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**Subject:** RE: Vaccines Budget measures

NR

You asked for a para for CX.

- You asked for further advice on UK mRNA vaccine capacity.
- The UK does not currently have capacity for population scale manufacture of mRNA vaccine substance, and does not manufacture any of the most advanced mRNA vaccines.
- We have smaller scale capacity for clinical trial scale manufacture e.g. at the Vaccines Future Manufacturing Hub at Imperial College London, which is making Imperial's saRNA (self-amplifying RNA) vaccine for clinical trials. The Centre for Process Innovation (based in the North East, part of UKRI's High Value Manufacturing Catapult) also has a small scale mRNA manufacturing capability which can support clinical trials (this is where we recommend supporting the R&D collaboration with CureVac to create an mRNA 'library' of rapid response Covid variant vaccines).
- **In 2017, HMG invested in a new facility, the Vaccines Manufacturing Innovation Centre**, based in Harwell, Oxfordshire. VMIC's original remit was to:
    - support the development and scale up of novel vaccine manufacturing technologies, including mRNA and viral vector technologies being used by Imperial and Oxford.
    - provide a centre of excellence in Vaccine Manufacturing & Skills development to support growth of the vaccines manufacturing industry in the UK.
    - provide an emergency response as part of the UK's epidemic preparedness. This emergency response capability was designed to provide a response for a small percentage of the population, estimated at I&S within 3 months, rather than a population scale response for a large epidemic.
- In April last year we reviewed with BEIS how this facility could be expanded and accelerated to deliver earlier, in order to deliver a population level response to the current crisis, and you agreed to fund an at-risk expansion and acceleration of the facility, bringing forward delivery from mid-2022 to this year, and enabling the facility to be capable of delivering a population scale manufacturing response I&S within a 6 month period. VMIC has the capability to manufacture any vaccine type, and capacity to manage the manufacture of two different vaccine types concurrently. It also has significant fill finish capacity which is one of the major global bottlenecks for vaccines manufacturing.

- We have pushed the VTF to accelerate VMIC further – but they have told us this is the quickest they can deliver the facility. Delivery has also slipped from mid-2021 to the end of this

year, meaning we will not be able to use it to deliver a response in this phase of this pandemic, although we will be able to use it from the start of next year if ongoing population-level vaccination is necessary. It will however have a long life span and will be a critical piece of vaccine sovereign capability and HMG will have step-in rights for vaccine manufacture during epidemics.

- **The other main short-to-medium term UK capacity for mRNA vaccines manufacturing will be the Cell and Gene Therapy Catapult** (C&GTC is an independent centre of excellence supported by BEIS's ALB, UKRI) site in **Braintree,** Essex. This is not currently operational: it is a former veterinary vaccines site which is in the process of being converted to human vaccines. The CST approved BEIS entering into a 5 year grant agreement with CGTC to create this short-to-medium facility to increase the UK's manufacturing options and the attractiveness of the UK's offer to vaccine developers during the pandemic period. As part of the agreement with CGTC, BEIS can direct CGTC to manufacture a Covid vaccine. The CGTC have an aspiration to establish another Vaccine Manufacturing Innovation Centre in the long term.
- BEIS estimate the Braintree facility will come on-line at the earliest in September 2021 with potentially full operating capability by December 2021 (approx. I&S doses per month). It can only produce one vaccine type at a time although it can also be flexed to produce antibodies (although not in parallel with vaccines and at up to I&S I&S We expect Braintree to be used initially to manufacture I&S that we have recently signed an agreement on.
- As a condition of funding Braintree, the CST asked BEIS to set out a vaccines and antibodies manufacturing strategy for the long term. BEIS did produce an (unpublished) strategy, which we did not however find compelling. We think there are a number of issues for mRNA manufacturing in particular which an independent review could helpfully address:
    - Forward-looking evaluation of overall UK vaccines manufacturing resilience, including whether it is resilient to responding to viral variants during an epidemic.
    - Although we have VMIC, we think that for resilience we will need to ensure that more than one mRNA facility is available to HMG at all times. Braintree is a 5-year arrangement (although C&GTC don't have a clear exit plan from the site) and we need to think now about what the successor to Braintree should be and how to set that up. We also think that for long-term preparedness sustainability, we need to look at ensuring that both VMIC and Braintree/successor remain commercially viable in non-pandemic periods. Given that the 'mission' and scale of VMIC has changed significantly in the last 12 months, we think their commercial model probably needs reviewing.
    - Examination of whether govt needs to incentivise end-to-end mRNA vaccine industrial supply chains in the UK. Although we do have suppliers of some key components of mRNA vaccines in the UK (such as Croda, who make the lipids for the Pfizer/BioNTech vaccine), we don't have anybody making final product at scale. We have seen over the last year, that even where we have pro-actively created temporary manufacturing capacity, non-UK firms have generally preferred to supply us from their non-UK sites, and the VTF's short-term risk mitigation strategy has shifted to managing the commercial supply relationships rather than onshoring capacity. To ensure sovereign capability, we think we may need to look at developing a permanent mRNA industrial ecosystem. A review could look at what the right organisation and coordination of public and industrial assets and investment for this is.
    - Finally we think we need to look at skills. The VTF has made some skills investments but we think that we would need to look at this again if we needed a larger scale advanced manufacturing workforce to support a much larger domestic industry.