Cabinet Office

Departmental Minute:

Indemnities Granted to Designers and Manufacturers in the Rapidly Manufactured Ventilator System Project

Presented to Parliament by the Chancellor of the Duchy of Lancaster and Minister for the Cabinet Office by Command of Her Majesty

April 2020

Alternative format versions of this report are available on request from publiccorrespondence@cabinetoffice.gov.uk

Cabinet Office: Departmental Minute

Indemnities Granted to Designers and Manufacturers in the Rapidly Manufactured Ventilator System Project

During the course of the coronavirus outbreak, the Government's strategy to increase ventilator capacity has focused on procuring more devices from existing manufacturers overseas, scaling up production of existing ventilator suppliers, and working with industry to design and manufacture new devices.

The Ventilator Challenge was launched in March, in response to scientific modelling that suggested an urgent need for further ventilator capacity within the National Health Service.

At present, two devices from the Ventilator Challenge are ready for use in hospitals, with the Penlon ESO2 device becoming the first newly-adapted device to receive approval for use during the pandemic from the regulator, the Medicines and Healthcare products Regulatory Agency (MHRA). A number of other devices are currently undergoing tests for regulatory approval.

Given the unprecedented circumstances of the pandemic, Cabinet Office has given indemnities both against IP infringement, in respect of the designs, and against product liability claims against the manufacturers of Rapidly Manufactured Ventilator System (RMVS) products.

To date, Cabinet Office has concluded six design contracts that give indemnity against IPR infringement claims and, as at 27 April, five contracts for the manufacture of the RMVS devices which give indemnities in respect of both IPR infringement and for claims arising out of defects in the products. However, two of these product lines may not proceed to manufacture, reducing the scope of this liability. The IPR indemnity may still be relevant if some infringement of 3rd party IPR has already occurred, but there will be no liability for HMG under the Product Liability indemnity as the products will not now be put into use

The precise commercial terms which have been negotiated for each supplier are, and will remain, commercially confidential. While it is difficult to estimate the potential liability exposure, it could exceed £300,000. For this reason, I have to inform parliament of these arrangements.

Generally, these indemnities cover potential infringements of third-party IP rights. Potential infringements could arise through the design and manufacture of the new RMVS ventilator designs (in which the IPR is now owned by the Crown) where, for example, the design encroaches on any pre-existing patents, copyright and design

rights and also modifications of existing designs. The indemnity is uncapped. HMG can avail itself of Crown Use authorisation provisions with respect to patents and designs, enabling it to mitigate the risk of third-party IPR infringement. The compensation payable for Crown Use authorisation is likely to be less than for IPR infringement.

The second class of indemnity covers all potential forms of claims arising from product liability, such as death/personal injury to a patient, patient loss of earnings and legal costs.

The rationale for providing an indemnity for products is to provide confidence to companies participating in the Ventilator Challenge, some of whom have not manufactured ventilators or their components before. Given the urgent need to ensure that the NHS has sufficient ventilator capacity, the products will go through an accelerated but nonetheless rigorous testing and regulatory approval procedure, overseen by the MHRA. Manufacturers will have contractual obligations to manufacture the products according to specification with due skill and care.

HMG will have certain rights of redress against manufacturers. These will however be more limited than would be the case for a fully CE marked product. The indemnities are broad and the exposure could be extensive as it covers personal injury. However, it is the case that the RMVS machines will be put into hospitals only after MHRA testing to assure safety and once they have been granted a licence for use. The licence will be limited to allow use of the RMVS ventilators only during the period of the pandemic. A letter has been sent to NHS Trusts setting out these arrangements, and advising that they should prioritise using existing stock of ventilators where possible.

The Treasury approved these liabilities before they were activated. Authorities for any expenditure required under the liability will be sought through the normal Supply procedure. If any Member of Parliament has concerns, he/she may write to me and I will be happy to examine their concerns and provide a response.

Michael Gove, Chancellor of the Duchy of Lancaster and Minister for the Cabinet Office

April 2020