

Medicines and Medical Devices Criticality Assessment Groups- Covid 19

Terms of Reference

1. Role/ Purpose

The Medicines Criticality Assessment Group and the Medical Devices Criticality Assessment group were set up as subgroups to the Department of Health Brexit operation group, chaired by HSE/HPRA, to work on Brexit related supply issues.

The groups have now been requested to refocus their efforts on Covid-19 related medicines and medical devices supply issues and shortages.

For all Covid-19 related work, the groups will be considered subgroups of the National Public Health Emergency Team (NPHE).

2. Term

This terms of reference is effective from 3rd March 2020 and will be ongoing until terminated by agreement between group member and NPHE.

3. Membership

The Medicines Criticality Assessment Group will comprise of members from the following organisations, as required:

- Health Products Regulatory Authority (HPRA)- QSAC, HPAR, Compliance
- HSE- HBS, Acute Hospital Drugs Management Programme, National Cancer Control Programme, Primary Care Reimbursement Services, National Immunisation Office
- Department of Health (DoH)- Medicines, Controlled Drugs and Pharmacy Legislation Unit

The Medical Devices Criticality Assessment Group will comprise of members from the following organisations, as required:

- HPRA- Medical Devices
- HSE- HBS, NCAGL (Clinical and Medical Devices Leads), Laboratory services expert
- Department of Health (DoH)- Medicines, Controlled Drugs and Pharmacy Legislation Unit

4. Roles and Responsibilities

The Medicines Criticality Assessment Group and Medical Devices Criticality Assessment Groups will:

- a) Establish extent of the availability of medicines and medical devices used in the following:
 - Diagnosis of Covid-19 (as per agreed diagnostic strategies) (including testing equipment)
 - Treatment of Covid-19 (Anti-Virals)
 - Treatment of secondary bacterial infections in patients with Covid-19 (pneumonia etc)

- Supportive Treatments used in patients with Covid-19
 - Treatments to manage disease at home
 - Treatments to manage disease in hospitals, including in ICU care
 - Devices and consumables used
 - Personal Protection
- b) Conduct ongoing horizon scanning activities to ensure that any potential medicines and medical devices shortages caused by Covid-19 related issues and any potential medicines, device or equipment shortages not directly related to Covid-19 but which could have a high impact on patients and healthcare professionals, are identified as early as possible
- c) Oversee the response to medicines and medical devices shortages caused by Covid-19 related issues and any medicines, device or equipment shortages not directly related to Covid-19 but which could have a high impact on patients and healthcare professionals

In order to carry out a), the groups must be provided with guidance from the HSE's High Consequence Infectious Diseases (HCID Group). The HCID Group should establish a list of essential medicines and medical devices that will be required. It is understood by the criticality groups that this may be an evolving list. Input will also be sought from the HSE's Covid-19 modelling group.

The groups' work will focus on addressing shortages and investigating availability. Decisions in relation to other issues such as procurement and indemnity will be outside the remit of the group.

5. Meetings

Meetings to be chaired by DoH representative, where possible.

Any issues that cannot be resolved at group level are to be raised by DoH Representative at the internal DoH Covid-19 working group. Issues may be escalated via this group to NPHE.

6. Amendment, Modification or Variation

This Terms of Reference may be amended, varied or modified in writing after consultation and agreement with group members and NPHE.