HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

28 OCT 2024

GUIDANCE NOTES ON SUPPLY OF REGISTERED THERAPEUTIC PRODUCTS THROUGH E-PHARMACY

HSA
Health Sciences Authority

PREFACE

This document is intended to provide general guidance. Although we have tried to ensure that the information contained here is accurate, we do not, however, warrant its accuracy or completeness. The Health Sciences Authority (HSA) accepts no liability for any errors or omissions in this document, or for any action / decision taken or not taken as a result of using this document. If you need specific legal or professional advice, you should consult your own legal or other relevant professional advisers.

In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.

REVISION HISTORY

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1 INTRODUCTION

The Health Sciences Authority (HSA) is putting in place appropriate fit-for-purpose requirements for pharmacies providing e-pharmacy service directly to the patients. This new mode of pharmacy service can offer patients with greater convenience and wider healthcare options.

HSA-licenced retail pharmacies and wholesalers in Singapore with good track record in handling therapeutic products, namely Prescription-Only medicines (POM) and Pharmacy Only medicines (P), may apply for a retail pharmacy licence or include such service in their existing retail pharmacy licence if they intend to carry out e-pharmacy operations. HSA will assess these applicants for compliance with our regulatory requirements before approval to start e-pharmacy operations. The regulatory requirements are needed to ensure that the right therapeutic products of the appropriate quality are supplied to the correct patients as prescribed by the patients' doctors.

Patients are strongly advised to only purchase therapeutic products from these licensed retail pharmacies and the corresponding e-commerce platforms in Singapore, to ensure that the products are from a reliable source.

2 SCOPE OF THE GUIDANCE DOCUMENT

This guidance document describes the regulatory requirements expected of retail pharmacies who supply registered POM and P through secured e-pharmacy online platform directly to the patients.

The scope of e-pharmacy service does not allow the supply for the following: (a) the retail supply of controlled drugs; (b) compounded medicines; and excludes the wholesale supply of therapeutic products through signed orders.

3 DEFINITIONS

3.1 **"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 licensed pharmacy in Singapore using a secured online platform. Prescriptions are transmitted electronically through a closed-loop electronic interface from the qualified practitioner or collaborative prescribing practitioner to the qualified pharmacist. The qualified pharmacist processes the received valid prescriptions through electronic means, and conducts professional counselling remotely, as needed. The products are then delivered directly to the patients, who enjoy the convenience of not having to go down to a physical retail pharmacy outlet to fill their prescriptions.

3.2 **"Qualified pharmacist"** is a person who is registered as a pharmacist under the Pharmacists Registration Act 2007, who holds a valid practising certificate granted under section 23 of that Act and is in active practice as defined in regulation 2 of the Pharmacist Registration (Practising Certificate) Regulations 2008.

3.3 **"Qualified practitioner"** is a person who is registered as medical practitioner under the Medical Registration Act 1997 or registered as a dentist under the Dental Registration Act 1999 whose name appears in the first division of the Register of Dentists maintained and kept under section 13(1)(a) of that Act.

3.4 **"Collaborative prescribing practitioner"** is a registered nurse or registered pharmacist who is approved by the credentialing committee of an approved institution to provide collaborative prescribing service under regulation 2 of the Healthcare Services (Collaborative Prescribing Service) Regulations 2023.

4 REGULATORY REQUIREMENTS

4.1 General

4.1.1 A retail pharmacy providing e-pharmacy service must be a Singapore registered company to conduct retail pharmacy business. This service must be hosted on a Singapore domain name. (IT solutions/ platform providers who support the IT infrastructure are not considered as an e-pharmacy)

4.1.2 Existing pharmacy licensee who intends to expand the pharmacy service to include the mode of e-pharmacy service must make an amendment to its pharmacy licence to notify and obtain approval from HSA.

4.1.3 The retail pharmacy providing e-pharmacy service must establish an effective system with adequate safeguards that are suitable for providing the service of e-pharmacy. It is subject to periodic pharmacy audits for compliance and suitability to operate such pharmacy services.

4.1.4 There must be controls in place to ensure that the right therapeutic products are dispensed to the correct patients.

4.1.5 The retail pharmacy must implement good governance and practices in operations (including acceptable standards of good pharmacy practice) to ensure good quality of the therapeutic products supplied. The retail

pharmacy must comply with the requirements set out in the relevant legislation on the prescription of therapeutic products.

4.1.6 The therapeutic products supplied must not be adulterated, unwholesome and substandard or falsified. All therapeutic products supplied by the mode of e-pharmacy must be registered with HSA and obtained through licensed manufacturers and dealers.

4.1.7 Parties involved in the provision of e-pharmacy service must ensure that all the activities (processing of prescription, picking, packing labelling, handling, storing, distribution etc) involving therapeutic products and its dispensing comply with all other applicable laws and regulations. The licensed retail pharmacy is overall responsible to ensure that any outsourced activities or services meet the requirements for the e-pharmacy operations.

4.1.8 A retail pharmacy intending to provide the e-pharmacy service may refer to Annex 1 on the Application Checklist for more information to help in the planning and submission of application for provision of e-pharmacy service in the Pharmacy Licence.

4.2 Personnel

4.2.1 Each pharmacy must appoint a pharmacist-in-charge who is competent to oversee the pharmacy service operations.

4.2.2 The pharmacist is overall responsible for the e-pharmacy service, including proper storage, packaging and secure delivery of the therapeutic products, to ensure safety and quality of these products.

4.2.3 The pharmacist must ensure that the legal requirements for the supply of therapeutic products are met, which includes the authentication of the received prescription, the processing and supply according to the prescriber, and documentation of all the e-pharmacy service provided. As with all dispensing, the pharmacist is expected to conduct the due professional review of the patient’s condition, suitability in supply and provide appropriate medication counselling to the patients.

4.3 Pharmacy premises

4.3.1 Premises should be suitably designed and maintained to allow the pharmacy activities to be performed. There should be sufficient space to allow efficient and logical flow of work processes, and minimise the risks of mistakes during picking and packaging of therapeutic products.

4.3.2 The premises for storing therapeutic products must be maintained with the right storage environment, to prevent product deterioration caused by exposure to light, moisture or heat and to protect the product against contamination and pest infestation.

4.3.3 Premises must be clean, neat and tidy at all times.

4.3.4 Premises should have sufficient security to prevent unauthorised access.

4.4 Information Technology (IT) and security

4.4.1 The e-pharmacy's infrastructure, such as Information technology (IT) hardware (e.g. computers, scanners, fax, printer, server and modem, etc) and software (e.g. dispensing systems, inventory systems, etc) should be appropriately set up, and processes must be robust and secured for the pharmacy operations.

4.4.2 The system must demonstrate its suitability for the e-pharmacy operations before it is approved for use. This also applies when changes are made to the system. The system must be maintained periodically to minimise disruptions to the services and to ensure cybersecurity.

4.4.3 The system must perform the procedures accurately and reliably to meet the requirements set out in the relevant legislation for the prescription of therapeutic products.

4.4.4 The system must ensure integrity through the adoption of adequate and appropriate technical solutions and security measures (e.g. secured and encrypted electronic interface). This should include:

a) A closed-loop system which transmits the e-prescription directly and securely from the prescriber to the pharmacist at the e-pharmacy;

b) System must be capable of generating an audit trail to facilitate detection of any changes made to the electronic records;

c) System must be capable of permitting traceability of the pharmacy activities conducted readily, and can attribute the authorised personnel to the correct execution of pharmacy activities at a given date and time;

d) System must have proper controls on storage and backup of data.

4.4.5 The system must have measures to ensure privacy and security of all electronically transmitted patient information for the protection of patient's confidentiality. It must comply with the current regulations governing personal data.

4.4.6 The appropriate level of security and security features required should be considered for the information stored in the system, and for the activities and the personnel who are authorised to access patient records (e.g. during prescription order reviews, medicines preparation). In particular, clearly defined levels of authorised access rights to the system according to a user's job function is required to prevent inappropriate retrieval or sharing of information.

4.4.7 The system must have measures to prevent unauthorised issuance of prescriptions, fraud or any manner of abuse involving prescription of the therapeutic products.

4.4.8 If there are restricted users' access and control to the system attributes or functionality, the retail pharmacy must still ensure that the user carries out his/her responsibility to use it correctly and comply with the prescribed safeguards.

4.5 Documentation and Records

4.5.1 There must be an established process for documentation control and data management. It must prevent inadvertent use of superseded procedures and templates. There should be adequate measures in place to avoid uncontrolled changes made to a document after its approval. Documents should be reviewed regularly and kept up to date.

4.5.2 The pharmacy should establish procedure(s) detailing how the e-pharmacy service, delivery of medication and any other mode of supply must be provided. The contents of these documents should be clear and unambiguous.

4.5.3 The pharmacy must provide objective documentary evidence to demonstrate control and monitoring of operations including:

a. storage and security of stocks
b. cleaning and maintenance of premises and IT systems
c. qualification and validation of equipment and IT systems
d. dispensing and distribution activities

e. investigations of incidents and near misses
f. staff training
g. outsourced contracts and responsibilities
h. internal audits
i. patient interfaces for counselling, if applicable
j. appropriate handling of complaints
k. maintenance of transaction records (including related documents of receipt and supply, returned products, recalls)

4.5.4 Records should be made or completed at the time each action is taken in such a way that all significant activities or events in the e-pharmacy service (e.g. system breakdown, cyberattack, etc.) are traceable.

4.5.5 There should be access control to the folder location in computerised system where the processed prescriptions and dispensing information are kept.

4.5.6 The records should be made available during audits and/or upon the Authority's request.

4.5.7 Electronic prescriptions should be controlled in accordance with the requirements as follows:

a) The retail supply of therapeutic products should comply with the legal requirements stipulated in the Health Products (Therapeutic Products) Regulations 2016 and Health Products (Licensing of Retail Pharmacies) Regulations 2016;

b) The electronic prescription should contain a secure and encrypted electronic signature that is verifiable by the licensed pharmacy to allow authentication to the prescriber;

c) Once a licensed pharmacy has fully filled all the therapeutic products in an electronic prescription, the electronic prescription should not be used again at any licensed pharmacy. Repeat prescriptions should follow the same requirements; and

d) Electronic prescription once issued, should not be amended, except by the qualified doctor who issued it. Any amendments that are made to the electronic prescription must be kept as an audit trail in the system. Record of the amendments should include metadata such as what details were amended, when and why the amendments were made and permission from the qualified doctor authorising the amendments (when applicable).

4.5.8 E-pharmacies must ensure that information captured during operations (e.g. electronic records such as patient medication records, pharmacist's clarifications with the prescriber) are securely maintained in accordance with the relevant legislations (e.g. Electronic Transaction Act 2010, Personal Data Protection Act 2012, etc). Cybersecurity measures (as described in Section 4.4) should also be in place to prevent any loss of personal data, medication records and other sensitive information.

5 HANDLING, STORING AND PACKING OF MEDICATION

5.1 Medication Handling and Storing

5.1.1 The retail pharmacy must comply with Good Distribution Practice (GDP) requirements for the handling and storage of therapeutic products.

5.1.2 Therapeutic products must be handled and stored with appropriate security measures, in clean, hygienic and appropriate environmental conditions.

5.1.3 Therapeutic products must be properly checked to ensure that the right products are supplied to the right patients. If medication delivery service is provided, it should comply with the storage and delivery requirements in Singapore Standard on Supply and Delivery of Medications (SS 644).

5.2 Packing of medications

5.2.1 All therapeutic products undergoing packing for supply through e-pharmacy service should comply with good packaging standards to ensure proper labelling and maintenance of records to provide traceability.

5.2.2 The therapeutic products packed should have sufficient shelf life to ensure they are safe for consumption when they reach the patients for course of treatment.

5.2.3 The therapeutic products must be properly packed to protect the products from heat and moisture which can cause product deterioration.

5.2.4 The therapeutic products supplied should contain patient's details, medication's details, dosing instructions, dispensed date, pharmacy address and contact details, and cautionary labels (when applicable).

5.2.5 The retail pharmacy must comply with the packaging requirements in the Singapore Standard on Supply and Delivery of Medications (SS 644) when providing the supply and delivery of the medications to patients.

6 AUDITS

6.1 Regular internal audits should be conducted to monitor the implementation of the e-pharmacy service for compliance with the relevant guidance and legislative requirements.

6.2 All findings and follow-up to the internal audits should be recorded in the audit report and kept. Corrective and preventive actions (CAPA) should be taken and followed up for continual improvements.

6.3 There should be ongoing review of incident/near misses reports and outcomes related to the e-pharmacy service/operation, including the outsourced services. This is to ensure that there is no abnormal frequency or trends of errors occurring in the e-pharmacy dispensing process.

7 REFERENCE

7.1 HSA Guidance Notes on Good Distribution Practices (GUIDE-MQA-013)

7.2 Singapore Standard on Supply and Delivery of Medications (SS 644)

7.3 Health Products (Therapeutic Products) Regulations 2016

7.4 Health Products (Licensing of Retail Pharmacies) Regulations 2016

7.5 PSS Good Pharmacy Practice Guide

END OF DOCUMENT

ANNEX 1 - E-PHARMACY APPLICATION CHECKLIST

A new or amendment application for Pharmacy Licence is required to notify HSA of the applicant's intention to operate a licensed retail pharmacy, and to include e-pharmacy service as a mode of the retail pharmacy service.

Licensee of retail pharmacies should be familiar with the provision of related documentary requirements to facilitate the assessment and processing process.

These checklists serve as a basic guide for a company to prepare and submit the required information relevant to the proposed inclusion of e-pharmacy service as a mode of pharmacy service in the pharmacy licence. Applicant can consider providing a detailed but concise written proposal to outline the relevance of these submissions.

Applicants are reminded to undertake the responsibility to ensure the accuracy, completeness and relevance of information when using these documentary submissions to supporting the application.

A	GENERAL	Yes	No	Comments
A1	Is the company applying for a Pharmacy Licence with provision to provide e-pharmacy service, a registered business entity in Singapore?			(*Please check and provide relevant information*)
A2	Will the e-pharmacy service be operated in Singapore and hosted on a Singapore domain name (.sg)?			(*Please provide relevant information of the address of operation, partnering IT service provider and the URL*)
A3	Do you have the supporting documents for submission? Basic documents required: − Pharmacy store layout plan (with dispensing counter; e-pharmacy service); − Valid Pharmacist Practising Certificate; − Company's standard operating procedures and Recording Forms for additional activities or services Other relevant information: − Process flow of e-pharmacy services − System specifications			(*Please provide relevant information, together with a summary listing of the documents submitted*)

	− Contractual agreement of outsourced services on responsibilities and duties (if any) − Training program and records − Completed validation reports on systems; facilitates etc			
A4	Do you have an effective system with appropriate safeguards specifically designed for e-pharmacy service?			(*Please provide relevant information about the system for e-pharmacy and list the safeguards*)
A5	Are there established procedures/ processes in place to ensure good governance and practices in the operations (including adherence to acceptable standards of good pharmacy practice)?			(*Please provide relevant information and list the relevant processes*)
A6	Are the therapeutic products intended for dispensing, registered for use in Singapore, and are they supplied through licensed manufacturers and dealers?			(*Please provide relevant information and list the sources of suppliers*)
A7	Do all outsourced activities or services comply with the requirements for the e-pharmacy service?			(Please provide relevant information and list the outsourced activities; also explain how the retail pharmacy can effectively discharge the overall responsibility on compliance)
B	**PERSONNEL**	**Yes**	**No**	**Comments**
B1	Have you appointed a qualified and competent pharmacist-in-charge?			(*Please provide relevant information and explain about the training and competency of appointed staff; the job description/scope that he will be able to discharge his duty and responsibilities in the e-pharmacy service?)*
B2	Are training records available for pharmacy staff who provide e-pharmacy service?			(*Please provide the training record describing the training details and*

				competency of appointed pharmacy staff)
C	**PREMISES**	**Yes**	**No**	**Comments**
C1	Are the premises suitably designed to support the e-pharmacy service?			(Please provide relevant information and explain how the setup meets the requirements)
C2	Are calibrated monitoring devices used to monitor storage conditions of the premises?			(Please provide relevant information and explain how the requirements are met)
C3	Are the premises clean, neat and tidy?			(*Please provide relevant information and explain how maintenance program ensure this requirement is met)*
C4	Do the premises have sufficient security measures to prevent unauthorised access and misappropriation of the products?			(*Please provide relevant information and explain how your security measures can meet the requirements)*
D	**INFORMATION TECHNOLOGY (IT) AND SECURITY**	**Yes**	**No**	**Comments**
D1	Is the information technology set up appropriate, robust and secured to support the e-pharmacy service?			(*Please provide relevant information and explain how the requirements are met)*
D2	Has your system demonstrated suitability for the e-pharmacy operations?			(*Please provide relevant information and explain how the requirements are met; including maintenance program)*
D3	Is there a process to ensure that your system performs accurately and reliably?			(*Please provide relevant information and explain how the requirements are met)*
D4	Does your e-pharmacy infrastructure have necessary safeguards/controls to ensure security, integrity, accuracy and confidentiality of the system used?			(*Please provide relevant information and explain how these requirements are met for Paras 4.4.4 to*

				4.4.8 of Guidance Notes)
E	**DOCUMENTATION AND RECORDS**	**Yes**	**No**	**Comments**
E1	Is there an established quality system to manage the currency and control documents (such as standard operating procedures), and data generated from the e-pharmacy services?			(*Please provide relevant information on the document and data management control, and explain how the requirements are met)*
E2	Are written procedures and recording forms for the e-pharmacy service available?			(*Please provide relevant information and list the relevant procedures and forms; also explain how requirements are met)*
E3	Is a record keeping system in place to ensure completeness of activities and traceability of all operations?			(*Please provide relevant information and explain how these requirements are met for Paras 4.5.3 to 4.5.6 of Guidance Notes)*
E4	Do electronic prescriptions comply with the requirements?			(*Please provide relevant information and explain how these requirements are met for Para 4.5.7 of Guidance Notes)*
E5	Do all the electronic information of e-pharmacy service comply with the relevant legislations?			(*Please provide relevant information and list the relevant procedures/features; to explain how they meet the requirements for Para 4.5.8 of Guidance Notes)*
F	**HANDLING, STORING AND PACKING OF MEDICATION**	**Yes**	**No**	**Comments**
F1	Are Good Distribution Practice (GDP) requirements for handling and storage of product being met?			(*Please provide relevant information and list the relevant procedures; to explain how they meet the requirements for Paras 5.1.1 and 5.1.2 of Guidance Notes)*
F2	Is there a procedure in place to ensure the correct products are supplied to the			(*Please provide relevant information and list the*

	right patients?			*relevant procedures; to explain how they meet the requirements for Paras 5.1.3 of Guidance Notes)*
F3	Are the products appropriately packed and labelled to protect patient's confidentiality and comply with the good packaging standards?			(*Please provide relevant information and list the relevant procedures; to explain how they meet the requirements for Paras 5.2.1 to 5.2.5 of Guidance Notes)*
G	**AUDITS**	**Yes**	**No**	**Comments**
G1	Is an internal audit program in place?			(*Please provide relevant information and list the relevant procedures and forms; to explain how they meet the requirements for internal audit program)*
G2	Are there reviews on ongoing review of incident/near misses reports and outcomes related to the e-pharmacy services/ operations, including the outsourced services?			(*Please provide relevant information and list the relevant procedures; to explain how they meet the requirements for Para 6.2 of Guidance Note. Explain how the outsourced services are reviewed for compliance)*

HEALTH SCIENCES AUTHORITY

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