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8 May 2020

Dear ██████████,

Thank you for your and your teams' efforts in recent weeks. I was reflecting on the progress we have made and it is incredible to consider what we have achieved in such a short space of time. It is a credit to Swagelok and your partners for accelerating a process which typically takes years to a number of weeks to develop the Piran Vent device.

I wrote to you on 28 April 2020 about the next steps in the Ventilator Challenge. The Technical Design Authority (TDA) on 22 April 2020 did not recommend the Piran Vent design to go forward but, in recognition of the outstanding progress made by Swagelok to that point, you were granted a period of one week to make further progress.

On 5 May 2020, we convened a follow-up TDA to inform further recommendations to Ministers about the progress of devices remaining in the Ventilator Challenge. These recommendations were reached in light of the best epidemiology information available at that time and, as appropriate, the maturity of each device designs based on the most recent assessments by the Medicines and Healthcare products Regulatory Agency (MHRA) and the Medical Devices Testing and Evaluation Centre (MD-TEC) as well as the balance of demand and supply. This included the MD-TEC video review of the Piran Vent completed on 1 May 2020.

The TDA on 5 May 2020 found significant progress had been made since the last meeting however further development would be required before it was ready for clinical testing. The TDA noted that the Piran Vent still needs to be able to limit the maximum PEEP that is deliverable, which should be a relatively simple software change. The device has good ability to support closed suction by automatically adjusting flow rate, but currently does not have a lab-assessed supported breathing functionality. Whilst the Piran Vent has many merits, the TDA recommended not to pursue further assessment and clinical service evaluation. Ministers agreed with this recommendation and the Cabinet Office will no longer support the development of the Piran Vent device.

A follow-up meeting will be arranged to take place next week, where we would welcome the opportunity to discuss next steps in more detail.

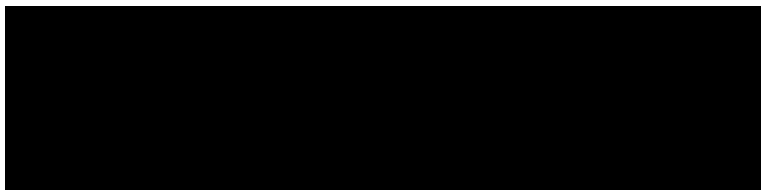
The work to develop the device to this point has been extraordinary, and you may wish to continue to progress the Piran Vent device towards obtaining CE marking, or other regulatory approvals, at your own cost. In addition, MD-TEC has offered to provide independent support

for further testing and clinical evaluation to support the development of devices to be used for the COVID-19 pandemic, should this be required. Such support could include, at no cost, the provision of expert opinion, testing in MD-TEC's simulated ICU for performance and safety, usability testing, reports and advice. Please let us know if you are interested in this opportunity.

As previously explained, the Cabinet Office will pay reasonable costs incurred by you in the week from 28 April 2020 to 4 May 2020 capped at £250,000. From this point on, further Cabinet Office financial support will cease. Therefore, please take all immediate steps to prevent any further costs from being incurred on our account, and to mitigate any existing costs relating to the ventilator project. We look forward to receiving a detailed breakdown of your costs incurred.

I recognise, of course, that this outcome will be disappointing. However, it is worth remembering that at the time the Ventilator Challenge was launched we were facing the biggest threat this country has seen for decades. Now, as a result of the social distancing measures that we've put in place, the overall number of new cases has been steadily falling and there are over 3400 spare critical care beds in the NHS. The virus is not beaten yet but this is an enormous relief, not only to the Government but our whole country. I hope that you will take great heart from what you and your team have achieved in such demanding circumstances. Your involvement in the Ventilator Challenge has been recognised by the Government and I would like to again offer my greatest appreciation and thanks to you and your team for the quite extraordinary endeavour, enterprise and ingenuity shown by you and your team.

Yours faithfully,

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Government Chief Commercial Officer.