From: Alexander Bourne <[redacted]>
Date: 6 September 2020 at 23:10:59 BST
To: "[redacted]" <[redacted]>
Subject: Industry Round Table Problems/Solutions

Dear Matt,

Further to the industry round table groups I thought I would let you know of two specific problems:

1. Working capital- if the scale up is to be achieved most manufacturers are being asked to scale up their production by up to 10 x. Upfront part payments against POs must be offered/applied retrospectively in order to allow purchase of capital items. Currently, prepayment is only offered if discussed in proposal phase which is now 5 weeks ago, since then supply chain has requested significant ramp up of production without providing orders. As an example, supply chain have asked us to increase capacity to 5million tubes per week by December. We currently produce 650k. To do this we will need c.£1.2million in order to fund capital items and cashflow as our credit limits are being stretched given the existing ramp up to 3million agreed. Pre-payment was denied on procedural grounds when raised with supply chain by our distributors.

   Solution: Pre payment against order of up to 50% as standard can be authorised by lowest level of governance. Don't allow loans to become the sollution as they will take too much time to work through. We literally have a 7 day window on this.

2. Standardisation/validation - as I mentioned on the call with the PM there is a need to standardise. However, given where we are and the time constraints we face standardisation is not an option: tool making time which is approx. 3 months for a tube tool, market capacity of capital items which is running dry as other nations/private companies vie for kit and regulatory time (a swab takes a minimum of 3 months for clinical trials once manufacturing begins which, in itself takes approx. 6 months) all make this impossible. What we need to do is concentrate on validation, both operational and clinical. Currently it takes up to 8 weeks to get an item i.e: a tube or swab or a combination i.e: a tube, VTM and swab kit, validated. This is largely a laboratory issue as they are responsible for confirming whether the items/combis will work with their assays/equipment. There is a lot of kit that can't be used because it simply hasn't been validated and validation is not seen as a priority in labs as it does not affect their immediate problem of processing existing samples. Suppliers will not hold on to capacity in the hope that HMG will order one day: it will simply get sold to the next person who asks for it.

   Solution: Labs and those involved in validation of consumable items/assays/diagnostic equipment to be obliged to validate as soon as reasonably possible and an emphasis on speed.

I have included the bullet points from the minutes of the three industry groups being run by the round table below. However, the above two points will solve 95% of the problem as most of the below is either repetition, a consequence of not doing the above or simply noise.

All the best

AB

Consumables

- Product Volume - Clarity required on estimates of product volume by technology type by Q for 12 months with commitment to purchase inventory in advance.
- Use Cases - Clear use cases needed for testing systems at lighthouse-scale; stadium scale; office-scale and home-scale which will lead to discreet workflows & Bills of Materials against which industry can map their products and services.
- HMRC Business Case - Confirm whether every business case will have to go through the treasury for sign off – is there a process to action these quickly?
- Working Capital - £25M working capital (loan) fund for SMEs to enable immediate investment in capital equipment and thereby secure the national supply chain.
- Timescales - Building facilities, populating them, securing tooling needs to be in the coming days, not weeks. It is a competitive international supply chain and unlikely to be available if we don't act now.
- Resourcing - Resources need to be available for 'reference' technology validation beyond PHE.
- Foreign Competition – Supply chain is already being courted by foreign governments for their products & services, some offering a 12-month contract for supply.

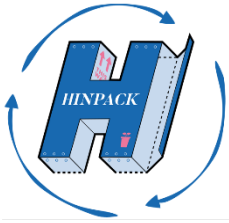
Reagent Manufacture Group

- Product Volume – Clarity required on estimates of product volume by technology type by Q for 12 months with commitment to purchase inventory in advance.
- Location of Manufacturing – Confirmation asked whether manufacture/scale can be in other parts of Europe if not able to do it in the UK
- Use Cases - Clear use cases needed for testing systems at lighthouse-scale; stadium scale; office-scale and home-scale which will lead to discreet workflows & Bills of Materials against which industry can map their products and services.
- HMRC Business Case - Confirm whether every business case will have to go through the treasury for sign off – is there a process to action these quickly?
- Regulatory Approval – Clarity on what is an acceptable level of validation.
- Working Capital - £25M working capital (loan) fund for SMEs to enable immediate investment in capital equipment and thereby secure the national supply chain.
- Technologies - Commitment to smaller range of technologies which can be validated and progressed.

Self Administered Testing Group

- Product Volume - 'No regret' commitment to volumes for a minimum of Oct-Feb and back that with POs (also publish target 6-month volumes post Feb 2021)
- Use Cases – Publish use cases (Target Product Profiles) for the testing settings
- Validation Process – Communicate the streamlined validation process.
- Working Capital – Provide Access to circa £20M working capital in the next 2 weeks to enable investment in tooling and manufacturing facilities.
- Timescales - Consortium to work on combining their offerings to enable maximum throughput by October.
- Manufacturing Capacity - Consortium to consider sharing manufacturing capacities

- Foreign Competition – Other countries are requesting supply, but currently being holding out for commitment for UK, although can't continue to hold product



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