

## E-Pharmacies: Prescribed to Succeed

### Introduction

E-pharmacies or online pharmacies have been a subject matter of debate in India for the last 3-4 years. Their offline counterparts have been lobbying to get a blanket ban on any online sale of drugs, whether prescription or over-the-counter. Their resistance is primarily on the following grounds:

- (i) Online pharmacies encourage self medication and illegal purchase of habit forming drugs;
- (ii) Patients can purchase prescription drugs without an original prescription; and
- (iii) The original prescription can be used for repeated drug purchase.

While the business of e-pharmacies can be categorized in two broad types, namely (i) a marketplace<sup>1</sup> and (ii) an inventory-led model, the present newsletter discusses the regulatory ambit which governs inventory led e-pharmacies in India, i.e. those who sell online through a licensed premise, and whether their business model can mould itself to ensure compliance with applicable law.

### 1. Regulatory framework

Drugs are divided into various schedules of the Drugs and Cosmetics Act, 1940 (“**D&C Act**”) and are licensed pursuant to the Drugs and Cosmetics Rules, 1945 (“**D&C Rules**”). Some are deemed as over-the-counter or OTC drugs whereas for others, a prescription is required. These prescription drugs typically fall within Schedule H,<sup>2</sup> H1,<sup>3</sup> and X<sup>4</sup>. When setting up a pharmacy, companies usually apply for licenses<sup>5</sup> that permit them to sell, stock, offer for sale or distribute, by wholesale and retail, all drugs except those listed in Schedule X. Of course, there are some that take specific licenses to sell Schedule X drugs as well.

#### 1.1 Sale by a pharmacist

Once the specific licenses are granted, a pharmacy has to comply with various requirements under the D&C Rules. Some of these are mentioned in Rule 65. Rule 65(2) mandates that “*the supply, otherwise than by way of wholesale dealing of any drug supplied on the prescription of a registered medical practitioner shall be effected only by or under the personal supervision of a registered pharmacist.*” This rule applies to all B2B (*wholesale*) and B2C (*retail*) sales and mandates that any prescription drug shall

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<sup>1</sup> Marketplace has only recently been defined by the Department of Industrial Planning and Policy for the perspective of foreign direct investment. It is essentially a technology platform that acts as an intermediary and connects buyers and sellers. In the pharmacy space, a marketplace does not dispense drugs but connects pharmacies with buyers. The sale of drugs is always carried out by the licensed pharmacy.

<sup>2</sup> Schedule H drugs are a class of prescription drugs that can be only sold against a valid prescription.

<sup>3</sup> Schedule H1 drugs were introduced through notification GSR 588 (E) dated August 30, 2013. They contain certain 3rd and 4th generation antibiotics, certain habit forming drugs, and anti-TB drug which can only be sold against a valid prescription.

<sup>4</sup> Schedule X drugs are also prescription drugs and which contain certain narcotic and psychotropic salts.

<sup>5</sup> Licenses for running a pharmacy are sought under Rule 61(1)-(3) of the D&C Rules. Rule 61(1) grants a license to sell, stock, exhibit or offer for sale or distribute drugs, other than those mentioned in Schedules C, C(1) and X, by retail or wholesale. Similarly, the license under Rule 61(2) grants the same right but for drugs listed in Schedule C and C(1), excluding those in Schedule X. Rule 61(3) grants a license to retail or wholesale drugs listed in Schedule X.

only be supplied under the personal supervision of a registered pharmacist. From a regulatory aspect, an online pharmacy can comply with this requirement since the physical disbursement/sale of drugs, after reviewing the prescription, can be affected by an in-house registered pharmacist.

This brings us to another important question. Does any law in India mandate that registered pharmacists can only dispense drugs based on an original medical prescription as opposed to a scanned or digital version? To understand this better, it is important to review Section 4 of the Information Technology Act, 2000 (“IT Act”), which is a more recent statute, and states the following:

*“Where any law provides that **information** or any other matter **shall be in writing** or in the typewritten or printed form, then, **notwithstanding anything contained in such law**, such requirement shall be deemed to have been satisfied if such information or matter is: (a) **rendered or made available in an electronic form**; and (b) accessible so as to be usable for a subsequent reference.”*

Therefore, if a prescription is in electronic form, it arguably fulfills the requirements of Rule 65(2) of the D&C Rules by virtue of the non-obstante clause in Section 4 of the IT Act. In fact, the IT Act shall also have an overriding effect on earlier legislations pursuant to Section 81 which clearly states:

*“The provisions of this Act shall have effect notwithstanding anything inconsistent therewith contained in any other law for the time being in force.”*

## 1.2 Written and signed prescription

The second contentious rule is Rule 65(9)(a) which states that “*substances specified in Schedule H and Schedule H1 or Schedule X shall not be sold by retail except on and in accordance with the prescription of a registered medical practitioner.....*”. Rule 65(10) further states that “*For the purposes of clause (9) a prescription shall (a) be in writing and be signed by the person giving it with his usual signature and be dated by him; (b) specify the name and address of the person for whose treatment it is given; (c) indicate the total amount of the medicine to be supplied and the dose to be taken.*”

Since Rule 65(9)(a) is absolute in nature, the argument put forth by offline pharmacies is that electronic prescriptions do not conform to Rule 65(10) of the D&C Rules. However, nowhere does Rule 65(10) make reference to the “original” prescription and there is no specific requirement in it that cannot be fulfilled by an electronic copy. Accordingly, the letter and spirit of this Rule can be complied with even with a scanned or digital prescription.

## 1.3 Stamping of prescriptions

The last and perhaps the most critical rule is Rule 65(11). It is from this rule that most offline chemists derive maximum thrust to their arguments, irrespective of whether they themselves comply with it or not. Rule 65(11) states that “*The person dispensing a prescription containing a drug specified in Schedule H and Schedule H1 and Schedule X shall comply with the following requirements in addition to the other requirements of these rules: (a) the prescription must not be dispensed more than once unless the prescriber has stated thereon that it may be dispensed more than once; (b) if the prescription contains a direction that it may be dispensed a stated number of times or at stated intervals it must not be dispensed otherwise than in*

*accordance with the directions; (c) at the time of dispensing there must be noted on the prescription above the signature of the prescriber the name and address of the seller and the date on which the prescription is dispensed.*

The argument put forth by offline pharmacies is that online pharmacies cannot comply with Rule 65(11)(c) and because of this non-compliance, they are more likely to also be in breach of Rule 65(11)(a).

If one evaluates Rule 65(11)(c) and 65(11)(a) with a legal lens, neither of the rules make reference to an “original” prescription. Interestingly, the word “prescription” has not been defined in either the D&C Act or the D&C Rules. It has been defined for the very first time by the Pharmacy Council of India in its Pharmacy Practice Regulations, 2015 (“**Regulations**”). As per section 2(j) of these Regulations, it means “*a written or **electronic direction** from a Registered Medical Practitioner or other properly licensed practitioners such as Dentist, Veterinarian, etc. to a Pharmacist to compound and dispense a specific type and quantity of preparation or prefabricated drug to a patient.*” Based on this, a simple reading of Rule 65(11)(c) would only go to show how online pharmacies are capable of complying with the requirements of the law provided customers/patients do not misuse it. With digitization of doctor-patient relationships, going forward we will only see more e-prescriptions as opposed to physical ones. Therefore, it becomes even more necessary for regulators to interpret Rule 65(11)(c) based on how the spirit of the law is being complied with as opposed to the literal letter. If the only ground for prosecuting online pharmacies is non-compliance with Rule 65(11)(c), there is absolutely no reason why offline pharmacies should be left outside the ambit of such prosecution.

## 2. Other legal red-flags

There are other aspects to the business model which also require a legal assessment.

### 2.1 Location specific licenses

Since licenses are given for a specific premise, it is important that “sale” as per the Sale of Goods Act, 1930 is concluded at the licensed premises. In fact, Rule 62 of the D&C Rules unambiguously states that “*if drugs are sold or stocked for sale at more than one place, separate application shall be made, and a separate license shall be issued, in respect of each such place.*” Therefore, the business model has to ensure that the “sale” and “stocking” of drugs is always in compliance with Rule 62.

To understand how the online model is legal, it is important to evaluate it based on an ongoing practice followed by offline pharmacies. The manner in which a physical pharmacy is able to sell drugs through its licensed premise but still deliver it to our homes is exactly how the online model can comply with the requirements of Rule 62. In other words, the “sale” must always conclude at the licensed premise.

### 2.2 Delivery

Delivery of drugs across India and their storage by courier companies has been a grey area in law. Rule 61 of the D&C Rules, which mandates taking a license for “stocking” and “distribution”, could possibly trigger if courier companies pick up drugs from a pharmacy, store it in their warehouse for the night, and deliver it the next day. However, as long as the drugs are properly packed and do not require special storage conditions, such narrow interpretation to the

law can be counterproductive since India's logistics network will also facilitate the most critical drugs to reach the remotest corners of the country. At the same time, e-pharmacies should also ensure that they do not sell drugs or injections online which require below freezing temperatures or special environments all the way till when they are delivered.

Notwithstanding the above, the delivery model has to comply with applicable laws regardless of how "noble" a task it may be. E-Pharmacies should evaluate creating contractual terms wherein the delivery person/courier company acts as an agent<sup>6</sup> of the customer through an express or implied authority. This implies that handing over the drugs to the agent will deem handing it to the customer. In fact, even if there is no express or implied authority, accepting the delivery of drugs could also contractually result in ratification of the acts of the "agent," thereby making the delivery legal.<sup>7</sup> Of course, these nuances would often depend upon the facts and circumstances of each instance and the overall business model adopted by the e-pharmacy.

### Conclusion

All of us know of at least one family that boasts of getting their medicines home delivered by making a phone call to their local pharmacy. Imagine the same service but with better accountability where the pharmacist dispenses the drug only after making sure there is a valid prescription. That, in short, is how most online pharmacies want to operate. It is a system that balances the needs of the consumer and the interests of the regulator. Needless to say, stringent methods should be adopted if companies are found selling without a pharmacy license or selling drugs that their license does not permit them to. However, an umbrella ban is never a solution.

Online pharmacies can have many benefits, such as - **(i)** a central database of prescriptions and drugs dispensed that will ensure prescriptions are not re-used contrary to the instructions of the doctors (*i.e. better compliance with Rule 65(11)*), **(ii)** analytics that will help ascertain what type of drugs are prescribed by doctors for specific diseases and result in better R&D by pharmaceutical companies, **(iii)** immense convenience for patients suffering from chronic diseases where their online orders will ensure timely delivery of medicines, **(iv)** sale with proper records to avoid any adulterated drugs to penetrate the supply chain and if they do, to be able to track the source, **(v)** sale of genuine drugs in remote towns and villages where pharmacies are often never audited and do not have enough stock or specialized infrastructure to hold stock for specific drugs, etc.

While most e-pharmacies in India have implemented a "Self Regulation Code of Conduct" based on industry good practices, the need of the hour is specific regulations that allow them and the regulators to ensure that the spirit of the D&C Act and D&C Rules is not compromised.

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<sup>6</sup> Section 182 of the Indian Contract Act, 1872 defines an "agent" as a "*person employed to do any act for another, or to represent another in dealings with third person.*"

<sup>7</sup> Section 196 and 197 of the Indian Contract Act, 1872 describes the legal impact of ratifying the actions of an agent.