Message

From: PsBethell [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6F0A1735F9834B5CA9C02D2016D42E9F-PSBETHELL]
Sent: 26/03/2020 11:52:04 AM
To: Tunbridge, Graeme [Graeme.Tunbridge@mhra.gov.uk]; Permanent Secretary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c95fac41d7c24f8ba5faa2072856bcdf-Permanent S]; Whitty, Chris [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b3ee62e0ca04e978730b14f9b416a1e-Whitty, Chr]; NR [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=731ae41932914a2b90daa92ec8cc56dd-NR]; PsBethell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6f0a1735f9834b5ca9c02d2016d42e9f-PsBethell]; NR [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d411bd2e4cc74471bbe952d01699b1c1-NR]; Noone, Vincent [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fe83ea320b8c40ae8e4709ce76c7b22e-VNoone]; psmatthancock [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dddc7f87798480280e3a7aa57cb8d62-psmatthanco]
CC: June Raine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4ac687ee354c9cac76d09f23ee6ade-June Raine]; Mogford, Jonathan [Jonathan.Mogford@mhra.gov.uk]; McPherson, Duncan [Duncan.McPherson@mhra.gov.uk]; Woodeson, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f02950ddfb2a448f831d41adba2da5e4-EWoodeso]; McGurry, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1df6be77f99d4548838f25081abf160d-CMcGurry]
Subject: RE: Ventilator challenge / James Dyson

Thanks Graeme for the helpful update. Copying to others in PO who are leading on ventilators.

Best,
NR

NR | Senior Private Secretary | T: I&S | M: I&S

From: Tunbridge, Graeme <Graeme.Tunbridge@mhra.gov.uk>
Sent: 26 March 2020 11:46
To: Permanent Secretary <permanent.secretary@dhsc.gov.uk>; Whitty, Chris <Chris.Whitty@dhsc.gov.uk>; NR NR <NR @dhsc.gov.uk>; PsBethell <PsBethell@dhsc.gov.uk>
Cc: June Raine <June.Raine@mhra.gov.uk>; Mogford, Jonathan <Jonathan.Mogford@mhra.gov.uk>; McPherson, Duncan <Duncan.McPherson@mhra.gov.uk>; Woodeson, Elizabeth <elizabeth.woodeson@dhsc.gov.uk>; McGurry, Carly <Carly.McGurry@dhsc.gov.uk>
Subject: Ventilator challenge / James Dyson

Dear all,

I wanted to let you know of an emerging issue in relation to the ventilator challenge work that MHRA has been closely involved in. The team here have been working to support the production of ventilators that will compress a process that normally takes years into weeks. The risk is substantial because of the complex and critical nature of ventilators and so regulatory oversight is critical to ensuring that the ventilators produced through this challenge do not harm more patients than they help. We've designed a regulatory process that works alongside manufacturers as they move from design through to production to ensure that regulation is not the rate limiting step to getting the ventilators produced.

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

FYI

From: Chief Executive of the Civil Service <chief.executive@cabinetoffice.gov.uk>
Sent: 25 March 2020 21:51
To: PS Michael Gove Mailbox <psmichaelgove@cabinetoffice.gov.uk>
Cc: PD McPherson, Duncan <Duncan.McPherson@mhra.gov.uk>; Gareth Rhys Williams <gareth.rhyswilliams@cabinetoffice.gov.uk>; Helen Williams <helen.williams@dyson.com>; NR @cabinetoffice.gov.uk>; NR @cabinetoffice.gov.uk>; NR @cabinetoffice.gov.uk>; matthew.childe@dyson.com; MOONESINGHE, Ramani (NHS ENGLAND & NHS IMPROVEMENT - X24) <ramani.moonesinghe@nhs.net>; Steffan Jones <steffan.jones@cabinetoffice.gov.uk>; NR @cabinetoffice.gov.uk>; PS Lord Agnew Mailbox <pslordagnew@cabinetoffice.gov.uk>; NR @cabinetoffice.gov.uk>; Raine, Dr June <June.Raine@mhra.gov.uk>; NR @cabinetoffice.gov.uk>; NR @cabinetoffice.gov.uk>
Subject: Re: ACTIONS FROM 1530 CALL WITH SIR JAMES DYSON

I do not often correct actions - but in this case I'm afraid this is too important, and many many people are working very hard to try to get this right. the actions as stated below are not right. Some of the important differences are ;

- while we may be able to design, manufacture and test product in parallel (i have asked the teams to try and do so) , even if todays prototype passed all tests, Sir James himself noted he would be able to manufacture for delivery in 4 weeks - not immediately. I am not clear that any final product for medical use such as this will be able to be certified until the final, completed manufacturing line (rather than the building) has been certified.

- the components need to be available in the UK for the reasons I outlined - there are likely be conflicts with other designs, and we need to ensure we can put limited components into the designs which offer the fastest overall delivery of ventilators to save lives. in parallel we need to deconflict the components as fast as possible in order to take out the bottlenecks

- as it turns out - after significant preparation by the team, no prototype was available from dyson this evening. the timelines will slip accordingly.

we will work to unblock whatever is felt by any of the prototypes to accelerate the registration, testing, auditing, and licencing activities, in order to ensure we can deliver the most ventilators as fast as possible. That is clearly the objective. I'd be grateful if Gareth could outline what we have learned in this regard as soon as possible - resources must not be a constraint.

jam

On Wed, 25 Mar 2020 at 18:44, PS Michael Gove Mailbox <psmichaelgove@cabinetoffice.gov.uk> wrote:

> All,
>
> Please find a readout of the key points from the call:
>
> - CDL said his understanding was that SJD had developed a model, and wanted to push ahead. He said the UKG was supportive of this. Others needed to make clear what obstacles remain, so that they can be removed as quickly as possible.
> - SJD said that Dyson were ready to go ahead, pull in components and make them as needed. Be in a position to to start delivering in 3 weeks, to deliver in the fourth week from now. His understanding they've met all the standards - if not, let's do that.

- 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
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E: psmichaelgove@cabinetoffice.gov.uk

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

Private Office: The Rt Hon Michael Gove MP, Chancellor of the Duchy of Lancaster and Minister for Cabinet Office
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