LICENCE CONDITIONS FOR OUTPATIENT MEDICAL SERVICE LICENSEES PRESCRIBING AND SUPPLYING CODEINE COUGH PREPARATIONS

IMPOSED UNDER SECTION 13(1) OF THE HEALTHCARE SERVICES ACT 2020

1 Application

1.1. These licence conditions ("**LCs**") apply to all persons that have been licensed under the Healthcare Services Act 2020 (the "**HCSA**") to provide an Outpatient Medical Service ("**OMS**") (such persons referred to as "**Licensees**"), and who prescribe and/or supply codeine cough preparations.

1.2. For avoidance of doubt, the defined terms as used in these LCs shall have the meaning ascribed to them in the HCSA and any Regulations made thereunder, unless otherwise stated.

1.3. A breach of these LCs may result in regulatory action being taken against Licensees under section 20 of the HCSA, including but not limited to:

(a) suspension or revocation of the Licensee's licence to provide OMS;

(b) shortening the term of the Licensee's licence to provide OMS;

(c) a direction requiring the Licensee to rectify the contravention, or prevent a recurrence of the contravention; and/or

(d) a direction requiring the Licensee to pay a financial penalty.

1.4 For avoidance of doubt, these LCs do not override a healthcare professional's duty to make clinical decisions that are in the best interests of each patient, and shall not affect the application of prevailing ethical codes and guidelines applicable to healthcare professionals, and the professional standards in relation to the prescription of opioids.

1.5 For avoidance of doubt, the requirements in these LCs are without prejudice, and in addition to the requirements imposed under the HCSA as well as any Regulations and other applicable licensing conditions, directions, codes of practice made thereunder.

2 Definitions

2.1 The following definitions shall apply to these LCs:

(1) "**Codeine cough preparation**" means a therapeutic product that –

(a) is in liquid or solid form;
(b) contains codeine or its salts; and
(c) is intended for the treatment of coughs.

(2) "**Patient health record**" shall have the same meaning as its definition in the Healthcare Services (General) Regulations 2021.

(3) "**Specialist**" means a medical practitioner who is registered as a specialist in the Register of Specialists under section 22 of the Medical Registration Act 1997.

3 Specific Obligations on the Documentation and Maintenance of Patient Health Records

3.1 The Licensee shall properly document and maintain the patient health records of each patient prescribed with codeine cough preparations. These patient health records shall minimally include the following:

(a) the patient's comprehensive medical and psychosocial history, including any previous use of codeine cough preparations and/or obtainment of additional codeine cough preparations from other medical practitioners;

(b) comprehensive clinical findings, including:

(i) the duration of cough and its associated symptoms; and

(ii) evidence of the patient's misuse of codeine cough preparations (e.g., early requests for refills of codeine cough preparations, and the use of codeine cough preparations for purposeful sedation, such as via requests for prescriptions of codeine cough preparations to aid in sleep), if any; and

(c) relevant clinical investigations conducted on the patient (e.g., chest radiograph) and referrals to appropriate specialists (e.g., respiratory medicine), if any.

3.2 On each occasion that a patient is prescribed with codeine cough preparations, the Licensee shall ensure that the following information is properly documented in the patient health records:

(a) the prescribed type/name of the codeine cough preparation, its dose, frequency and duration of use;

(b) indication(s) and/or justification(s) for prescribing codeine cough preparations; and

(c) any physical signs or evidence of the patient's tolerance, physical/psychological dependence or any misuse of codeine cough preparations (e.g., early requests for refills of codeine cough

preparations, and the use of codeine cough preparations for purposeful sedation, such as via requests for prescriptions of codeine cough preparations to aid in sleep).

4 Specific Obligations on the Supply of Codeine Cough Preparations

4.1 The Licensee shall ensure that any supply of codeine cough preparation is within the limits as stipulated under regulation 14 of the Health Products (Therapeutic Products) Regulations 2016 and any other regulatory requirements for the maximum quantity/duration of codeine cough preparations allowed to be supplied.

5 Specific Obligations on Referrals to Specialists

5.1 The Licensee shall ensure that any medical practitioner employed or engaged by the Licensee shall not prescribe codeine cough preparations to his or her patients and must refer the patients to an appropriate specialist for further management if the patient's cough persists for more than eight (8) weeks or remains undiagnosed after all the relevant investigations and treatment are completed.

5.2 The Licensee shall ensure that patients who refuse to be referred to a specialist based on the conditions specified in paragraph 5.1 shall be counselled appropriately, and such refusal and counselling shall be documented in the patient health records.

6 Obligation to Furnish Information on Suspected Drug Addicts

6.1 The Licensee shall ensure that medical practitioners employed or engaged by the Licensee comply with Regulation 19 of the Misuse of Drugs Regulations, in relation to the notification of suspected drug addicts.