

Guidelines for Telepharmacy 2009

Endorsed by



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1. Introduction

- 1.1. Telepharmacy is the provision of Pharmacy services by a Serving Pharmacy to one or more Remote sites through computer, video and audio link. It is a unique and innovative way to deliver Pharmacy services. This includes dispensing Prescription-Only and Pharmacy (P) medication, pharmacist verification of prescription before dispensing, medication review and patient education/counselling.
- 1.2. In some developed countries, telepharmacy is used to restore or retain Pharmacy services in communities that are located in remote medically under-served areas or rural communities
- 1.3. As modern medications become increasingly potent and capable of curing and mitigating diseases, the involvement of the pharmacist becomes more important in ensuring rational, safe, and cost effective use of medications.
- 1.4. Telepharmacy was first introduced in 2002 for the sales of Pharmacy (P) Medicines in Singapore to approved pharmacies. In 2009, the Health Sciences Authority extended telepharmacy to include Prescription-Only Medicines (POM) to pharmacies which met additional regulatory requirements and safeguards.
- 1.5. As practice and regulation governing practice is continually changing, the Pharmaceutical Society of Singapore (PSS) acknowledges that any published guideline can neither be exhaustive nor final. This guideline will be reviewed periodically as deemed necessary by PSS or Singapore Pharmacy Council (SPC) or Health Sciences Authority (HSA).
- 1.6. This set of guideline provides the basic framework for the implementation of telepharmacy service in pharmacies registered in Singapore. Pharmacists providing Pharmacy services through telepharmacy must abide by the SPC's Code of Ethics and current practice standards and regulatory requirements in the discharge of their professional duties and responsibilities.

1.7. Registered pharmacies must have an attending pharmacist physically present to provide a minimum dispensing service of 35 hours per week, as required by HSA in collaboration with SPC. Registered pharmacies which intend to provide telepharmacy services shall seek additional prior approval from the HSA. Pharmacy Auditors from HSA shall conduct preand post-licensing audits, where necessary, to verify compliance to the Telepharmacy Guidelines. The approval is a formal process that involves inspection and written changes to the existing licence. The validity remains until there are further changes to the existing pharmacy licence.

2. Scope

This set of guideline is applicable to all pharmacies providing telepharmacy services for both P Medicines and POM, except for Controlled Drugs and Extemporaneous preparations. Export sales of drugs and signed orders should not be carried out via telepharmacy.

3. Objectives

- 3.1. Two of the biggest challenges facing the profession of Pharmacy today are:
 - 3.1.1 Access to pharmacy service

Pharmacists possess specialised knowledge in medication and disease management. He/She ensures proper use of medication and reduces medication-related problems. Hence, enabling dispensing of medication via telepharmacy will increase access of pharmacy services to more patients.

3.1.2 Increasing healthcare demands

as the population ages, national morbidity profiles will shift towards a greater incidence of chronic and degenerative diseases. The increasing demand by an elderly population necessitates a ready pool of pharmacists and pharmacy services catering to the needs of the elderly and for chronic diseases management.

3.2. The purpose of this document is to offer relevant information and guidelines on how to implement and provide a telepharmacy service to enable access to pharmacy services in registered pharmacies, where the resident pharmacist is not available, e.g. during lunch breaks, certain evenings and weekends, attending meetings and training sessions.

4. Definitions

- 4.1. **"Telepharmacy"** is defined as the provision of Pharmacy services by a Serving Pharmacy to one or more Remote sites through computer, video and audio link.
- 4.2. "Registered Pharmacist" is a pharmacist with a valid Practicing Certificate with the Singapore Pharmacy Council
- 4.3. **"Resident Pharmacist"** refers to the pharmacist-in-charge of the Remote site. The pharmacist stated in the Certificate of Registration of a Pharmacy (Pharmacy Licence) is the resident pharmacist.
- 4.4. "Serving Pharmacy" refers to a Pharmacy with a registered pharmacist, who is trained to carry out dispensing of P Medicines and POM via telepharmacy.
- 4.5. "Remote site" refers to a Pharmacy without a registered pharmacist on duty, but have a Pharmacy technician or qualified staff that is trained to carry out dispensing of medication via telepharmacy.
- 4.6. **"Trained Staff**" refers to Pharmacy Technician, Pre-registration Pharmacist or other designated pharmacy personnel.

5. <u>Pre-requisites for Telepharmacy Service</u>

5.1. Premises

- 5.1.1 Serving Pharmacy and Remote site must be registered pharmacies with the Health Sciences Authority and licensed to provide telepharmacy services.
- 5.1.2 The premise must comply with current guidelines and regulations. This includes, but is not limited to, construction, security, consultation/dispensing area and sanitary standards.
- 5.1.3 It is essential that the layout of the premise facilitate logical and efficient workflow, and is conducive for the provision of Pharmacy services via telepharmacy.
- 5.1.4 A serving pharmacy may be a remote pharmacy and vice-versa. A remote pharmacy may interchange with the serving pharmacy as long as it meets all the requirements of a remote pharmacy as stipulated in the Telepharmacy Guidelines and is licensed by the Health Science Authority to operate telepharmacy services.
- 5.1.5 If the remote site is an independent pharmacy service provider, there must be a written contract and a common quality system in place between the independent service provider and remote site.

5.2. Information Technology

- 5.2.1 The technological set-up and capabilities is integral to the successful delivery of a telepharmacy service.
- 5.2.2 Due consideration should be given to ensure that the hardware and software provides security of information and ease of access to patients records in both the Serving Pharmacy and remote telepharmacy sites.

5.2.3 Important technological consideration includes:

(a) Hardware Support

- i) These include, but are not limited to, standard PC set-up, webcam, speakers, microphone/headset, modem, scanner/fax and printer. Scanner, if used, must ensure clarity of image.
- ii) The audio system used should ensure clarity in communication between the Serving Pharmacy and Remote sites.
- iii) The images from the webcam should be of sufficient resolution to allow the pharmacist to read the prescription, the label of the manufacturer's original drug container, the label on the packed prescription to be handed to the patient, as well as to see the presentation and dosage form of the medicinal product to be dispensed.
- iv) Digital images of the prescription processing function should be stored on the computer hard-drive or writeable CD for later recall or they can be printed and filed with the original prescription. This type of documentation provides important quality assurance to validate that the prescription is filled correctly.

(b) Security of information

- The set-up must ensure privacy and security of all electronically transmitted information on patients for the protection of patient confidentiality, such as using data encryption.
- Secured network communication should facilitate ease of communication between pharmacists, pharmacy technicians and patients.
- iii) The system should be equipped with an audit trail to track any changes or deletions made to any electronic data, and that measures are in place to ensure that periodic backup of data is conducted.

(c) Accessibility of patients' records

i) Pharmacist from the Serving Pharmacy should be able to access patients' medical/drug records. This could be done via centralized patient records for easy retrieval of information for assessment of suitability and risk minimisation. ii) In the absence of centralized patient records, other procedures should be in place to allow access to patient information by both pharmacist and pharmacy technician such as by faxing printout of patient record.

5.3. Personnel Pharmacist

- 5.3.1 The primary responsibility of the pharmacist at the Serving Pharmacy site is to provide professional consultative services to the Remote site, for all prescriptions and non-prescriptions dispensed at the Remote site. These activities include, but are not limited to
 - (a) Performing an assessment of the patient's condition (where applicable)
 - (b) Performing a medication review
 - (c) Performing final check of the medication prepared by the trained staff at the Remote site
 - (d) Providing patient education/counselling
- 5.3.2 The pharmacist at the Serving Pharmacy is responsible for all professional aspects of the patient's care, even though assisted by the pharmacy technician or trained staff.
- 5.3.3 The resident pharmacist at the Remote site has the duty and responsibility to perform verification checks on the relevant processes such as accuracy of medication/ prescription processing. The resident pharmacist shall be responsible for ensuring that the telepharmacy service is carried out in accordance with the relevant requirements.
- 5.3.4 Periodic self-audits should be conducted to ensure compliance to regulatory requirements at both Serving Pharmacy and Remote sites.
- 5.3.5 Pharmacist at the Serving Pharmacy and resident pharmacist must receive training to operate the telepharmacy system.

Pharmacy Technician

5.3.6 Pharmacy technician shall work under the personal supervision of the resident pharmacist. The responsibilities of the pharmacy technician at the Remote telepharmacy site include maintaining the drug inventory and performing all aspects of the drug dispensing process. Activities include, but are not limited to:

- (a) Obtaining the medication order from the patient
- (b) Picking, packaging and labelling
- (c) Operating the telepharmacy technology to connect the audio and video link to the pharmacist at the Serving Pharmacy site
- (d) Providing digital images of the medication order, the manufacturer's original drug container, the actual tablet or capsule for proper tablet/capsule identification, and the prescription label for the patient
- (e) Assisting the patient in the use of the telepharmacy technology
- (f) Updating the inventory records
- 5.3.7 The pharmacy technician must have appropriate training and qualifications to process medication orders. He/she should have
 - (a) graduated from the Certified Pharmacy Technician Course awarded by PSS or have received other equivalent training which demonstrates knowledge and experience in preparation of medication for dispensing (Refer to appendix 1 Competency Checklist for Preparation of Medicine for Dispensing)
 - (b) received training and demonstrated competency in operating the telepharmacy system. The training program should cover the following aspects:
 - Training scope
 - Competency assessment
 - Staff training program
 - (c) Training and assessment records

Pre-registration Pharmacist

- 5.3.8 A pre-registration pharmacist shall work under the personal supervision of the resident pharmacist. He/She may be given responsibilities of a Pharmacy technician as outlined above. He/she should have
 - (a) completed at least three months of Pre-registration training
 - (b) received training and demonstrated competency in operating the telepharmacy system

Other Designated Pharmacy Personnel

5.3.9 Other designated pharmacy personnel may be given responsibility to process non-POM via telepharmacy provided:

He/She should have

- (a) minimum work experience of three months in dispensing duties
- (b) received training and demonstrated competency in operating the telepharmacy system

5.4. Process

- 5.4.1 The work processes for consideration include, but are not limited to:
 - (a) Compliance to Good Pharmacy Practice Guidelines by PSS
 - (b) Process for registration of patient record and update of new patient information
 - (c) Process for documenting and handling of drug-related problems
 - (d) Procedure for management of prescriptions and other relevant records
 - (e) System to store the data so as to facilitate audits by resident pharmacists or external auditors
 - (f) Contingency plan in the event of disruption to data transfer, video and audio link. Telepharmacy service should not be provided if any of the requirements stipulated in this set of guidelines cannot be met.
 - (g) Procedure to safeguard patient privacy and confidentiality of information
 - (h) Procedure to prevent diversion of Pharmacy-only or prescription medication to unauthorised parties
 - (i) Procedure to assess the authenticity of prescription and handling of dubious prescriptions.
 - (j) Procedure to handle incidents related to the delivery of telepharmacy services, including dispensing errors.
- 5.4.2 The following are the essential steps to provide medication via telepharmacy:

- (a) The pharmacy technician/ pre-registration pharmacist/ designated personnel at the Remote site, shall obtain the medication order from the patient and seek advice from the pharmacist at the Serving Pharmacy via telepharmacy system.
- (b) He/she will process the medication for dispensing and assist the patient in the use of the telepharmacy system.
- (c) The pharmacist at the Serving Pharmacy must approve each medication order prior to processing by the pharmacy personnel at the Remote site.
- (d) The pharmacist at the Serving Pharmacy shall confirm via video link that the stock packaging/container, drug dispensed and strength are correct. The entire label must be checked for accuracy.
- (e) Counselling must be done by the pharmacist at the Serving Pharmacy.
- (f) Both the pharmacist at the Serving Pharmacy and the pharmacy technician/pre-registration pharmacist/designated personnel must sign off (electronically or otherwise) at the end of dispensing process.
- (g) During the delivery of the telepharmacy service, the Remote site shall maintain uninterrupted connection to its Serving Pharmacy via computer link, video link and audio link. In the event of disruption, the pharmacist at the Serving Pharmacy must re-initiate verification process.
- (h) The resident pharmacist at the Remote site has the duty and responsibility to perform verification checks on the relevant processes such as accuracy of medication/ prescription processing, when he/she returns for duty.
- 5.4.3 Consideration should be given to educate the public on telepharmacy services.

6. Quality Assurance

6.1. Policies and Procedures

- 6.1.1 There should be established written policies and procedures, as well as the maintenance of relevant records related to the delivery of telepharmacy services at the Serving Pharmacy and Remote site. This is to ensure the safe and effective provision of medication and patient care.
- 6.1.2 There should be adequate measures implemented to deter any person from misappropriation medicinal products kept in the pharmacy. Such measures may include surveillance cameras and closed circuit television, as well as periodic stock counts.
- 6.1.3 The policies and procedures for telepharmacy shall be periodically reviewed and updated by the pharmacist-in-charge, working closely with the company's management. "Pharmacist-in-charge" refers to the pharmacist whose name appears in the Certificate of Registration of a Pharmacy.

6.2. Manpower

6.2.1 Pharmacies providing telepharmacy services must ensure adequate staffing at both the Serving Pharmacy and Remote telepharmacy sites for safe and effective dispensing of medication and patient counselling

6.3. Internal Audit

- 6.3.1 Periodic inspections or self-audit of Pharmacy sites providing telepharmacy services must be carried out.
- 6.3.2 Policies and procedures for telepharmacy should include self-audit criteria and method of self-audit.
- 6.3.3 Internal audit should be done to monitor compliance with telepharmacy guidelines, these should include but not limited to,
 - (a) Use and maintenance of the telepharmacy system
 - (b) Medication order entry, review and verification processes
 - (c) Documenting and handling of drug-related problems

- (d) Management of prescriptions and other relevant records
- (e) Contingency plan in event of disruption of data transfer, video and audio link
- (f) Measures in place to safeguard patient privacy and confidentiality of information
- (g) Training of personnel, and assessment of competency
- (h) Reviewing and monitoring of internal audit, including stock count
- (i) Checking of security system and action taken for misappropriation of medicinal products
- 6.3.4 There must be an ongoing review of incident reports and outcomes related to the delivery of telepharmacy services. This is to ensure that there is no abnormal frequency or trends of errors occurring in dispensing drugs or devices to patients. Records of appropriate corrective action taken when necessary must be kept for audit purposes.
- 6.3.5 For audit purposes, each personnel involved in the telepharmacy service must be identifiable in the relevant documents, through signatures, or initial or electronic identifier or other equivalences.
- 6.3.6 The audit reports should be kept for at least two years and be made available upon request.

7. Restrictions and Precautions

- 7.1. The dispensing of Controlled Drugs and Extemporaneous preparations should not be carried out via telepharmacy.
- 7.2. Export sales of drugs and signed orders should not be carried out via telepharmacy.
- 7.3. Caution is required when dispensing medications for high risk groups, such as paediatrics and geriatrics.
- 7.4. Caution is required when dispensing medications with potential for abuse. Pharmacist is to comply to Ministry of Health published guideline(s), where relevant.

8. References

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9. Acknowledgements

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Competency Checklist for Pharmacy Technician Preparation of Medication for Dispensing

SOCIETY OF SHOOL OF STREET
ON SELF BUT FOR

Pre	Preparation of Medication for Dispensing				
Name of Pharmacy Technician:		Type of assessments: Baseline/Follow-up			
Dat	e Joined:	Date of Assessment:			
	COMPETENCY STANDARDS	Always	Usually	Sometimes	Does Not
Chec	king of Prescription		•		
1.1	Prescription is checked for - Validity (date prescribed) - Availability of medicines prescribed - Completeness				
/erifi	cation with prescriber or pharmacist				
1.2	Verification/intervention, if done, is indicated on the prescription				
Pack	ing of medicines				
1.3	Dispensing label(s) generated is/are checked against prescription				
1.4	The following information is printed on the label(s): - patient's name and date dispensed - name of medicine, strength and quantity dispensed - instruction on dose and frequency - cautionary advice, if applicable - direction for storage, if necessary - expiry date, if applicable - name, address and telephone number of pharmacy				
1.5	Read the name and strength on medicine before picking				
1.6	Check quantity of medicine picked				
1.7	Check the name, strength and quantity of medicine against label(s) before packing				
1.8	Affix label neatly				
1.9	Complete picking/packing one prescription before proceeding to the next prescription				
2.0	Use appropriate equipment for counting loose tablets/capsules				
2.1	Avoid direct contact with loose tablets/capsules. Wound on hand(s), if present, is covered with suitable dressing				
2.2	Sign/Initial on prescription at the end packing				
Nan PRI				_	
Star	mp of organization			_	_

ALWAYS (100 - 85%) Demonstrates the expected standard of practice with very rare lapses	USUALLY (84 - 51%) Implies standard practice with occasional lapses
SOMETIMES (50 - 21%) Much more haphazard than 'usually'	NEVER (<20%) Very rarely meets the standard expected. No logical thought process appears to apply



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