HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

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GUIDANCE NOTES ON DUTIES OF RESPONSIBLE PERSONS NAMED IN THE IMPORTER'S LICENCE AND WHOLESALER'S LICENCE

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

Under the Health Products (Therapeutic Products) Regulations, a responsible person(s) (RP) must be named in the Importer's Licence (IL) and Wholesaler's licence (WL).

The licensee may have one or more RP named in the IL and WL and specific aspects of oversight for each RP can be clearly stated in the PRISM application. This information will be named in the licences upon licence approval.

2 SCOPE OF THE GUIDANCE DOCUMENT

This guidance document describes the requirements and duties of RPs who are named in the IL and WL by companies intending to import and/or wholesale therapeutic products (TPs) in Singapore.

The guidelines provide guiding principles for licensees in their appointment of RPs to fulfil the prescribed legislative requirements for a RP under the Health Products (Therapeutic Products) Regulations. It also serves as basic information for the industry on the regulatory expectation and approach when processing the licences.

3 DEFINITIONS USED IN GUIDANCE NOTES

3.1 "*Good Distribution Practice Standard*" means Good Distribution Practice (GDP) as described in the Health Sciences Authority (HSA)'s Guidance Notes on Good Distribution Practice published by HSA (henceforth referred as the Authority). This ensures that the quality and integrity of TPs are maintained throughout all stages of the supply chain.

3.2 *"licensee"*, in relation to a TP, means a licensed importer or licensed wholesaler.

3.3 "*qualified pharmacist*" means a person who —

(a) is registered as a pharmacist under the Pharmacists Registration Act (Cap. 230);

(b) holds a valid practising certificate granted under section 23 of that Act; and

(c) is in active practice, as defined in regulation 2 of the Pharmacists Registration (Practising Certificates) Regulations 2008 (G.N. No. S 438/2008).

3.4 *"responsible person(s)" means* a person employed and appointed by the licensee to implement and maintain an effective quality system that meets GDP Standard.

3.5 "*quality system"* is the system for managing quality which should encompass the organisational structure, procedures, processes and resources, as well as activities necessary to ensure confidence that the TP delivered maintains its quality and integrity and remains within the legal supply chain during storage and/or transportation.

4 REQUIREMENTS OF APPOINTED RESPONSIBLE PERSONS

4.1 Under the Health Products (Therapeutic Products) Regulations, the licensee must appoint competent personnel to be responsible for implementing and maintaining an effective quality system that meets GDP Standard. The licensee remains responsible for the compliance to the duties and obligations for the licence held and will be liable for any contravention of the regulations, as prescribed under the Health Products (Therapeutic Products) Regulations.

4.2 The licensee may appoint one or more person as the RP.

4.3 The licensee shall ensure that the appointed RPs are suitable for their roles and are able to implement and maintain the quality system to meet the GDP Standard.

4.4 A RP is not usually expected to carry out therapeutic product safety reporting (e.g. adverse reactions) However, it is up to the company to decide on the overall scope of duties of an RP. More information on therapeutic product safety reporting can be obtained from the HSA website (Guidance for Industry – Post-marketing Vigilance Requirements for Therapeutic Products).

4.5 Relevant personnel appointed as RPs by their licencees should have appropriate competence and working experience as well as knowledge of and training in GDP. This is because the RP is expected to have an in-depth appreciation of the importance of ensuring and maintenance of quality and integrity of therapeutic products in the importation, wholesale and distribution processes.

4.5.1 The licensee should carefully assess the following aspects such as:

i. Qualification - RP is competent and qualified to discharge the licensee's duties as a licensed importer and/or wholesaler, and has relevant qualifications in the related fields including Pharmacy, Pharmaceutical Sciences, Applied Chemistry with Pharmaceutical Sciences, Medical and Pharmaceutical Technology and the equivalent, and technical knowledge on physicochemical properties and stability of drugs;

ii. Knowledge and Experience - RP has adequate knowledge and relevant working experience on the GDP-related activities to be carried out and the procedures to be performed under the licence.

iii. Training – RP has training in GDP, understands the GDP requirements and can maintain and implement an effective quality system to meet GDP Standard.

4.6 The licensee shall ensure that the appointed RP meets the eligibility criteria for handling the respective therapeutic products. The RP named in the licence must be a qualified pharmacist for the following activities:

4.6.1 IL and/or WL for the import and/or supply by wholesale of registered Pharmacy-only medicine (P-Only)

4.6.2 IL and/or WL for the import and/or supply by wholesale of registered Prescription-only medicine (POM)

4.6.3 IL and WL for the import and supply by wholesale of unregistered TPs for patients' use

4.7 A qualified pharmacist working on a full time or part-time basis is allowed to be the responsible person named in the IL and/or WL.

4.8 Only under special circumstances or for activities other than those mentioned above, a person other than a qualified pharmacist (e.g. a qualified practitioner) may be approved as the RP by the Authority.

4.9 During the process of licence application, the licensee shall provide clear justification to the satisfaction of the Authority that the aforementioned requirements have been met to fulfil the prescribed legislative requirements, before a person can be named as the RP in the licence.

5 DUTIES OF APPOINTED RESPONSIBLE PERSONS

5.1 The appointed RPs should have adequate resources, clearly specified authority and responsibility needed to fulfil their duties.

5.2 The RPs should carry out their duties in such a way as to enable the licensee to demonstrate GDP compliance and thus ensure that the quality and integrity of the TP are maintained and distributed to patients in good condition.

5.3 There should be at least one RP who is contactable by the Authority by way of a mobile phone number or an electronic mail address.

5.4 The duties, which an appointed RP undertakes on behalf of the company, include:

i. ensuring that an effective quality system is implemented and maintained that meets GDP standard;
ii. focusing on the management of authorised activities and the accuracy and quality of records;
iii. ensuring that initial and continuous training programmes are implemented and maintained;
iv. coordinating and promptly performing any recall operations for therapeutic products;
v. ensuring that relevant customer complaints are dealt with effectively;
vi. ensuring that suppliers and customers are legally approved or authorised to enable lawful supply of TPs;
vii. approving any subcontracted activities which may impact on GDP;
viii. ensuring that self-inspections are performed at appropriate regular intervals following a prearranged programme and necessary corrective measures are put in place;
ix. keeping appropriate records of any delegated duties;
x. deciding on the final disposition of returned, rejected, recalled or counterfeit products;
xi. approving any returns to saleable stock;
xii. ensuring that any additional requirements imposed on certain products by national legislation are adhered to, e.g. controlled drugs.

5.5 The appointed RP may delegate some of the duties to another person in the team but the responsibilities will reside with the RP. The scope of duties of the RP as specified at Para 5.4 highlights the specific functions that the RP is required to coordinate/undertake. In this regard, the licensee who is responsible for the duties and obligations as a licence holder will need to appropriately allocate adequate resources for the RP to implement and maintain an effective quality system that meets GDP Standard.

6 REFERENCE

1. Health Products (Therapeutic Products) Regulations 2016, Regulation 39 – Responsible person

2. Guidance Notes on Good Distribution Practice, August 2015

3. PIC/S Guide to Good Distribution Practice for Medicinal Products (PE 011-1)

4. EU Guidelines on Good Distribution Practice (GDP) of Medicinal Products for Human Use (2013/C 343/01)

5. Guidance for Industry – Post-marketing Vigilance Requirements for Therapeutic Products

END OF DOCUMENT

HEALTH SCIENCES AUTHORITY

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