

# REGULATORY GUIDANCE

### **01 NOVEMBER 2016**

# GUIDANCE NOTES ON SUPPLY OF REGISTERED GENERAL SALE LIST (GSL) THERAPEUTIC PRODUCTS AND OTHER MEDICINAL PRODUCTS VIA AUTOMATIC VENDING MACHINES



#### **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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## **TABLE OF CONTENTS**

| 1  | INTRODUCTION                   | 4 |
|----|--------------------------------|---|
| 2  | SCOPE OF THE GUIDANCE DOCUMENT | 4 |
|    | REQUIREMENTS                   |   |
| 4. | REFERENCE                      | 5 |

#### 1 INTRODUCTION

Medicines in Singapore are classified as Prescription Only medicines (POM), Pharmacy Only medicines (P) or General Sale List medicines (GSL).

POMs can only be supplied by a doctor or by a pharmacist according to a prescription by a doctor. P medicines can be supplied by or under the supervision of a pharmacist without a doctor's prescription. GSL medicines include GSL therapeutic products and other medicinal products such as Chinese proprietary medicines, traditional medicines, homoeopathic medicines, quasi-medicinal product, medicated oil and balms, which can be purchased off the shelves and are deemed to be sufficiently safe to be used by public without medical supervision.

#### 2 SCOPE OF THE GUIDANCE DOCUMENT

This guidance document is intended to specify the requirements on the supply of registered GSL therapeutic products and other medicinal products such as Chinese proprietary medicines, traditional medicines, homoeopathic medicines, quasi-medicinal product, medicated oil and balms via automatic vending machines in Singapore.

#### 3 REQUIREMENTS

The supply of any GSL therapeutic products and other medicinal products such as Chinese proprietary medicines, traditional medicines, homoeopathic medicines, quasi-medicinal product, medicated oil and balms may be carried out via an automatic vending machine, if all the following requirements are satisfied:

- The <u>company's (e.g., operator's) name and contact information are</u> <u>prominently displayed on the automatic vending machine</u> so that consumers may contact the automatic vending machine operator directly regarding any feedback arising from the purchase of a product via the automatic vending machine (e.g., broken packaging, expired products etc.);
- b) the automatic vending machine is <u>sufficiently equipped and secured</u> with appropriate storage conditions;

For example, the automatic vending machine is required to be equipped with monitoring device to ensure that the products are maintained at the manufacturer's recommended storage conditions (e.g. store below 25°C, or at any specified storage conditions as stated on the product) and equipped with adequate security features to ensure quality of the product and prevent any tampering of the products.

- c) for GSL therapeutic products,
  - i. the product is labelled and packaged in accordance with the conditions required by Health Sciences Authority (HSA) upon registration of the Therapeutic Products under the Health Products Act; where applicable.
  - ii. the package size of the product is the same as the package size specified for registration with Health Sciences Authority (HSA) and the total amount of the medicine in each package does not exceed a total dosage of 3 months.
- d) for all other medicinal products, the total amount of the products in each package does not exceed a total dosage of 3 months.

#### 4. REFERENCE

1. Health Products (Therapeutic Products) Regulations 2016, Regulation 15 – Supply of general sale list medicine by retail sale vending machine

#### **END OF DOCUMENT**



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