

E-Prescription & E-Pharmacy : Opportunities & Challenges for India

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Topics

- Current rules in place
- How can technology help ?
- Regulating Online Pharmacies

Current Rules in Place

Drugs – Types

Sec 3(a) “Ayurvedic, Siddha or Unani drug” includes- - - - -

Sec 3(b) “drug” includes—

- (i) all medicines- - - - -;
- (ii) such substances (other than food) intended - - - - -;
- (iii) all substances intended for use as components- - - - - ; and
- (iv) such devices intended for internal or external use in the diagnosis- - - - -;

Rule 2(dd) “Homoeopathic medicines” include any drug which is recorded in Homoeopathic provings or therapeutic efficacy- - - - -;

Prescription Drugs – Sch. H, H1, X, G / NDPS

Non Prescription Drugs ?

D&C Act Highlights

Section 18. Prohibition of manufacture and sale of certain drugs and cosmetics – From such date, no person shall himself or by any other person on his behalf (**online or otherwise**) —

(a) (iv) any drug or cosmetic in contravention of any of the provisions of this chapter or any rule made thereunder;

(c) 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 license issued** for such purpose under this Chapter

Prescription - Rx

- **Rule 65. Conditions of licenses.** - subject to the conditions stated therein and to the following general conditions
- **(9)(a)** 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 and in the case of substances specified in Schedule X, the prescriptions shall be in duplicate, one copy of which shall be retained by the licensee for a period of two years.
- **(9) (b)** The supply of drugs specified in Schedule H and Schedule H1 or Schedule X **to Registered Medical Practitioners, Hospitals, Dispensaries and Nursing Homes** shall be made only **against the signed order** in writing which shall be preserved by the licensee for a period of two years

Prescription - Rx

Rule 65 (10) 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;

Prescription - Rx

Pharmacy Practice Regulations, 2015

Government of India Notification No. 14.148/2012 January 16, 2015

GOK order No. HFW 163 PTD 2016, Bengaluru, the 17th June , 2016 effective from November 24, 2016

Regulation 2(j) defines “**Prescription**” 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.

Contents of the Prescription: - there are 9

IT Act Highlights

Sec. 2 of DCA: Application of other laws not barred,- The provisions of this Act shall be in addition to, - - - - -any other laws for the time being in force.

Sec 4 of the Information Technology Act defines as under: Where any law provides that information or any other matter shall be in writing or in the type written or printed form, them 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 electronic form** (b) accessible so as to be usable for a subsequent reference.

Sec 5 of the Information Technology Act defines as under: Legal recognition of **digital signatures:** Where any law provides that information or any other matter shall be authenticated **by affixing the signature** or any document shall be signed or bear the signature of any person notwithstanding anything contained in such law, such requirement **shall be deemed to have been satisfied,** **if such information or matter is authenticated by means of digital signature** affixed in such manner as may be prescribed by the Central Government.

Dispensing of Prescription Drugs / stamping

Rule 65(11) 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 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.

Substitution – permission

Rule 65(11-A)

No person dispensing a prescription containing substances specified in Schedule H and Schedule H1 or X, **may supply any other preparation**, whether containing the same substances or not in lieu thereof.

Current practice of operating based on scanned Rx

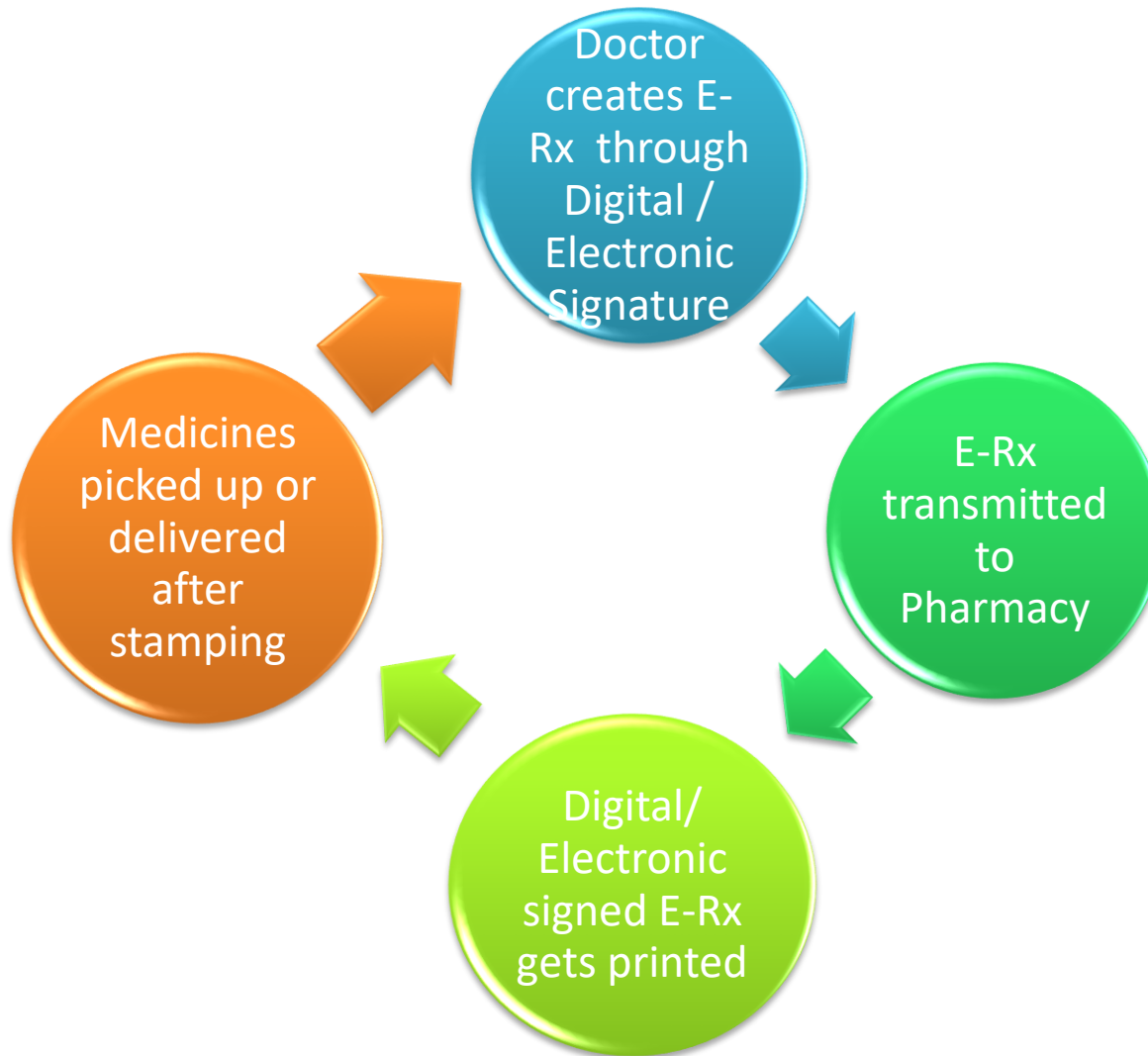
- Online sale of drugs using **scanned prescription** violates all the critical rules of existing D&C Act – viz:
 - Dispensing **without valid prescription** as scanned signature is not valid even as per IT ACT (but electronic signature is valid)
 - Dispensing **without stamping of valid** prescription (**what is valid no where defined**).
 - IT ACT is being misinterpreted and being misquoted by the so called few of the market place Online Pharmacies
- Fabricated scanned Rx can cause legal implications for the doctor whose Rx has been copied
- Scanned Rx including signatures can be easily copied / created using any editing software and leads to abuse and multiple dispensing.

How Can Technology Help?

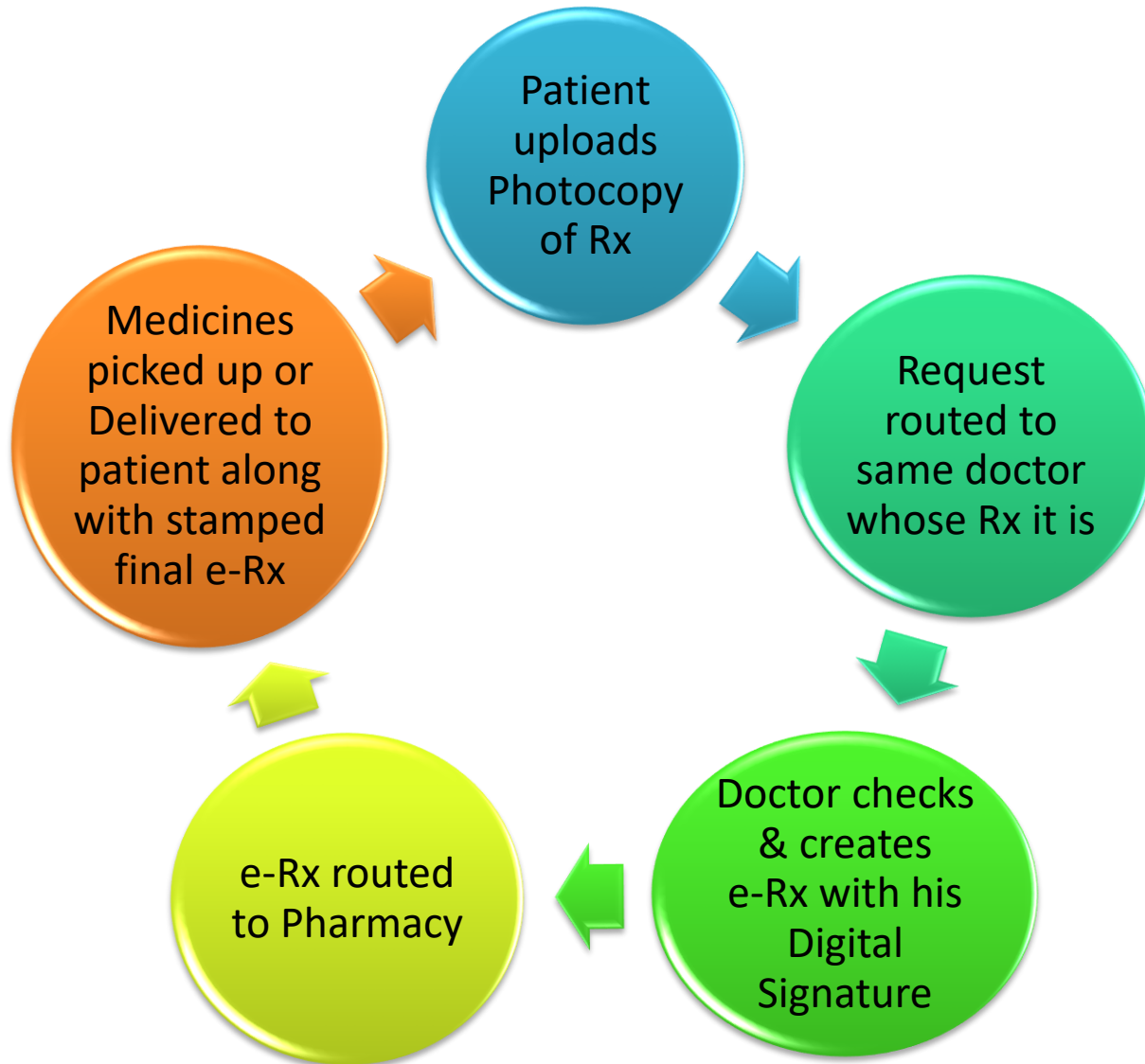
E-Prescription – The Futuristic Model - Digitisation

- Electronic Rx (E-Rx) is created by the Doctor using software and it is digitally / electronically signed
- E-Rx helps in doctor and pharmacy integration
- E-Rx prevents misinterpretation of Rx thereby avoiding errors while dispensing
- E-Rx helps in easy dispensing of medicines and prevents batch or wrong expiry, mismatch
- E-Rx helps in easy moving of refills from one pharmacy to another as per customer choice with Rx validity clearly known to the new pharmacy
- E-Rx gives
 - FDA a much cleaner and better long term records than manual keeping.
 - FDA can demand complete copy of Rx records on it's own server, if needed.
 - FDA will be able to see entire end to end movement of Rx from prescribing till dispensing.
- E-Rx setup modernizes overall healthcare setup of India and creates environment for only serious players which would also reduce healthcare costs tremendously while at the same time increasing patient safety. A clear win-win for FDA, GOI, Patients, Doctors, Pharmacists and Chemist shops

In-clinic E-Rx



Remote E-Rx



Practices in Regulated Markets

- US – VIPPS Program



- Common seal for VIPPS accreditation

- Only 40 approved VIPPS Pharmacies in entire USA in 6 Years

- Main criteria to maintain 3 things:

 - Integrity, Legitimacy & Authenticity of Rx

 - Integrity ensures Multiple dispensing cannot happen
 - Legitimacy ensures Rx is correct, valid & from a valid prescriber
 - Authenticity ensures Rx is actually from prescriber and not faked

Note: **Scanned Rx dispensing not to be allowed**

Only E-Prescription from Doctor directly to Pharmacy may be allowed

Practices in Regulated Markets

- New EU regulation that govern sale of medicines online mandated online pharmacies in EU to carry EU logo w.e.f., 1 July 2015
- All the retailers will have to be registered with the medicines and healthcare product regulatory Medicines and Healthcare Products Regulatory Agency (MHRA) and display the same in all the webpages which confirm that the seller is registered



 Zur Überprüfung
der Legalität
dieser Website
hier klicken

Regulating Online Pharmacies

Regulating Online Pharmacy Intermediaries

- Fixing hefty fees for registration with CDSCO and updating – Ensure only serious players start
- Strict rules for displaying Dispensing Pharmacy information on the website with full address and contacts & should have a retail license from the respective state.
- Ensuring Rx sanctity – Only E-prescription with digital / electronic signature to be allowed
- Severe punishments for violations including hefty fines

Investment Potential for India

- Online pharmacies operating on **scanned Rx** can be easily setup and the number of players will easily become 20,000+ in 2 years because of ease of setup. This will severely fragment the market and no one will have enough share of market to invest heavily in modernizing or improving current delivery / supply chain system.
- Setting up E-Rx companies is capital intensive with extensive dependency on technology, infrastructure and resources which leads to only few players in the market who are ready for higher investment which would lead to modernization of entire system and also helps in higher valuation.
- Since the number of E-Rx companies will be limited, they will have the potential of attracting investment earnings to the tune of USD 20 to 40 billion with stakeholders who are getting interested.

END NOTE

- E-Rx is the only model which can create a true **WIN-WIN-WIN** for all
- E-Rx will ensure patients have convenience, EHR records, affordability, accessibility
- E-Rx will ensure FDA has very good control with ability to see meta data of disease trends, Rx records, easy recalls, easy alerts, end to end visibility
- E-Rx will ensure AIOCD all 7 lakh chemists have equal opportunities to be on such platform
- E-Rx will ensure Online Pharmacies can operate in the correct legal manner
- E-Rx matches with Digital India dream of Government. Some online pharmacies are pitching their regressive scanned Rx models as Digital India which is wrong as it is not progression but regression
- E-Rx assures Doctors that someone cannot misuse their name and create fake Rx with their names

GOI Notifications

- GSR 817 (E) dt. 28.08.2018 Draft Rules on e-pharmacy
- **Telemedicine Practice Guidelines - 25th March 2020**
 - **1.3.1 A Registered Medical Practitioner** is entitled to provide telemedicine consultation to patients from any part of India
 - **1.3.2** RMPs using telemedicine shall uphold the *same professional and ethical norms and standards* as applicable to traditional in-person care, within the intrinsic limitations of telemedicine
- Patient consent is necessary for any telemedicine consultation. The consent can be Implied or explicit depending on the following situations:
 - **3.4.1** If, the patient initiates the telemedicine consultation, then the consent is **implied**.
 - **3.4.2** An **Explicit patient** consent is needed if:
 - A **Health worker, RMP or a Caregiver** initiates a Telemedicine consultation.
- GSR 220 (E) dt. 26th March 2010 - Doorstep delivery of the drugs by retail

Advantages

- the foremost advantage is lower prices due to absence of many operating costs
- are extremely convenient - can be delivered directly to the patient's home or be picked up from a local site.
- affords consumers with more privacy than the traditional doctor or pharmacy visit.
- helps in doctor and pharmacy integration, prevents misinterpretation, avoids errors of reading the hand writing of doctors while dispensing & stalls batch number and wrong expiry mismatch
- E-Prescription (e-Rx) gives FDA a much cleaner and better long term records than manual keeping.
- E-pharmacy is a part of the Digital India campaign because from e-governance to e-learning, the idea of the movement is to transform the country into a digitally-empowered society.
- Electronic prescription is the futuristic model of drug dispensing

Disadvantages

- The ability to access prescription drugs without a confirmed face-to-face physician consultation creates a large risk of misdiagnosis which, in turn, results in the wrong prescription being dispensed.
- provide a relatively effortless way for drug abusers and addicts to acquire prescription drugs
- the biggest risk that online pharmacies pose is to the patient's health.
- drugs that can only be purchased with a prescription such as those of antibiotics, habit forming, psychotropic etc., can be purchased without prescription from online pharmacy
- Some websites may also misuse patients' personal and financial information
- **There are two major issues as far as online pharmacy is concerned i.e. the one with regard to the type of prescription to be honored and other one with regard to mode of delivery that is whether home delivery in person or by post or by courier.**

Latest News - - Khaleej Times dt. 06 March 2018

UAE bans hand written medical prescriptions : The UAE's Ministry of Health and Prevention has issued a circular that private medical facilities can no longer issue handwritten prescriptions and instead must give electronic or printed versions.

Nearly 7,000 deaths worldwide result from illegible hand writing

Court Matters – Madras HC

- TN Chemists & Druggists Association – Gen Sec K K Selvan Vs. UOI, CDSCO, DC TN - WP **5611 / 2016 & 28325 / 2016** @ Madras HC –
- on 20.12.2016 Learned Asst. Solicitor General states that it may be put in public domain whereafter final decision will be taken. The process require about 3 months. **WPs are accordingly closed**

Court Matters – Madras HC

- TN Chemists & Druggists Association – Gen Sec K K Selvan Vs. UOI, CDSCO, DC TN & others –
WP 28716 / 2018
 - On 31.10.2018 - Taking note of the seriousness of the issue and public issue this court grants **interim injunction against the online sale of medicines without license &** directs the first Respondent or CA **to stall such online sales forthwith**
 - **On 17.12.2018 - Para 37.** ----- R1 & R3 are directed to notify proposed D & C amendment rules, 2018 in the Gazette at the earliest however not later than 31.01.2019. **Para 38.** As the draft rules are framed by the central Govt. after deliberations including the stakeholders, till the aforesaid rules are notified, **the online traders are bound not to proceed with** their on-line business in drugs & cosmetics. Having regard to the submissions of either side, the **order passed today will not be given effect to till 10.30am on 20.12.2108**

- **WA 2810 / 2018 & Others---**
 - **On 20.12.2018** - learned judge has suspended Paragraph 38 of the impugned order passed by in the WP till 10.30am today and since this court has already entertained the writ appeals and after hearing the rival submissions has reserved orders in these petitions for interim orders, **till it pronounces orders the order of suspension shall continue ---**
 - On 02.01.2019 – Para 26. In the result, there shall be an order of **ad-interim stay of Paragraph 38 of the impugned order dated 17.12.2018** made in WP 28716 / 2018 until further orders. Post for final disposal on 24,01.2019

Court Matters – Delhi HC

- Dr. Zaheer Ahmed Vs. UOI & Others - WP (C) 11711 / 2018 & CM Appeal 45307 / 2018 @ Delhi HC – PIL
 - **On 12.12.2018** - - - also invites our **attention to an interim order passed by the Madras HC in WP 28716 / 2018 & WMP 33542 / 2018 on 31.10.2018** wherein taking note of all factors and seriousness of issue and public cause is involved., interim injunction has been granted with regard to online sale of medicines without license and the CA has been directed to stall such online sales forthwith. **We see no reasons why similar directions be not issued in the present case.**
 - **Respondents are injuncted from online sale of medicines without license** and the respondents are directed to ensure that same is prohibited forthwith until further orders.
 - **On 08.01.2019** - - - Keeping in view of the averments made by UOI in their counter affidavit, for the present, **we are not inclined to vacate the interim order dated 12th December 2018 till the next date of hearing**

THANK YOU

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