HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

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GUIDANCE NOTES ON RETAIL SUPPLY OF REGISTERED THERAPEUTIC PRODUCTS (PHARMACY ONLY MEDICINES AND PRESCRIPTION ONLY MEDICINES) VIA VENDING MACHINES

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.

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1 INTRODUCTION

Therapeutic products, commonly known as pharmaceuticals, are health products that are intended for use in humans for therapeutic, preventive, palliative or diagnostic purposes. Therapeutic products are forensically classified as Prescription Only medicines (POM), Pharmacy Only medicines (P) or General Sale List medicines (GSL) in Singapore. POM can only be supplied by a doctor or by a pharmacist according to a prescription by a doctor. P can be supplied by or under the supervision of a pharmacist at or from a licensed retail pharmacy. GSL can be sold freely by any retailer without restriction on the person and premises in which the supply can be made.

The Health Sciences Authority (HSA) administers a regulatory framework that facilitates licensed retail pharmacies in Singapore in the use of digitalization and technology. In 2016, the HSA published a Guidance Note on the requirements in the use of a vending machine to supply GSL. GSL is deemed to be sufficiently safe to be used by the public without medical supervision and allowed to be sold freely by any retailer without restriction on the person and premises in which the supply can be made.

To safeguard public health and safety, a robust system with more stringent controls including proper supervision by healthcare professionals will be necessary in the use of vending machines for the retail supply of P and POM. This new mode of retail pharmacy service (i.e., supply by retail of P and POM through a vending machine) is considered an extension of the retail pharmacy service from a licensed retail pharmacy.

When implemented appropriately, the supply of medicines through a vending machine can complement existing in-person retail pharmacy services of a licensed retail pharmacy. This will enhance the convenience and delivery of healthcare to patients.

2 SCOPE OF THE GUIDANCE DOCUMENT

This guidance document describes the regulatory requirements for a licensed retail pharmacy to supply medicines directly to patients using a vending machine. This mode of supply of medicines shall not include supply of products containing controlled drugs and drugs with abusive potential. The supply of medicines through a vending machine is a retail pharmacy service which is subject to licensing by HSA.

This guidance document does not cover the professional practice requirements. Pharmacists should refer to the relevant professional practice guidelines when providing pharmacy services.

3 DEFINITIONS

3.1 **"Controlled drugs"** means any substance or product which is specified in Part 1, 2 or 3 of the First Schedule of the Misuse of Drugs Act 1973, or anything that contains any such substance or product.

3.2 **"Licensed retail pharmacy"** means the premises specified in a pharmacy licence under the Health Products (Licensing of Retail Pharmacies) Regulations 2016.

3.3 **"Medicines"** mentioned in this guidance document means Pharmacy Only medicines (P) and Prescription-Only medicines (POM).

3.4 **"Pharmacy licensee"** means the holder of a pharmacy licence.

3.5 **"Qualified pharmacist"** means 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.

4 GENERAL

4.1 The pharmacy licensee must obtain prior approval from HSA before conducting retail supply of medicines through vending machines. Pharmacy licensee must submit an application in Pharmaceutical Regulation Information System (PRISM) to include this retail pharmacy service as an additional service provided by the licensed retail pharmacy.

4.2 Pharmacy licensee should obtain HSA's approval on the address and location of the vending machine prior to starting operations.

4.3 Medicines supplied through the vending machine must be registered in Singapore and obtained from licensed dealers and manufacturers.

4.4 Medicines supplied through the vending machine must comply with the requirements under the Health Products (Therapeutic Products) Regulations 2016 and Health Products (Licensing of Retail Pharmacies) Regulations 2016. This includes maintenance of records of supply and requirements for labelling of the dispensed medicines.

4.5 The Pharmacy licensee has the ultimate responsibility to ensure an effective quality system is in place to manage the retail supply of medicines to patients through a vending machine. There should be adequate and appropriate resources to implement and maintain the system and that personnel roles and responsibilities are defined, communicated and implemented.

5 EQUIPMENT

5.1 The vending machine should be located at a well-lit, secure and clean location whereby activities in the vicinity will not pose any risk of adverse impact to the quality of the medicines.

5.2 The vending machine must be designed and operated to fit its intended purpose. It should be used solely for the supply of the medicines.

5.3 The vending machine should be assigned with a unique equipment identification number for traceability of the medicines in the approved mode of supply.

5.4 Name and contact information of the licensed pharmacy should be prominently displayed on the vending machine for patients to provide feedback when needed.

5.5 The vending machine should be designed and fabricated to facilitate regular cleaning and prevent the entry of pests, dust and other contaminants.

5.6 The vending machine must be adequately equipped to ensure security of the medicines stored in it. There should be measures (e.g., closed-circuit television) to detect and prevent any tampering, theft, break-in or forced access. Additionally, there should be effective safeguards (e.g., automatic shut-down system) to prevent the access of the medicines to the public in the event of vending machine malfunction including, but not limited to, situations such as power failure.

5.7 The vending machine must be equipped with a calibrated measuring device(s) to monitor the storage conditions of the medicines in the vending machine and ensure that they are appropriately stored at the manufacturer’s recommended storage conditions. Any excursions of required storage conditions should be investigated, timely corrective actions taken and documented.

5.8 The vending machine should be equipped with the capability to enable verification by the pharmacist that the medicine and quantity dispensed is correct before the medicine is supplied to the patient.

5.9 Control measures should be in place to prevent the mix-up of medicines during operations (e.g., during restocking, dispensing, etc.)

5.10 The vending machine should have control measures to prevent access of uncollected medicines to persons other than the intended patient.

5.11 Facilities (e.g., consultation booth) to enable privacy and confidentiality of the patient during consultation with the pharmacist should be provided as appropriate, with the vending machine.

5.12 The vending machine must be qualified to demonstrate that the system and equipment can perform effectively and reproducibly as intended before commencing operations. Qualification records should be maintained. Re-qualification of the vending machine to confirm that it remains in a state of control should be considered on a risk-based approach (e.g., after changes made to the vending machine, after major maintenance activities, etc.), and should cover all applicable aspects of Section 6. Any changes proposed to the vending machine should be evaluated to determine the potential impact on its proper functioning and to avoid unintended consequences.

6 INFORMATION TECHNOLOGY (IT) SYSTEM

6.1 IT hardware (e.g., computers, scanners, printers, webcams, speakers, servers, modems, etc.) and software (e.g., dispensing systems, inventory systems, etc.) should be appropriately set up, robust and secured.

6.2 Safeguards for IT hardware and software should commensurate with the level of data risks and specific requirements of an operation in the vending machine. The processing of electronic prescriptions and patient identifier(s), where applicable, should be carried out in a closed-loop system as approved by HSA. A prescription presented in an email, fax or screenshot(s) will not be accepted as an electronic prescription. If medicines are supplied through a vending machine in accordance with electronic prescriptions, the pharmacy licensee should additionally be approved by HSA to provide e-pharmacy service.

6.3 Appropriate IT hardware (e.g., webcams, speakers, microphones, etc.) should be provided to facilitate the correct supply of medicine to a patient through the vending machine in order to avoid errors which could compromise patient's safety. For example, webcam should permit high quality and clear video images for verification of patient identity and the medicine name, strength and expiry date to be supplied. If speakers and/or microphones are used, these should provide good sound clarity for clear communication.

6.4 Hardware and software should ensure security of the information and traceability of activities including patient's supply records.

6.5 IT equipment must be maintained periodically to minimise any disruption to services and ensure the security of the entire IT infrastructure.

6.6 The IT system must include effective measures to ensure secure and correct electronic transmission of information (including patient information) between different systems or applications used in the process of supplying medicines through the vending machine.

6.7 The IT system should be equipped with capabilities to generate an audit trail to track any additions, changes or deletions made to any records. Measures should be put in place to ensure adequate backup of data. During the retention period, the captured information should allow unambiguous recreation of the performed activities that were documented.

7 PERSONNEL

7.1 It is the responsibility of the Pharmacist-In-Charge named in the pharmacy licence to ensure adequate oversight on the operation of the vending machine. This should include activities such as machine repair and maintenance, control software support, dispensing activities, etc.

7.2 The Pharmacist-In-Charge should have clearly defined responsibilities. The level of oversight should commensurate with the types of products supplied through the vending machine.

7.3 Qualified pharmacists should have the necessary training and competency to provide the retail pharmacy service for supply of medicines through a vending machine.

7.4 Personnel should be trained on the maintenance and cleaning of the vending machine in accordance with the written procedures approved by the pharmacy.

7.5 Training records should be maintained, and re-training conducted as appropriate.

8 DOCUMENTATION AND RECORDS

The system should effectively support the traceability of the activities performed by the vending machine. The pharmacy licensee should establish written procedure(s) detailing clear step-by-step instructions describing the following areas (see Sections 8.1 to 8.7). The related records should be made at the time that each action is performed.

8.1 Medicine supply initiation

8.1.1 The various types and models of the hardware and software module(s) used to support the consultation service for medicine supply initiation.

8.1.2 The list of medicines including their name, strength, forensic classification and their common indications to be supplied through the vending machine.

8.1.3 How the patient initiates the request for medicines when using the vending machine.

8.1.4 How the necessary patient identification steps (e.g., identification card, passport, etc.) are performed before initiating a supply from the vending machine.

8.1.5 How valid prescriptions (if any) are received and processed to ensure that the correct medicines from the vending machine are supplied to the patient.

8.1.6 How partial and repeat prescriptions are handled for the supply of the medicines to the patient through the vending machine.

8.1.7 How pharmacist intervention, when required for a prescription, is performed and documented for the supply of medicines through a vending machine.

8.2 Medication counselling

8.2.1 How the patient's diagnosis, treatment and counselling is carried out and documented by the qualified pharmacist in connection to the supply of the medicines through a vending machine.

8.3 Medicine storage and restocking

8.3.1 How the different types of medicines are stored and arranged in the vending machine.

8.3.2 The types of information (e.g., name of product, batch number, expiry date, dose, patient details, date of supply, etc.) on the label of the medicine to be supplied to a patient through the vending machine.

8.3.3 The controls in place to prevent supply of expired medicines.

8.3.4 How medicines are pre-loaded into and removed from the vending machine.

8.3.5 The frequency of restocking of medicines and the controls to prevent errors during restocking.

8.3.6 Describe the records to be completed and maintained during restocking of the vending machine.

8.4 Security and maintenance of records and data

8.4.1 For vending machines dealing with valid prescriptions, describe how the prescriptions are processed, retained and maintained to fulfil legal and regulatory requirements.

8.4.2 Describe how and where the records (e.g., supply records, storage conditions monitoring records, machine cleaning records, restocking records, etc.) are stored.

8.4.3 Describe the retention period of records and record/data archival process.

8.4.4 Explain measures taken to ensure security of patient particulars and information.

8.5 Maintenance and cleanliness program

8.5.1 Explain how the vending machine is cleaned and maintained, including the frequency of these activities.

8.5.2 Describe how maintenance and cleaning records are kept.

8.6 Handling of uncollected or returned medicines

8.6.1 Describe how uncollected or returned medicines are handled.

8.7 Handling of complaints and/or feedback

8.7.1 Describe how complaints and feedback are received, investigated and documented.

9 INTERNAL AUDITS

9.1 Regular internal audits should be conducted to ensure the processes in place remain compliant with the relevant regulatory and legislative requirements and for continuous improvement. The conducted internal audit should be able to demonstrate that the system and processes are consistently in control.

9.2 The internal audit should cover various areas as described in this guidance note. If deficiencies are observed, the root cause should be determined, and corrective actions should be implemented. A risk-based approach can be applied to evaluate the audited areas. Potential risks should be identified and adequately mitigated.

9.3 Results of the internal audit, including any outcomes and actions taken, should be documented.

10 REFERENCE

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

10.2 HSA Guidance Notes on Supply of Registered General Sales List (GSL) Therapeutic Products and Other Medicinal Products Via Vending Machine (GUIDE-MQA-029)

10.3 HSA Guidance Notes on Supply of Registered Therapeutic Products Through e-pharmacy (GUIDE-MQA-032)

10.4 Health Products (Therapeutic Products) Regulations 2016

10.5 Health Products (Licensing of Retail Pharmacies) Regulations 2016

END OF DOCUMENT

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

Contact:

GDP Audit & Licensing Unit
Audit & Licensing Division
Health Products Regulation Group
Health Sciences Authority

11 Biopolis Way #11-01 Helios
Singapore 138667
www.hsa.gov.sg
Email: HSA_gdp@hsa.gov.sg

HSA
Health Sciences Authority