HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Terms of Reference and Rules of Procedure
Codeine Classification Subcommittee

CONTENTS

1 ESTABLISHMENT

1.1 The subcommittee to advise on the classification review with respect to non-prescription codeine containing medicinal products ('medicines') is established by the Advisory Committee for Human Medicines ('ACHM') to the Health Products Regulatory Authority (the 'Authority').

2 MANDATE

2.1 The subcommittee provides independent advice to the ACHM on scientific and technical matters related to the HPRA classification review with respect to non-prescription codeine containing medicines under Article 74 of Directive 2001/83/EC as amended ('Directive 2001/83/EC') (the 'Classification Review').

The subcommittee will be tasked with providing, via a report, advice in response to specific questions addressed to them regarding the HPRA draft assessment report ('DAR') prepared for the Classification Review.

The subcommittee will report to the ACHM who will review the subcommittee advice, as well as the HPRA DAR, and provide the subcommittee's advice and ACHM advice to the HPRA.

3 COMPOSITION

3.1 The subcommittee consists of persons who have a special knowledge and experience related to the purpose of the subcommittee who are appointed by the ACHM, and any person appointed to it by the Minister for Health for a period not exceeding the duration of the term of office of the ACHM. It is expected that the work of the subcommittee will be conducted between September and December 2024.

3.2 In order to maximise the independence of the subcommittee and obtain the best representatives to address the questions to be asked, the anticipated expertise to be appointed to the subcommittee will include the following:

- a general practitioner nominated by the Irish College of General Practitioners.
- a community pharmacist nominated by the Pharmaceutical Society of Ireland.
- a pain specialist nominated by the College of Anaesthesiologists of Ireland.
- a specialist in the management of headache especially medication overuse headache nominated by the HSE Neurology Lead
- an addiction specialist nominated by the Health Services Executive ('HSE') Addiction Lead
- a member of HSE Medication Safety Services nominated by the HSE National Medication Services Lead

3.3 If any organisation outlined above is unable to provide nominations, then alternative professional organisations may be approached to provide nominations to ensure the required expertise is obtained.

3.4 Due to the limited timeframe for the activity of this subcommittee, and the specific expertise contributed by each subcommittee member each nominating organisation will be requested to provide an alternate nominee who can participate should the nominated individual be unable to for any reason. All conditions applying to the subcommittee members will also apply to the alternate members.

3.5 Subcommittee members are paid allowances for expenses as the Authority may, with the consent of the Minister for Health and the Minister for Public Expenditure and Reform, determine.

4 CHAIRPERSON

4.1 The Chairperson is appointed from among the subcommittee members by the members.

4.2 The Chairperson is responsible for the efficient conduct of the business of the subcommittee, in particular by:

- planning the work of the subcommittee together with the secretary to the subcommittee,
- monitoring, together with the secretary to the subcommittee, that these terms of reference and rules of procedure are respected,
- ensuring that at the beginning of each meeting, any potential conflict of interest is declared regarding any particular item to be discussed by the subcommittee,
- aiming to achieve consensus on issues discussed by the subcommittee,
- ensuring, together with the subcommittee and the secretary to the subcommittee, the regulatory and scientific consistency of the subcommittee's advice, and
- reporting on the activities of the subcommittee to the ACHM as appropriate.

5 MEETINGS

5.1 Meetings are held with sufficient frequency to enable the subcommittee to conduct its functions. If appropriate, the Chairperson will consult with members of staff of the HPRA in determining the frequency of meetings. It is intended that three meetings will be held between September and December 2024 (one introductory meeting followed by two meetings to deliver the outputs from the subcommittee).

5.2 It is strongly preferred that members of the subcommittee attend the substantive two meetings in person at the HPRA offices. However, if necessary, members of the subcommittee may participate in meetings by telephone, teleconference, or videoconference. Members so participating are considered to be present at the meeting. The secretary to the subcommittee also attends the meetings.

5.3 Meetings are chaired by the Chairperson.

5.4 All members of the subcommittee (or their designated alternate) are required for a quorum.

5.5 The agenda is established by the Chairperson and if appropriate, in consultation with the ACHM or the members of staff of the HPRA, and the secretary to the subcommittee. The agenda is circulated with related papers in advance of the meeting.

5.6 Each member present has one vote. Decisions are made by consensus or by a majority of the votes of the members present. If there is an equal division of votes, the Chairperson has a casting vote.

5.7 Any employee of the HPRA or other person may be invited to attend for particular items at the discretion of the Chairperson, but they are not entitled to vote.

6 MINUTES OF MEETINGS

6.1 Minutes of each meeting are prepared by the secretary to the subcommittee.

6.2 Draft minutes are sent to the members before the next meeting. They are adopted at the following meeting or by written procedure and signed by the Chairperson.

7 REPORTING

7.1 The outcome of meetings is reported to the ACHM. The Chairperson will inform the ACHM of significant issues discussed at the subcommittee and present the advice of the subcommittee for the ACHM's consideration.

8 GUARANTEES OF INDEPENDENCE AND CODE OF CONDUCT

8.1 The names of the subcommittee members and their professional qualifications are made public.

8.2 Members of the subcommittee will make a declaration of financial or other beneficiary interest in any industry regulated by the HPRA prior to their appointment to the subcommittee and annually thereafter, if necessary. Any interests declared will be evaluated and any potential conflicts will be addressed in advance of requesting any advice to ensure that the impartiality of the HPRA's Classification Review is maintained. No individual will be eligible to be appointed to the subcommittee if they have any direct financial interest in the sale of codeine containing medicines.

8.3 Members of the subcommittee will abide by the HPRA Code of Conduct.

8.4 Members of the subcommittee are required not to disclose information received by them while performing their duties, even after their duties have ceased and will be required to sign a confidentiality undertaking.

9 GENERAL PROVISIONS

9.1 These terms of reference and rules of procedure are approved by the ACHM and the subcommittee and are made public.

MEMBERS OF SUBCOMMITTEE

Organisation	**Nominee**
HSE National Medication Safety Program	Ms. Ciara Kirke
Pharmaceutical Society of Ireland	Dr Dennis O`Driscoll
College of Anaesthesiologists of Ireland	Dr Áine O'Gara
HSE Neurology	Dr Petya Bogdanova-Mihaylova
HSE Addiction Services	Prof Eamonn Keenan
Irish College of General Practitioners	Dr Bernard Kenny