DRAFT RULES FOR E-PHARMACY UNDER THE DRUGS AND COSMETIC RULES, 1945

1. INTRODUCTION

The draft amendment to the Drugs and Cosmetic Rules, 1945 (the "**Draft E-pharmacy Rules**") was published by the Department of Health and Family Welfare under the Ministry of Health and Family Welfare (the "**Ministry of Health**") on August 28, 2018, primarily setting out the requirements and conditions for the sale of drugs by an 'e-pharmacy'. Objections and suggestions to the Draft E-pharmacy Rules have been invited from the general public until October 12, 2018, which will be considered by the Central Government before finalizing the regime governing this sector.

As a background, the Drugs and Cosmetic Rules (the "**Rules**") were formulated in 1945 under the Drugs and Cosmetic Act, 1940 (the "**Act**") for regulating the import, manufacture, distribution and sale of drugs and cosmetic in India. Given that the Act and the Rules were enacted prior to the advent of the internet, they did not contemplate the sale of drugs over the internet. With numerous e-pharmacies flourishing online, the office of the Drugs Controller General (India) issued a circular on December 30, 2015 clarifying that the Act and the Rules do not distinguish between the sale and distribution of drugs through conventional means and online. Consequently, entities selling drugs through e-pharmacies were required to obtain a pharmacy license and comply with the Act and the Rules.

Even though entities selling through e-pharmacies were being governed by the Act and the Rules, due to the lack of operational efficiency and monitoring mechanisms, a need was felt to frame specific rules for regulating the online sale and distribution of drugs.

2. HIGHLIGHTS

We highlight below the key proposals in the Draft E-pharmacy Rules.

2.1 Key definitions

Under the Draft E-pharmacy Rules:

(a) The term '*e-pharmacy*' has been introduced to mean the business of distribution or sale, stock, exhibit or offer for sale of drugs through a web portal or any other electronic mode ("**E-pharmacy**").

(b) The term '*e-pharmacy portal*' has been defined to mean a web or electronic portal or any other electronic mode established and maintained by the e-pharmacy registration holder to conduct the business of e-pharmacy (the "**E-pharmacy Portal**").

(c) The term '*sale by way of e-pharmacy*' has been defined to mean a sale whether to a hospital, or dispensary, or a medical, educational or research institute or to any other person through an E-pharmacy by way of retail sale.

2.2 Application for registration and its validity

Any person desirous of conducting an E-pharmacy business through an E-pharmacy Portal will need to obtain a registration (the "**Registration**") by filing an application[1] with the central licensing authority (the "**CLA**"). The application can be made through an online portal along with the documents and the fees[2] mentioned under the Draft E-pharmacy Rules.

If the CLA is satisfied with the application, the Registration[3] will be granted to the applicant (the "**Registration Holder**") within a period of 30 (thirty) days. Otherwise, the CLA may reject the application or request the applicant to rectify the deficiencies in the application within 30 (thirty) days from the date on which the application was made.

The Registration will be valid for a period of 3 (three) years from the date of issue. An application for renewal (the "**Renewal Application**") can be made by the Registration Holder before its expiry or within 3 (three) months from the expiry, in which case the Registration will be valid till an order has been passed on the Renewal Application. If the Renewal Application is not made within 6 (six) months after the expiry, the Registration will be deemed to have been expired.

2.3 Conditions for registration imposed on the E-pharmacy

The Draft E-pharmacy Rules impose the following conditions:

(a) **Location**

The E-pharmacy Portal (*through which the business of E-pharmacy is proposed to be conducted*) must be established in India;

(b) **Disclosure of information and data localization**

The Registration Holder will always need to keep all data received from its customers, including prescriptions and the details of the patient, confidential. Such information cannot be disclosed to any person other than the Central or the State Government by the Registration Holder. Further, the Registration Holder needs to comply with the Information Technology Act, 2000 and associated rules.

The data generated through the E-pharmacy Portal needs to be maintained locally and cannot be sent, stored or mirrored by any means outside India.

(c) **Procedure for distribution and sale of drugs, through E-pharmacy**

The following steps are required to be followed for the online sale and distribution of drugs:

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[1] Please refer to the application under Form 18AA of the Draft E-pharmacy Rules and the list of documents to be enclosed with such application. Also, a duly notarised affidavit from the applicant needs to be attached.

[2] Fee of INR 50,000/- will need to be paid along with the application form.

[3] Please refer to the registration certificate under Form 21AA of the Draft E-pharmacy Rules.

(i) Step 1: Receipt of orders for retail sale through the E-pharmacy Portal;

(ii) Step 2: Verification of the details of the patient and the registered medical practitioner on the prescription by the registered pharmacist on behalf of the Registration Holder;

(iii) Step 3: Procurement of the drugs as per the prescription of the registered medical practitioner (*from any licensed retail or wholesale premises under the Act and the Rules*) within the time communicated to the customer at the time of placing an order; and

(iv) Step 4: Supply of the procured drugs to the customer against a cash or credit memo[4] generated through the E-pharmacy Portal. This memo needs to be maintained as a record by the Registration Holder.

(d) **Customer support**

The Registration Holder needs to maintain a customer support and grievance redressal mechanism for all the stakeholders, for atleast 12 (twelve) hours on all days. A registered pharmacist is required to answer the queries of the customers through the customer helpline.

(e) **Details to be published on the E-pharmacy Portal**

The details such as the Registration number of the Registration Holder, the constitution of the Registration Holder including the details of directors, the official logo of the E-pharmacy Portal, the details of the logistic service provider, the return policy of the dispensed drugs, the name of the registered pharmacist, the contact details of the E-pharmacy, the procedure for lodging grievances and complaints on the E-pharmacy Portal and the redressal mechanism, need to be mentioned on the E-pharmacy Portal.

(f) **Other conditions**

The Registration Holder will need to maintain and update the information such as the availability of drugs, the types of drugs offered for sale, the supply channels or the vendor lists, the details of the registered pharmacists, the registered medical practitioner (if any) and any other requirements of the Act and the Rules on the E-pharmacy Portal. Further, in relation to an e-prescription, the prescription must be uploaded on the E-pharmacy Portal and kept as a record by the dispenser.

2.4 Restrictions imposed on the E-pharmacy

(a) **Prohibition of advertisement**

An E-pharmacy cannot advertise any drugs on radio, television, internet, print or any other media for any purpose.

[4] The memo must contain particulars such as, name and sale license number of the licensee dispensing drugs mentioned in the prescription and name, quantity, batch number, date of expiry and name of the manufacturer of the drugs, etc.

(b) **Dealing in narcotic drugs**

The E-pharmacy cannot sell narcotic and psychotropic drugs as defined under the Narcotic Drugs and Psychotropic Substances Act, 1985, tranquilizers and the drugs specified in the Schedule X of the Rules.

2.5 Monitoring of E-pharmacy

(a) To ensure compliance with the Act and the Rules, the CLA and the state licensing authority (the "**SLA**") will have a right to periodically monitor the information maintained by the Registration Holder on the E-pharmacy Portal;

(b) For a transaction audit[5], the CLA or the SLA may request the Registration Holder to provide the prescription used for dispensing drugs to the customer; and

(c) The premises from where the E-pharmacy business is conducted will be inspected every 2 (two) years by a team of officers authorized by the CLA, with or without the experts in the relevant field, or the officers authorized by the concerned SLA.

2.6 Complaint redressal mechanism

In addition to the rights under the Consumer Protection Act, 1986, a customer will also have an option to file a complaint to the state drugs controller (the "**Drugs Controller**") for any suspicion of supply of non-standard quality, adulterated or misbranded drugs through the E-pharmacy. The Drugs Controller will have a right to take appropriate action under the Act and the Rules to decide the complaint.

2.7 Intimation for change in constitution

For any change in the constitution of the Registration Holder operating the E-pharmacy, a notification to the CLA will need to be made. In such a case, the current Registration of the Registration Holder will be valid only for 3 (three) months from date of such change unless a fresh registration has been obtained from the CLA.

2.8 Cancellation or suspension of registration

If the Registration Holder contravenes any provision of the Act or the Rules, the CLA may suspend or cancel their Registration after providing them an opportunity of being heard.

The Registration Holder has a right to appeal against the order of suspension or cancellation by the CLA to the Central Government in the Ministry of Health, within 45 (forty five) days from such an order of suspension or cancellation. The order may be confirmed, reversed or modified at this stage.

Further, if the license obtained by the Registration Holder for the retail or the wholesale premises under the Act and the Rules is cancelled for 2 (two) or more States, the Registration granted by the CLA under these Draft E-pharmacy Rules will also deemed to have been cancelled for all purposes.

[5] '*Transaction audit*' has been defined to mean audit of the received prescription by the Registration Holder and the drugs dispensed on that basis for risk - based data samples or system generated random data samples.

3. INDUSLAW VIEW

The rules on data localization and establishment of the E-pharmacy in India appear to be a continuation of the Government's policies and recent actions and pronouncements. However, we have provided below certain considerations which, in our view, may be pertinent to be addressed, keeping in mind the various business models operating in India.

3.1 Definition of E-pharmacy

The definition of E-pharmacy seems to be broader than what would appear relevant to monitor and regulate the online dispensation and sale of drugs. The business of only *exhibiting* drugs available, seems to be too wide an ambit and could drag within the fold of the regulations, entities that merely *operate* a marketplace.

From the wording of the Draft E-pharmacy Rules, it appears that a pharmacy already registered under the Act, and which also uses an online model (whether a marketplace or its own website), would therefore also be required to apply for an E-pharmacy license. Since the currently registered pharmacies appear to be sufficiently covered by the existing Act and Rules, we wonder whether the law makers intended to double up on licenses.

3.2 Difference between retail sale and marketplace model of e-pharmacies

In our view, the current form of the Draft E-pharmacy Rules only envisages entities directly undertaking the sale (including '*retail sale*') of drugs and does not explicitly contemplate the '*marketplace model*' under which certain e-pharmacies currently operate in India. Under the '*marketplace model*', an entity merely provides a technology platform to connect sellers and interested customers for the sale of drugs. Normally, such platforms do not own the inventory of the drugs, nor do they conclude the sale, as opposed to the way a pharmacy would operate in the case of a sale (particularly '*retail sale*').

If a marketplace entity was to obtain a registration under these rules (*by the virtue of exhibiting or offering for the sale of drugs through the web portal*), certain obligations laid down in the rules may not be relevant for their business model. These conditions include procuring the drugs for the customer from any licensed retail or wholesale premises, having a registered pharmacist, maintaining a record of e-prescription uploaded on the portal by the dispenser. These are obligations to be fulfilled by a retailer or a seller selling drugs on the e-pharmacy portal and not by an entity managing the portal. It is unclear whether such entities need to procure a registration under these rules. We hope that the Central Government clarifies this aspect in the final rules.

3.3 Foreign exchange regulations perspective

The e-pharmacy license appears not to distinguish between a marketplace and an actual seller of drugs. Even if a marketplace entity having foreign direct investment obtained a registration under these rules, due to the broad ambit of '*E-pharmacy*' which includes exhibiting drugs (*despite not having any ownership over the inventory or being a seller*), such entity may, in our view, still be construed as an e-commerce marketplace under the existing foreign exchange regime in India. Therefore, merely by virtue of obtaining an e-pharmacy license, an online marketplace should not be considered as being involved in retail sale if none of its activities constitute retail sale. This view is necessary to interpret the two pieces of

legislation harmoniously, even though the current form of the rules does not provide any clarity on the marketplace business model of e-pharmacies.

3.4 Lack of clarity on time period within which registration needs to be obtained under these rules

The Draft E-pharmacy Rules currently do not provide for a specific time period within which entities operating e-pharmacies (*to whom the rules apply*) need to obtain a registration under these rules. Therefore, in our view, the final rules must specifically address this issue to provide comfort to e-pharmacy operators and allow them to continue their business operations without any interruptions, until the registration is obtained, or a defined license application period expires.

3.5 Other considerations

Prior to the finalization of the Draft E-pharmacy Rules, we urge the Central Government to also consider the following:

(a) Whether entities operating an e-pharmacy under a '*marketplace model*' will need to obtain a registration under the Draft E-pharmacy Rules? If yes, considering their reach across the country, would such entities also be required to take a license for every State in India where they facilitate sales?

(b) Whether pharmacies already registered under the existing Act and Rules would also be required to obtain an E-pharmacy license to participate on an online marketplace or sell through their own website?

(c) How will the verification of the details of the patient and the registered medical practitioner be undertaken by the registered pharmacist on behalf of the Registration Holder prior to dispensing of drugs to the patient?

(d) What is the duration for which the details of the patients and the drugs dispensed need to be maintained by the Registration Holder?

(e) There is little guidance in relation to the circumstances under which the Registration Holder is required to share the information with the Central Government or the State Government. Clause 67K (2) of the Draft E-pharmacy Rules specifically states that it needs to be done so for public health purposes, however, Clause 67M has been left open-ended. While Clause 67M may have been meant to be subject to the rider of public health purpose similar to Clause 67K (2), it would be useful to clarify this.

(f) Whilst the Draft E-pharmacy Rules purport to apply only to the "*business of distribution or sale, stock, exhibit or offer for sale of drugs through web portal or any other electronic mode*", it does make a mention of an e-prescription (in Clause 67P (4)). It would be useful to clarify what is meant by an e-prescription and the way it will be authenticated for the purposes of dispensing the drugs.

3.6 Parting thoughts

E-pharmacies may well be the catalyst that enables genuine prescription drugs being available to every person in every corner of India.

At the outset, the Draft E-pharmacy Rules do provide a fair amount of clarity to e-pharmacies for conducting their business online. Whilst the introduction of these Draft E-pharmacy Rules is a sensible move towards defining the e-pharmacy business in India, in our view, the revised rules should address the concerns highlighted above to encourage e-pharmacy operators and create a stable environment for investment, whether domestic or foreign. We further suggest that a regular and methodical monitoring and administration of the Act and the Rules would also go a long way towards addressing the issues in the dispensation and sale of drugs in India.

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