EXPLANATION NOTE FOR APPLICATION OF A PHARMACY LICENCE

1. SCOPE

The purpose of this explanation note is to outline the requirements that must be fulfilled for operating a retail pharmacy to supply specified health products, i.e. Pharmacy medicines (P) and Prescription only medicines (POM) and Oral Dental Gums (ODG) in Singapore. This document also describes the requirements for retail pharmacy services (e.g. Telepharmacy, delivery of medicines, secured self-collection stations, etc.) carried out by a qualified pharmacist or a person acting under the supervision of the qualified pharmacist when providing pharmacy services at or from the retail pharmacy.

2. DEFINITIONS

2.1 Pharmacy Licence is a licence issued under the *Health Products (Licensing of Retail Pharmacies) Regulations 2016*.

2.2 Specified Health Products refer to Therapeutic Products except General Sale List medicines and Oral Dental Gums.

2.3 Pharmacy-only medicine (P) means a registered therapeutic product that is entered into the Register of Health Products under the classification of “pharmacy-only medicine”.

2.4 Prescription-only medicine (POM) means a registered therapeutic product that is entered into the Register of Health Products under the classification of “prescription-only medicine”.

2.5 Qualified pharmacist means a person who is registered as a pharmacist under the Pharmacists Registration Act (Cap.230), 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 Pharmacists Registration (Practising Certificate) Regulations 2008.

3. PRE-REQUISITES FOR SETTING UP A RETAIL PHARMACY

3.1 PERSONNEL

3.1.1 Each retail pharmacy must appoint a permanent full-time pharmacist as the pharmacist-in-charge (PIC) to provide adequate oversight and control over the supply of specified health products carried out at or from each retail pharmacy at all times.

(Note: The appointed pharmacist should not already be a named PIC of an approved pharmacy or Responsible Person (RP) named in the Therapeutic Product Importer’s Licence and/or Wholesaler’s Licence.)

3.1.2 The pharmacist must be a qualified pharmacist.

3.1.3 The pharmacist must be physically present at the retail pharmacy to provide at least 35 hours of dispensing service per week.

3.2 PREMISES AND EQUIPMENT

Applicant must comply with the requirements described in Regulations 4 and 5 under Health Products (Licensing of Retail Pharmacies) Regulations, including the following:

a) designated dispensing area which permits efficient flow of work

b) clean, adequate lighting and effectively ventilated premises

c) recorders and devices for monitoring the storage conditions. These devices should be located in areas that are most likely to show fluctuations and/or the hottest and coldest locations where appropriate. The measuring equipment should be regularly calibrated

within the required operating range at defined intervals. Such calibration records should be maintained.

d) necessary technology and equipment set-up to support the various mode of retail pharmacy service.

3.3 RETAIL PHARMACY SERVICES

3.3.1 Retail Pharmacy must obtain approval from Health Sciences Authority (HSA) if the retail pharmacy wishes to provide other modes of services at or from the retail pharmacy. Examples include but not limited to:

a) Telepharmacy service to dispense P and/or POM

b) Home Delivery service

c) Medication Pick-up services (e.g. self-collection via secured boxes/kiosks)

d) Pharmacy Automation Service for retail pharmacy business (e.g. Automated Pharmacy storage system, robotic dispensing system, etc.)

3.3.2 Procedure detailing how the supply of specified health products is being made through various modes of services should be approved by the company and submitted to HSA during the application of the other modes of services that the retail pharmacy would be providing at or from the retail pharmacy.

3.3.3 Retail Pharmacy supplying specified health products using the special mode(s) of service should adhere to the Professional Guidelines established by Pharmaceutical Society of Singapore.

3.3.4 Retail Pharmacy must ensure the specified health products are stored and distributed in a clean, hygienic environment at the temperature that is suitable for the products. This is to prevent possible contamination and/or degradation of the products which could affect the intended therapeutic effect and pose safety risks to patients.

3.3.5 The specified health products must be delivered with the appropriate security measures to ensure they reach the right patients.

3.4 RECORDS

3.4.1 Records of every receipt and supply of P and POM at or from the retail pharmacy must be made and maintained in accordance with the requirements described in the Health Products (Therapeutic Products) Regulations.

3.4.2 Records should be kept for a period of at least 2 years after the date of the supply.

3.5 HANDLING OF PRODUCTS

3.5.1 Products should be stored under suitable conditions recommended by the manufacturer.

3.5.2 Products with broken seals damaged packaging or suspected of possible tampering/contamination must not be sold/supplied.

3.5.3 Periodic stock reconciliation should be performed comparing actual and recorded product quantity. All significant stock discrepancies should be investigated to check for inadvertent mix-ups and wrong issuance of stocks.

3.5.4 Products must not be supplied after their expiry date.

3.5.5 A system should be in place to ensure that products due to expire first are sold and/or distributed first (Earliest-Expiry-First-Out, EEFO).

3.5.6 When products are disposed, this should be done in accordance to the national legislative and regulatory requirements and with due consideration to protect the environment.

3.5.7 Records of all disposed products should be kept and retained for at least 2 years after the expiry date.

3.6 PROFESSIONAL REFERENCE BOOKS AND RELATED ACCESS

3.6.1 Adequate professional references such as Martindale, British National Formulary (BNF), Monthly Index of Medical Specialities (MIMS) or equivalent are recommended to be kept at the retail pharmacy. These references may be in hardcopy or electronic copy.

3.6.2 Access on the forensic classification of the therapeutic products and list of registered medical and dental practitioners are recommended.

4. AUDIT

A pharmacy audit of the retail pharmacy will be arranged and conducted by the pharmacy auditors from HSA. During the audit, the retail pharmacy will be assessed for compliance with the requirements as specified at paragraphs 3.1 to 3.6, as well as the requirements in the Health Products (Therapeutic Products) Regulations and the Health Products (Licensing of Retail Pharmacy) Regulations.

5. TARGET APPROVAL TIMELINE

A new pharmacy licence will be issued or an amendment application will be approved within 10 working days from the date of the audit close-out (excluding any stop-clock time incurred by the applicant).

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