

E-PHARMACY V/s E-PRESCRIPTION

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E-Pharmacy

- An online pharmacy, internet pharmacy or mail-order pharmacy is a pharmacy that operates through the internet and sends the orders to customers through mail or shipping companies.
- There has been lot of discussion in online pharmacies in India since last 4 years but still general public do not have a clear understanding of what it is and how it operates.

Models of E-Pharmacy

A. Organized e-pharmacy

There are two models

1. The **market place model**, where a technology company connects neighborhood licensed pharmacies to the end user;
2. The **inventory based model**, where e-pharmacy is the online service of an offline licensed pharmacy.

Models of E-Pharmacy continue.....

B. Non-organized e-pharmacy

- In this model prescription medicines are ordered without any validated prescription.
- There is no check on the genuineness of the order due to absence of qualified pharmacists.
- Also, improper record keeping and no audit is a major area of concern.

Illegal trade through e-pharmacy

- Drugs are shipped across the international borders without any prescription and approval from the concerned authorities. E.g., Order of cheaper version of drugs like Viagra.
- The laws governing pharmacies in India are derived from Drugs and Cosmetics Act, 1940; Drugs and Cosmetics Rules, 1945; Pharmacy Act, 1948; Indian Medical Act, 1956 and Code of Ethics Regulations, 2002 etc.
- These all laws written before the computer era

- There are no **laws/ guidelines** to regulate, control and monitor e-pharmacies, it seems very difficult to control, monitor and track sale of drug through e-pharmacies.
- When e-pharmacy regulation is concerned, there is lack of accuracy in stated laws
- **Current D&C Act 1940** does not distinguish between **online** and **offline** pharmacies
- E-pharmacy players make interpretation of laws and rules as per their convenience for their business.

Drugs and Cosmetics Act, 1940

- Section 18 (c) of the D & C Act, 1940 prohibits manufacture and sale of any drug without a license.
- As per the Section 18 (c) of D & C Act , 1940 to be read with Rule 65, only a licensed retailer is entitled for the sale of drugs and that too on the basis of prescription of a doctor only.

The Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules, 1945

- Have clear guidelines on the sale of Schedule H and Schedule X drugs (**Narcotics**), which are 'restrictive drugs' and can be sold only on the prescription of a registered medication practitioner.

Rule 65 of Drugs and Cosmetics Rules, 1945

- Stipulates sale of drug under the supervision of a registered pharmacist which also involves signing of the bill and stamping of the prescription by the pharmacist and the doctor.
- Schedule H1 of the D & C Rules, 1945 mandates a licensed pharmacist to maintain a separate register for sale of Schedule H1 drugs with details of the patient, doctor and the name of the drug/s including quantity; it is to be kept for 3 yr and is open to inspection by regulatory authorities.

Indian Medical Council Act, 1956 and code of ethics regulations, 2002

MCI Code of Ethics, 2002

- Regulation 5.3 stipulates that pharmacists and doctors should work together. By e-pharmacies this relationship will be lost.
- Regulation 7.14 does not allow a registered medical practitioner to disclose the secrets of a patient
- Regulation 6.4 prohibits from giving or receiving any rebates or commissions. E-pharmacies may provide rebates/ commissions to doctors to provide prescriptions on the basis of online information of patients.

The Indian Pharmacy Act, 1948

According to subsection 1 of section 42
“no person other than a registered
pharmacist shall compound, prepare, mix,
or dispense any medicine even on the
prescription of a medical practitioner”.

Drugs Controller General of India (DCGI)

- DCGI bans sale of medicines through e-pharmacies on 30th December, 2015.
- DCGI emphasized to keep eye on the online sale of medicines to stop breaching rules and regulations.
- Hence all e-pharmacies operating in India are under the regulatory scanner.

- Concerned authorities try to draft new rules for online model which would not hurt business of existing model player.
- Both models should be operated, worked and regulated in harmonized and synchronized manner.
- The report has suggested amendments to drug rules and a “negative list” which specifies drugs prohibited to sell to ensure the safe running of online pharmacies.
- It has suggested integrating AADHAR Number into the overall e-pharmacy framework to make the retail process more transparent.

- E-pharmacies market is > \$35 billion and will grow to \$65 billion by 2025.
- Industry experts estimate the market to be generating 4,000-5,000 orders on a daily basis.
- Globally, e-pharmacy is growing as a steady 15% and expected to be a \$200 billion industry by 2025.
- It has been estimated that more than 250 online pharmacies have sprung up in India in recent years.
- Investors are willing to fund the e-pharmacies because they knew this model is potential enough to revolutionize the pharmaceutical industry.

- According to an April 2019 report by [The Economic Times](#), the sales in India top three online pharmacies- [Netmeds](#), [Medlife](#) and [1Mg](#) grew three fold in the financial year 2018-19.
- Currently, there are many leading e-Pharmacy players such as [Zigy](#), [Bookmeds](#), [mChemist](#), [Medidart](#), [SaveOnMedicals](#), [Pharmeasy](#), [Savemymeds](#), etc.

What should do to improve regulations?

- Design website for checking legality of e-pharmacy.
- Make guidelines for consumers for safely accessing e-pharmacies and explains how to buy medicines safely from e-pharmacies.
- Specific and clear-cut rules should be made for selling, prescribing, dispensing, and delivering prescription drugs through e-pharmacies.
- List of illegal and blacklisted e-pharmacies should be provided to help out consumers and stop them using such fake websites.

What should do to improve regulations?

- Government should make a common logo for legally operating e-pharmacies to distinguish them from illegal one.
- Make guidelines for online drugs importation and re-importation for legislators and consumers.
- It is mandatory for e-pharmacies dealing with online drugs importation and re-importation to be registered and to get license for the same from regulating body.

What should do to improve regulations?

- As the power of drug regulation is distributed between Central and State government, role of Central government and State government should be well defined.
- E-pharmacies' should not be allowed to use the data generated from online business for commercial purpose.
- Government schemes like National Rural Health Mission (NRHM) can aid in promoting proper procedures to acquire drugs, prevent self-medication through campaigns on television, radios and social media

What should do to improve regulations?

- Watch should be kept on importation of banned drugs through e-pharmacies outside India which **don't come under Indian jurisdiction**.
- E-pharmacy must establish its **server in India** as if it is outside the boundaries of India, it is difficult to control and regulate it.
- Each and every activity and transactions made through e-pharmacies must be under regulatory scanner **to prevent it from underworld and smuggling**.
- To ensure efficient running of e-pharmacies great compliance & strict adherence to laws is required. So, regularly check whether e-pharmacies follow it or not.

Conclusion

- **No doubt, E-pharmacies benefits** a consumer in many ways mainly providing convenience and efficiency in their busy life **but at their own health cost.**
- Regulatory authorities find it difficult to control, monitor and track sell of drugs via internet as there is lack of clear cut guidelines in India for regulating e-pharmacies.
- **It will promote self medication, drug abuse, drug addiction, drug resistance.**
- **E-pharmacy may be proved as dangerous trend in future if not regulated properly.**

E-Prescription
or
E- Prescribing
or
E-Rx

Introduction

E-prescription is an electronic way to generate and transmit prescription and prescription related information among prescriber, pharmacy & payer.

The E-Prescription (eRx) service is made up of electronic prescribing and electronic dispensing between doctor & Pharmacist

Electronic prescribing allows to send accurate and legible prescription online.

Once the medicine is dispensed, the dispenser shall report via software the information about the dispensed medicine(s).

Electronic prescribing is not faxing or printing paper prescription.

Definition of e-Prescription

National Council for Prescription Drug Programs (NCPDP), USA gives two definitions

NCPDP Definition 1:

e-Prescribing is the ability of a physician to submit a "clean" prescription directly to a pharmacy from the point of care.

NCPDP Definition 2 : in two parts:

Part 1: Two way [electronic] communication between physician and pharmacy involving prescription fill messages to track patient compliance.

Part 2: Potential for information sharing formulary information and medication history.

Health Canada: e-prescribing as a means of streamlining the prescription process by enabling prescription to be created, signed and transmitted electronically.

National e-Pharmacy Task Forces (NePTF):

e-Prescribing is the **secure** electronic transmission from an **authorized prescriber of a prescription to a patient's pharmacy of choice** integrated with pharmacy software.

There are **several definitions** of e-prescribing and it is important to have a common definition in **multiple jurisdictions to ensure consistency among technical solutions**.

Problems with Paper Based Prescribing System

Fraud

- Prescription pad theft
- Altered prescription dispensation
- substitution, short of the correct quantity, or indeed,
- by adding items to prescriptions or changing the
- amounts of the drugs prescribed, etc.
- Data Integrity
- Administrative Workload
- Efficiency and Safety
- Patient Exemptions / Identification
- Waste of paper, time and money.
- Hence, one must find alternatives to paper based system.

Advantages of e-Prescription

- Doctors can have previous medication history, lab history, patient history, complete patient drug profile, patient allergy information and drug-drug interaction etc. including family members and background, routine life and habit, which help in the analysis of disease and plan for the best course of treatment.
- There may be a potential decline in drug interactions and adverse drug reactions. Hence it supports enhanced patient care.
- Reduced cost of dealing with adverse drug events (ex. fewer tests, additional treatment and length of stay).

Advantages

- Patient-specific alerts such as overdose warnings and allergy alerts.
- Alerts for contra-indications, allergic reactions and drug interactions.
- Guidance for inexperienced prescribers.
- Discharge prescriptions.
- There will be instant transmission of information from practitioner to pharmacist.
- It will have huge benefits for research to the villages of our country.
- Reduction in paper-based process problems.

Advantages

- E-Rx are easier to read than handwritten prescriptions. It may minimize medication and dispensing error caused by misinterpretation of prescription. There is zero /less chances of dispensing the wrong drug or dose.
- It eliminates the problem of patient having lost prescription. Reduce missed doses as prescription available at all times
- Thus, eRx can keep everyone safe & secure.

Principles of eRx

It requires legal transfer of prescription and related patient-specific information between prescribers and pharmacists are as:

1. The process must maintain patient confidentiality/privacy.
2. The process must be able to verify the authenticity of the prescription (i.e., the prescriber initiating the prescription).
3. The accuracy of the prescription must be able to be validated, and the process must include a mechanism to prevent forgeries.

Principles of eRx

4. The patient must determine the practitioner as patient choice to receive the prescription authority.
5. As a patient choice, the prescription authorization cannot be transmitted to more than one pharmacy.
6. GP and Pharmacist both must have the access and ability to write to the patient profile and other clinical support decision tools.
7. Software vendors must be compliant with the standards implemented through a jurisdictional conformance process that outlines security and implementation protocols.

Security Components of eRx

Six components to secure eRx delivery system:

1. **Transaction integrity:** (digital signature: "secure electronic signature" means "an electronic signature that result from the application of a technology or process whereby it can be proved).
2. **Data integrity & Confidentiality:** (encryption): **Encryption** ensures the integrity and confidentiality of a transmission so that data cannot be modified or accessed by anyone except an authorized users)
3. **Authentication:** Authentication allows control of user access to a system. Users of eRx delivery system would require authentication.

Security Components of eRx

4. Secure routing: (server integrity and intrusion detection) - The patient arrives at their pharmacy of choice and the prescription is retrieved from the Drug-Information-System (DIS). The method of delivery is either through a secure provider portal or via a system-to system integration).

5. Alternate security structure: Health Information Access Layer (HIAL) (Health Canada)

6. Standards

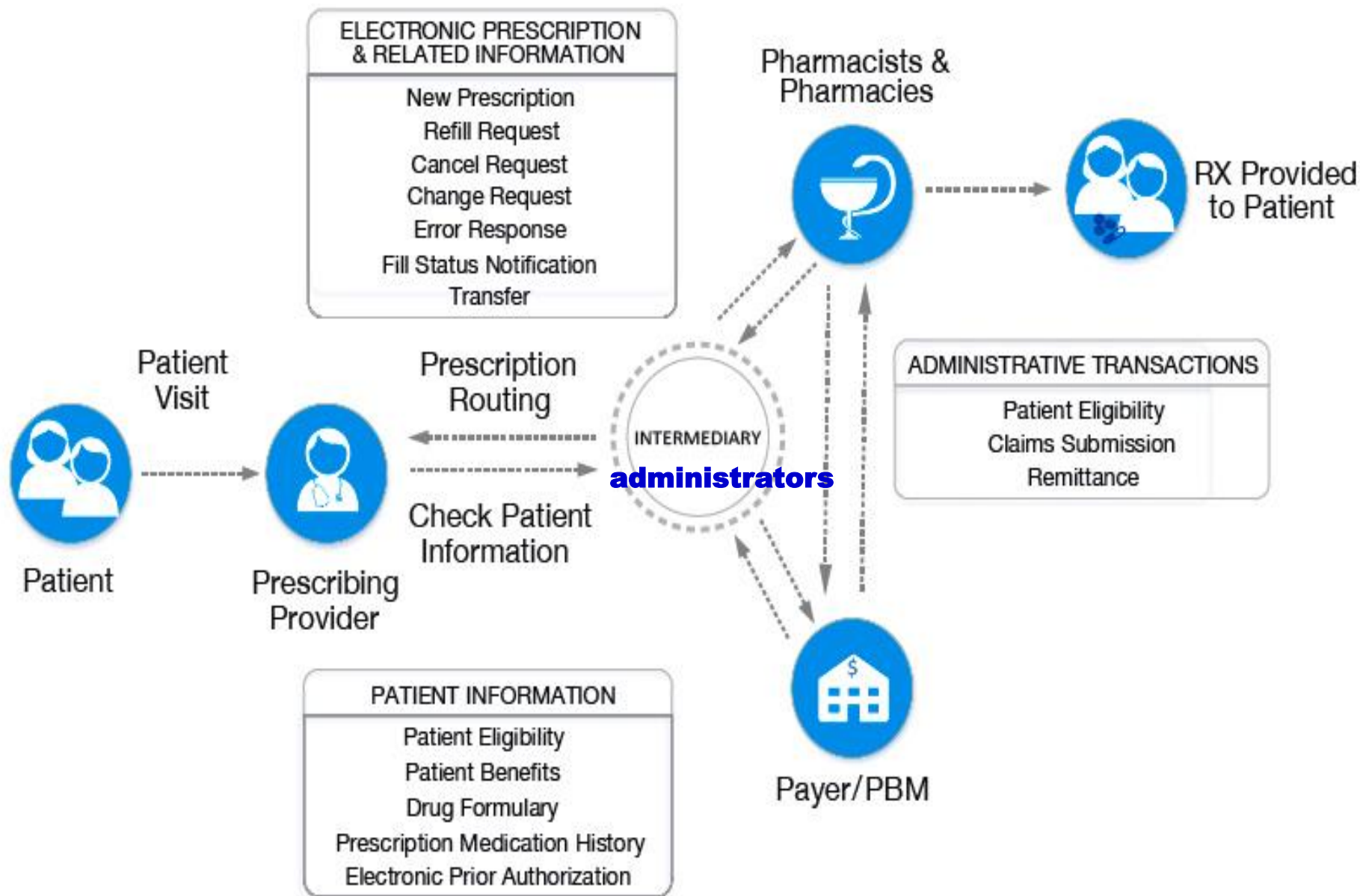
complete requirement for eRx system

- Support software,
- Electronic medication
- Administration records,
- Automated pharmacy systems,
- Bar coding,
- e-pad, electronic discharge
- Prescriptions and
- Targeted patient information.
- Requires IT hardware e.g. laptops, tablets, mobile, PCs, etc

Stakeholders

Three Stakeholders:

- **Prescriber(s)**: including licensed providers & their agents
- **Pharmacy(ies)**: including facilities and pharmacists
- **Payers/PBMs**: including payers, group purchasers, and **Pharmacy Benefit Managers (PBMs)**



eRx system includes three phases

1. Registration phase,
2. Prescribing phase and
3. Dispensing phase.

1. **Registration phase** involves the registration of all the entities that will include the prescribers, the dispensers and administrators.

The administrators are responsible for

- Updates a list of current medications,
- Provides a list of doctors & registered pharmacies,
- Creating & granting authorization to different users.

2. Prescribing phase: Doctor is authenticated to access the system using username & password

The prescriber first identifies the patient from the Electronic Health Records (EHR) which allows the prescriber to review the patient's data, medication history, checks for allergies and potential drug interactions before generating the prescription.

3. Dispensing phase: Pharmacist logs on to the system with a designated username and password.

After dispensing, the pharmacist would upload information about the dispensed medication back to the database server confirming that the prescription has been filled.

Level of e-prescription practice in various countries at present

Country	Estonia	USA	Italy	Slovenia
% of practice of E-prescription	99	55	94	94
Country	Norway	England	Australia	
% of practice of E-prescription	93	69	93	

eRx mandatory?

- In India, so many doctors struggle with basic equipment in their clinics, even a computer/ printer in every clinic is not available. A large number of doctors, especially senior doctors, are still not using computers in their day-to-day practice and even in life.
- We live in a country where doctors routinely prescribe pharmaceutical brands in lieu of gifts or foreign holidays from pharma company. Will they stop doing it when e-prescription comes? I could go on.
- large parts of India are still not covered by electricity, road, Internet broadband etc.

Conclusion

- E-prescribing ensures patient safety, increases quality healthcare and tunes hospitals in right stride towards “Digital India”.
- eRx can keep everyone safe.
- Paper Based Prescribing System is becoming obsolete.
- Prevent medication errors, enhance legibility and avoid confusion in reading and verbal communication.
- Generic drug prescribing be preferred, irrational and unethical prescribing will decrease.

Conclusion

- It secures right dose to right patient at right time & right cost. benefits for research to the villages of our country.
- Millions pieces of paper per year between GP, Pharmacy and Pricing systems.
- Countless numbers of phone calls checking prescription validation
- Moreover, let us not forget that large parts of our country are still not covered by electricity, road, Internet and broadband.

THANKS

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