A number of manufacturers that have put forward proposals with the most promising proposals being those where established ventilator manufacturers have partnered with other companies. These proposals have the benefit of having an established design that has already been used on patients and manufacturing sites used to working to standards of production for medical devices and so the risk is substantially lessened.

The MHRA's Clinical Director of Devices, Duncan McPherson, joined a call yesterday with the Chancellor of the Duchy of Lancaster (CDL), James Dyson, John Manzoni and others in Cabinet Office to discuss Dyson's proposal for a ventilator. The Dyson proposal involves a totally new design, built in manufacturing facilities normally used for standard industrial products (or potentially decommissioned from producing electric cars); for this reason it wasn't intended to be pursued because of the risk involved and the additional work that would be required to ensure that the ventilator produced at the end was meeting appropriate standards. James Dyson has expressed his concerns with Ministers and you will also have seen that he has been speaking to the press this morning.

The readout from CDL's Private Office and a response by John Manzoni are below – in short you will see that CDL was keen to press forward with Dyson's proposal to a timescale that is totally unrealistic, based in part on promises made by Dyson that are already not being fulfilled. In addition, however, CDL did not appreciate the level of risk involved in the manufacture and use of ventilators and wanted to circumvent the expedited regulatory process that has been put in place. John Manzoni's response is very helpful – he followed up with a call to June this morning – and the MHRA team are working with Cabinet Office today to examine what more can be done to accelerate the process – but with a particular focus on those manufacturers where we think that viable products are likely to be available the soonest. My understanding is that we are now at a stage where manufacturing capacity and availability of parts is the rate limiting step, not any regulatory hurdles in place.

Colleagues in Cabinet Office feel that CDL may not be convinced and this issue may be escalated which is why I wanted to make you all aware. There may be further meetings or discussions on this issue that I will ensure that I join but I will be clear that MHRA are doing everything we can to support this but absolutely will not cut any corners when it comes to issues of critical patient safety.

June or I are happy to discuss with anyone if that is helpful.

Graeme

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Medicines & Healthcare products Regulatory Agency

From: Raine, Dr June <June.Raine@mhra.gov.uk>
Sent: 25 March 2020 21:55
To: Tunbridge, Graeme <Graeme.Tunbridge@mhra.gov.uk>
Subject: FW: ACTIONS FROM 1530 CALL WITH SIR JAMES DYSON

- There was consensus that the most recent design was an improvement, and has a much higher chance of passing MHRA tests. This was not the version being sent to Birmingham however, and a prototype of this version still needed to be developed.
- SJD was clear that the moment they get the green light they could start production.
- It was agreed that there were 11 models still in the running, 3 of which were new and 8 which were based on existing models that had been MHRA approved, and would be able to be quickly approved again following modifications to upscale in a short time period.
- DM said that the Birmingham testing would take around a day. The next step was for a small number (10 or so) to be submitted to hospitals to be tested on patients. Then final approval would be granted after that.
- CDL asked to push for the Dyson product to be be tested tomorrow in Birmingham, for Dyson to produce a dozen for patient testing, and for it to go to the production line by the end of the week. While there were other considerations around this, such as the need to certify premises, but the aim should be to get a model to the production line by the end of the week.
- MC clarified the changes to the Dyson device from the earlier prototype, noting particularly there was now a "bag in a box", which avoided a lot of the problems caused by plastics.
- It was agreed that MHRA needed to be in constant contact with all suppliers to make sure that issues could be resolved in real time.
- GRW made clear the UKG would cover the costs incurred by Dyson for components, and it was agreed by all that SJD and his team should immediately begin ordering the necessary components.
- CDL made clear that there was no excuses not to move this forward at great speed. Resources cannot be a blocker and issues of resource must be resolved by whatever means necessary.
- It was clarified that Dyson's potential output was around 3000 and possibly up to 5000 a week.

NR

Private Office: The Rt Hon Michael Gove MP, Chancellor of the Duchy of Lancaster and Minister for Cabinet Office
PPS Steffan Jones: **T:** I&S
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On Wed, 25 Mar 2020 at 18:38, PS Michael Gove Mailbox <psmichaelgove@cabinetoffice.gov.uk> wrote:

> Dear all,

Many thanks for the call with CDL and Lord Agnew. Please find the actions below. I will follow up with a readout of the key actions later this evening:

- **SIR JAMES DYSON AND TEAM** to start buying the components needed to make their product;
- **GARETH RHYS WILLIAMS AND TEAM** to review where components are best used to maximise output of ventilators in the shortest time period and to update Lord Agnew and CDL by COP Thursday
- **MHRA** to supply all 11/13 potential producers with constant clinical support in real time by close of play tomorrow to make sure that products can pass the MHRA testing in the shortest timeframe possible;
- **MHRA/BSI** to make sure that there are plans in place to certify all 11/13 potential producers' premises are by the end of the week, with any issues to be flagged to CDL PO by COP tomorrow.
- **MHRA and GRW** to ensure that by the end of Friday, the Dyson product has been tested and approved by MHRA, a small number of products have been provided to hospitals for human testing, and the final product has started to be manufactured. **GRW** to immediate escalate any blockages to Ministers.
- **CDL PO** to set up another call with the same cast list to review progress.
- **ALL** to make sure that whatever resources needed are deployed during this national emergency, and if more resources are needed, CDL PO are to be made aware immediately to escalate and resolve as necessary.

Many thanks for your continued effort all.

NR

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