



Medical Devices Criticality Assessment Group Monday, 16th March 2020

Attendees: **HSE:** Fergal Collins (*chair*), Emma Benton, Dr. Michael Power, Prof. George Mellotte, Ger Flynn, Anne-Louise Neenan, Brendan White
HPRA: Judith Martin, Niall MacAleenan, Nicola Hickie
DoH: Colm O'Loughlin, Karen McNamara, Breifne O'Rourke

- HSE Procurement have responsibility for updating the Master List and accompanying Red-Amber-Green risk register Dashboard.
- Any issues arising with regard to items on the list are to be brought before the Group for resolution. In cases where resolution cannot be reached within the Group, issues to be escalated to HSE National Crisis Management Team (NCMT) and NPHE.
- With a view to streamlining ICU supply process, ICU clinical leads will now send all procurement needs to a specific HSE email address for Covid-related supply issues.
- HSE emphasised the importance of accuracy in procurement requests when going to the market, due to the highly competitive global market for medical supplies. HSE should therefore be informed of projections of demand arising from modelling work.
- The HPRA has been working with the HSE in examining potential alternative supply chains and whether necessary products can be sourced from Irish manufacturers/suppliers.
- The HPRA outlined its process for derogation of non-CE marked devices in critical circumstances. If the HPRA needs HSE assistance in the follow-up to derogation applications, will direct these to MDCAG chair to find the appropriate point of contact in the HSE.
- Government decisions to ramp up testing will increase the volume of sample collection swabs required. HSE are therefore seeking alternative swab sources globally and will consider offers of point of care testing if clinically recommended. HPRA will be kept informed in order to facilitate any new testing arrangements from a regulatory standpoint.
- For information of group, it was noted that there are different types of tests entering the market, the distinction between tests for detection of antibodies and tests for detection of viral RNA was made.
- Hand sanitiser:
 - HSE is assisting the repurposing by an indigenous company for production of hand gels.
 - An alcohol producer will be able to assist with the supply of alcohol for manufacture of hand sanitiser.
 - These measures are being implemented to address Ireland's needs in the context of a global shortage of hand sanitisers.
- HSE confirmed they are assessing decommissioned ventilators as a potential supplementary source should it not be possible to procure sufficient additional ventilators. Use of decommissioned ventilators not required at this time. Sufficient ventilators in stock to meet current clinical needs.
- National restrictions: Med Tech companies may need to be considered essential providers/services in the event of any escalation of national restrictions.
- HSE's procedures for distributing supplies of devices and PPE are continuing to be refined, to ensure demands are met in the event of a significant surge in case. Policy of what groups to receive PPE is not within the remit of the group.