

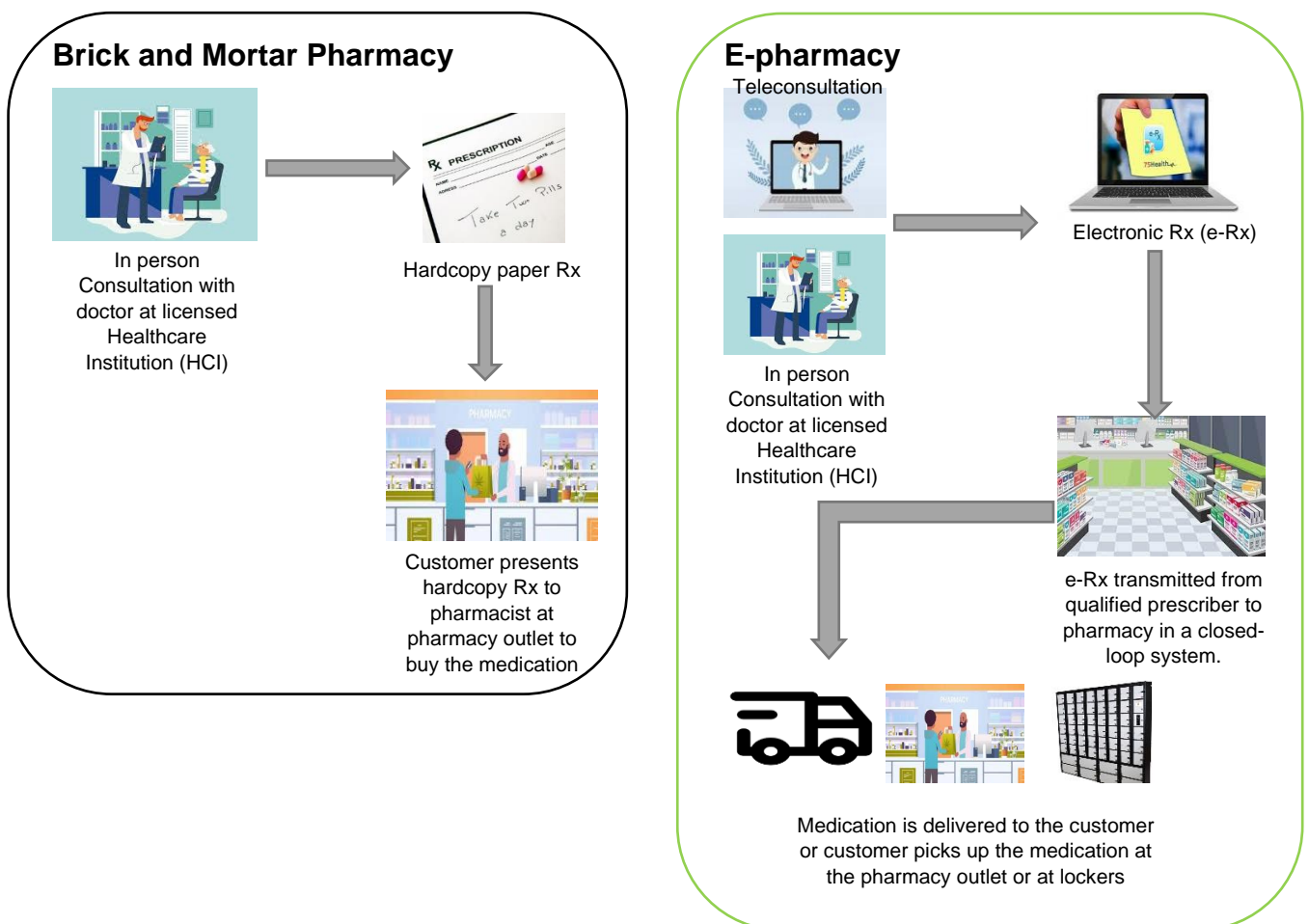
# 1 Introduction

The Health Sciences Authority (HSA) has put in place fit-for-purpose requirements for pharmacies providing e-pharmacy service directly to the patients. This new mode of pharmacy service offers patients greater convenience and wider healthcare options. The rollout of the e-pharmacy service commenced on 05 May 2020.

## 1.1. What is e-pharmacy?

E-pharmacy is a mode of pharmacy service that utilises technology to better serve patients by providing more convenient access to pharmacy services. This new mode of pharmacy service is provided by a licensed pharmacy in Singapore using a secured online platform. Prescriptions are transmitted electronically through a closed-loop electronic interface from the qualified practitioner to the qualified pharmacist. The qualified pharmacist processes the received valid prescriptions through electronic means, and conducts professional counselling remotely, as needed. The medicines may then be delivered directly by the pharmacy to the patients, who enjoy the convenience of not having to visit a physical retail pharmacy outlet to fill their prescriptions. Alternatively, patients may also choose to pick up the medication at the pharmacy outlet.

## 1.2. Brick and Mortar pharmacy versus e-pharmacy



### 1.3. Frequently Asked Questions (FAQ)

#### General

#### 1. Are telemedicine service considered E-pharmacy service?

No. The telemedicine service and e-pharmacy service are different operations. Telemedicine refers to the provision of healthcare services over a distance (i.e. not in-person) via Information and Communications Technology (e.g. video calls, audio calls, text messages such as SMS, iMessage and WhatsApp). Telemedicine services will be licensed by Ministry of Health (MOH) under the Healthcare Services Act (HCSA).

E-pharmacy is a mode of pharmacy service that allows a qualified practitioner (also known as a prescriber) to transmit prescription electronically through a closed-loop electronic interface to the licensed pharmacy for the supply of registered therapeutic products to the patients through a qualified pharmacist. E-pharmacy service is regulated by HSA.

Telemedicine Service Providers may partner with a licensed pharmacy with e-pharmacy service for the dispensing of prescribed medications to patients. Contractual Agreement should be established to clearly describe the roles and responsibilities of each party including compliance with the relevant standards and legislations for the supply of medication.

#### 2. Is my company eligible to provide e-pharmacy service?

HSA-licensed retail pharmacies and wholesalers in Singapore with good track record in handling Prescription-Only medicines (POM) and Pharmacy Only medicines (P), may apply for a pharmacy licence or include such services in their existing pharmacy licence if they intend to carry out e-pharmacy operations.

#### 3. What are the prerequisites of setting up e-pharmacy service?

The company must be a Singapore registered business entity and holds a pharmacy licence or Therapeutic Products Wholesaler's licence issued by HSA.

A licence holder of a retail pharmacy who intends to carry out the e-pharmacy service is required to submit an amendment application to add this service as an additional service/activity to the current pharmacy licence.

A licensed wholesaler is required to submit a new application for pharmacy licence and add the e-pharmacy service as an additional service/activity that will be provided by the pharmacy.

For more details, please refer to the [HSA Website](#).

#### 4. My company is considering supplying registered Therapeutic Products through e-pharmacy service. Are there any guide or reference document I can refer to and the steps involved to obtain the pharmacy licence to provide e-pharmacy service?

You may refer to the [Retail Pharmacy Licensing](#) on the basic requirements for operating a pharmacy and the following guidance documents to understand the

specific regulatory requirements to supply registered therapeutic products through e-pharmacy service.

- a) [Explanation Note for Application of a Pharmacy Licence;](#)
- b) [HSA Guidance Notes on Supply of Registered Therapeutic Products Through E-Pharmacy;](#)
- c) [HSA Guidance Notes On Good Distribution Practice;](#)
- d) Singapore Standard on Supply and Delivery of Medications (SS 644 : 2019). This Standard is available on [Singapore Standards e-shop](#).

A pre-approval audit will be arranged upon the receipt of the pharmacy licence application to assess the company's compliance to the regulatory requirements found in the above Guidance Notes/Standards. The pharmacy licence and/or e-pharmacy service will then be approved upon successful close-out of the pre-approval audit.

**5. Do the licensed retail pharmacies and wholesalers need to establish any procedures for operating an e-pharmacy?**

Yes, licensed retail pharmacies and wholesalers are required to establish clear procedures and practices for the storage, picking, packing, labelling, dispensing, medication counselling and secure delivery of medicines to the intended patients. These activities must be in accordance with the e-prescriptions received, and with the appropriate professional supervision by a qualified pharmacist. Pharmacies providing e-pharmacy service are expected to comply with the above-mentioned Guidance Notes/Standards. There should also be adequate patient interface processes to handle calls and queries related to medicines supply.

**6. Will licensed retail pharmacy and wholesaler be subject to periodic audits once issued with the pharmacy licence to operate e-pharmacy service?**

Yes. Licensed retail pharmacies providing e-pharmacy service and wholesalers will be periodically audited by HSA. The purpose of the audit is to ensure that the system is established to perform the various services and activities in support of the licence issued to the company and continues to comply with the applicable legal and regulatory requirements.

HSA will publish alerts on non-compliant or illegal e-pharmacy operators, and enforcement actions taken as needed

**7. Are prescriptions presented in digital format (pdf or a screenshot) sent from prescribers to the pharmacy providing e-pharmacy service be considered as valid electronic prescriptions?**

No. In the context of a pharmacy providing e-pharmacy service, a prescription in a digital format (e.g. email, fax, screenshot, pdf, etc) is not considered a valid electronic prescription. This digital format does not provide adequate safeguards to prevent it from being misused at the pharmacies. To be considered a valid electronic prescription, it must be transmitted/sent from the prescriber directly to the pharmacy in a closed-loop system and traceable to the original prescriber issuing the prescription.

**8. Is a pharmacy licence with e-pharmacy service required for the online sale of registered Therapeutic Products classified as General Sales List (GSL) directly to the consumer?**

No. This is not considered an e-pharmacy service. Please refer to [HSA Website](#) for details on activities that are considered e-pharmacy service. The company may also check the classification of the therapeutic products using the [Infosearch E-service](#) on the HSA website before the product is sold.

## **e-Pharmacy System**

### **9. What are the requirements for setting up the e-pharmacy system?**

The licenced retail pharmacies and wholesalers must have a validated e-pharmacy system that allows safe and secure transmission of the electronic prescription directly from the prescriber to the qualified pharmacist practising at the licensed pharmacy.

The e-pharmacy system should also have a secure means to allow the qualified pharmacist to update the prescriber on the status (e.g. pending medication preparation, pending collection, completed, etc.) of the dispensing activity. The e-pharmacy system must also have the capability to trace the identity of the prescriber and where the prescriber works (e.g., healthcare institution, etc.).

Information captured during e-pharmacy activities (e.g. electronic prescriptions) must also comply with the requirements of the Electronic Transactions Act (ETA) to ensure necessary safeguards/controls to maintain the security, integrity, accuracy and confidentiality of the system. An electronic prescription must include a secure and encrypted electronic signature that the pharmacy can trace to the prescriber who had issued it.

### **10. How can the company ensure that the e-pharmacy system is secured?**

The e-pharmacy system must be secured to protect the company against the risk of data breaches to safeguard the confidentiality of the patient and other sensitive information. Below are some examples of the different ways to achieve this, though companies may adopt other approaches if equivalent security can be achieved. It is the responsibility of the company to demonstrate the measures taken to ensure system and data security.

- a) Restricting access to the e-pharmacy system to trained/authorised pharmacy staff using tools like unique login ID, passwords, biometrics, etc.
- b) Having a system in place to document and approve any creation, change or cancellation of access authorisations.
- c) Having an audit trail to detect any changes to electronic records and ensure traceability of activities which have taken place. The audit trail should also have the function to attribute the execution of pharmacy activities at a given date and time to the authorised personnel.

Additionally, telemedicine providers should work with their partnering licenced pharmacies providing e-pharmacy service to ensure the security of e-pharmacy system.

### **11. What are the requirements for data management in e-pharmacy system?**

Because e-pharmacy service involves handling of confidential patient data (e.g. NRIC, addresses, illnesses, etc.), such data should be secured against damage or loss.

Stored data should be checked for accessibility, readability and accuracy. Access to data should be ensured throughout the retention period.

Regular backup of all relevant data should be done. Integrity and accuracy of backup data and the ability to restore the data should be checked during validation and monitored periodically.

**12. Why should the e-pharmacy system be validated and what should be considered during validation?**

The purpose of e-pharmacy system validation is to ensure that the system can perform reliably for its intended use. Because e-pharmacy service involves handling of confidential patient data (e.g. NRIC, addresses, illnesses, etc.), validation also ensures that the system remains robust, reliable and secure to mitigate any risks of breaches involving confidential data.

Risk management should be done as part of validation. Decisions on the extent of validation and data integrity controls should be based on a justified and documented risk assessment of the e-pharmacy system. When third parties are engaged to provide, install, configure, integrate, modify or retain a computerised e-pharmacy system, contractual agreements must be established to define clear statements of responsibilities of each party. Validation activities should be documented clearly.

Whenever there are changes to the e-pharmacy system, assessment should be made and documented to determine whether these changes are significant enough that re-validation is required.

**13. How can validation of the e-pharmacy system be carried out?**

During validation of e-pharmacy system, company must at least establish and document the following:

- (a) User Requirement Specification (URS) to describe what the user needs from the software and how they will use it;
- (b) Functional Specifications (FS) to describe how the software needs to work and look to meet the user needs;
- (c) Design Specifications (DS) to explain the technical elements of the system (e.g., database design, logic/process design, security design, interface design, network requirements and other specific peripheral devices like printer used, etc.);
- (d) Installation Qualification (IQ) to provide confirmation that the system is installed and set up according to the DS;
- (e) Operational Qualification (OQ) to confirm that all functionality defined in the FS is present and working correctly;  
Performance Qualification (PQ) to confirm that the system is suitable for the intended use.

Company may refer to [PIC/S Guidance on Good Practices For Computerised Systems in Regulated "GXP Environments \(PI-011\)](#) or other applicable guides such as [US FDA Guidance on Computerised Systems](#), [ISPE Guide on Computerised Systems](#) and [PDA Practical Guide on Computerised System](#) to understand more about computerised system validation.

**14. What are the cybersecurity measures required for provision of quality and safe healthcare services in ensuring patient safety and welfare?**

The MOH has developed a set of Healthcare Cybersecurity Essentials (HCSE), that is intended as guidance documents for healthcare service providers to adopt basic safeguards for their information technology (IT) assets and data. Pharmacies may wish to consider adopting these measures where applicable to safeguard their endpoints, IT systems, and data.

The HCSE offers 12 key recommendations which can be implemented in 3 key steps:

- 1) Create IT asset inventory
- 2) Secure data, detect, respond to, and recover from breaches (i.e. this covers aspects ranging from technical, process and people aspects)
- 3) Implement by putting measures into practice

For further details on the measures, please refer here:

[https://www.moh.gov.sg/licensing-and-regulation/regulations-guidelines-and-circulars/details/healthcare-cybersecurity-essentials-\(hcse\)](https://www.moh.gov.sg/licensing-and-regulation/regulations-guidelines-and-circulars/details/healthcare-cybersecurity-essentials-(hcse))

<https://www.moh.gov.sg/licensing-and-regulation/cybersecurity-for-healthcare-providers>