace model wherein they obtain license under the DCA and store certain medicines for the purpose of sale and second are those working as intermediaries who merely function as a platform between the patient and the pharmacies.

While the former business model may

not be a breach of existing legal regulations per se, the latter may have face legal

challenges. The Rules 2018 states that no person shall distribute or sell, stock, exhibit or offer for sale of drugs through e-pharmacy portal unless registered.[10]

Therefore, the intention of the legislation is clear that irrespective of the online pharmacy acting as full-fledged pharmacy or intermediary, it is required

to be registered.

There is also a valid concern

that drugs included in Schedule H, H1 & X of the DCA which is permitted to be sold only with a valid prescription and under the supervision of a

registered licensed pharmacist may be misused on an online platform and be ordered multiple times using the same prescription on a number of online portals.

Adequate checks and balances should therefore be built into the draft Rules 2018.

Conclusion

On the basis of the existing legal regime and the pronouncements of the courts, we are of the view bearing in mind the seriousness of the issue and considering the effect on public health and safety, the judiciary has rightly stepped as a guardian of the larger public welfare. While we may see contrary opinion between the High Court of Madras and Delhi, the same seems to be a direct result of lack of legislation and delay in passing a new one. It is now upto the Government to expedite the legislation process and set in place a system that augurs well for all the stakeholders involved.

Contributed by – Rajesh Sivaswamy, Partner & Sindhuja Kashyap, Corporate - Associate

[1]

[http://www.cdscsco.nic.in/writereaddata/2018_08_28_Draft%20GSR%2017\(E\)_Sale%20of%20Drugs%20by%20E-Pharmacy.pdf](http://www.cdscsco.nic.in/writereaddata/2018_08_28_Draft%20GSR%2017(E)_Sale%20of%20Drugs%20by%20E-Pharmacy.pdf)

[2] <http://ficci.in/pressrelease/2600/ficci-press-nov21-e-pharmacy.pdf>

[3]

W.P. 5611/2016

[4]

W.P. 28325/2016

[5] Notified in the Gazette of India bearing No. 602 dated August 28, 2018

[6] W.P/28716/2018

[7] W.P No. 28716/2018

[8] W.P (C) No. 11711/2018

[9] As

per Section 18(c), no person shall himself or by any other person on his behalf

manufacture for sale or for distribution, or sell, or stock or exhibit or offer

for sale, or distribute any drug or cosmetic, except under, and in accordance with the conditions of, a licence issued for such purpose.

[10] Section 67J of the Rules 2018.

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