An Roinn Sláinte
Department of Health

Medicines Criticality Assessment Group –Terms of Reference

1. Role

The Medicines Criticality Assessment Group (MCAG) is a collaborative working group of relevant government, regulatory and healthcare agency bodies that is convened by the Department of Health and chaired by the Health Service Executive (HSE) to facilitate ad hoc rapid assembly of nominated representatives to assess and address emerging human medicinal product (prescription and non-prescription) supply issues. MCAG enables collaborative work and system wide perspective on non-routine, potentially high impact events.

MCAG was established in 2018 by the Department of Health as part of a whole of government response to Brexit. The group has since evolved to its current form, through various iterations during the COVID-19 pandemic and as the end of the Brexit transition period approached.

2. Term

The following Terms of Reference are effective from 14 November 2025 and will apply until further revised, as agreed by the Membership of the Group, or until the Group is stood down by the Department of Health.

3. Type

The MCAG is a health service stakeholder group, convened by request at Principal Officer level within the Primary Care Oversight and Performance Division of the Department of Health.

Following notification of a supply issue from a relevant health service stakeholder (DOH, HSE, HPRA and/or PSI) that is requiring more extensive and more immediate cross health-service input and is considered necessary to effectively prevent and/or mitigate a high impact supply issue, the Secretariat liaises with the Chair of the Group to convene an MCAG.

The Chair issues an invitation to the Group's Standing Members and nominated Subject Matter Experts in line with the procedure set out in these Terms of Reference.

4. Roles and Responsibilities

The Medicines Criticality Assessment Group (MCAG) will:

- Discuss the impact of any identified or expected supply chain issues on medicines availability, including, but not limited to, increased demand brought about by public health threats, regulatory or manufacturing issues, geopolitical factors.

- Assess implications of identified specific medicinal product supply issue on the healthcare system and patients and escalate any key concerns to Ministerial level.
- Identity, develop and implement specific shortage mitigation strategies.
- Identify any further actions required and assign responsibility for completion of said actions.
- Assist in the development of clinical guidance for mitigation of impact of specific medicinal product supply issues, as necessary, and where appropriate to do so. This workstream will be led by relevant HSE clinical personnel who will hold responsibility for final output.
- Prepare coordinated communication plan to support dissemination of the recommendation(s)/clinical guidance to relevant health system stakeholders and patients/patient groups, as required.
- Disseminate communication(s) via a mechanism agreed by the group.

The Convenor/Secretariat (Department of Health) will:

- Be a point of escalation for members of the MCAG to raise items for attention of the group.
- Liaise with the Chair regarding convening of the group, as deemed necessary.
- Liaise with the Chair regarding inviting Subject Matter Experts, as deemed appropriate.
- Prepare a high-level action minute of meetings of the group for dissemination by the Chair.
- Be a point of contact for questions arising from the action minute, or processes outlined in these Terms of Reference.
- Follow up on actions to ensure delivered within agreed timeframes.

The Chair (*Assistant National Director of HSE*) will:

- Convene the Standing Members of the MCAG, via email, following discussion with the Secretariat.
- Invite Subject Matter Experts, as deemed appropriate to meeting topics, as discussed with the relevant stakeholder.
- Chair the meeting, monitoring the attendees at online meetings, keeping the meeting to time, and keeping order on discussions.
- Summarise agreed actions at the end of the meeting, as relevant. Agreed actions will include timeframe for completion, where possible.
- Engage with the Secretariat regarding an action minute, as appropriate.
- Engage with HSE Clinical Programmes, as necessary and relevant to MCAG attendance and/or as relevant to agreed actions arising from a meeting of the MCAG.

5. Format and Membership

Chair: Assistant National Director, Health Service Executive

Secretariat: Medicines, Controlled Drugs and Pharmacy Legislation Unit, Department of Health

The Medicines Criticality Assessment Group comprises of relevant 'Standing Members' from:

- The Department of Health (DoH),
- Health Products Regulatory Authority (HPRA),
- Pharmaceutical Society of Ireland (PSI), and
- Health Service Executive (HSE), including:
    - HSE Primary Care Reimbursement Service (PCRS),
    - Access and Integration Drug Management Programme (AIDMP), and
    - Medicines Management Programme (MMP),

and

'Subject Matter Experts' that may include any relevant clinical team and/or programme e.g. National Cancer Control Programme (NCCP) of the HSE, and additional expert stakeholders e.g. HSE Communications, invited to meetings of the MCAG by the Chair, on a case-by-case basis.

6. Amendment of these Terms of Reference

An annual review of the work of the group, including rationale behind convening MCAG, appropriateness of attendance/membership and group output will be carried out by the Department of Health. Review findings may result in further revisions to the Terms of Reference.

This Terms of Reference may be amended in writing after consultation and agreement between standing members of the group.