Lockington, Elliott (SPAC/PSPC)

From: McCloskey, Shane <shane.mccloskey@tc.gc.ca>
Sent March 25, 2020 4:19 PM
To: Gordon2, Travis (HC/SC); Chan, Marco (IC)
Cc: Caira, Celine (IC); Murdock, Kelly (SPAC/PSPC)
Subject: RE: Questions: SAP, oxylator, sanitizer

Sorry... this was a bit more complicated than I thought. Looks like Transport has a bit of work to do on easing up some restrictions.

Shane

Hand sanitizers typically contain ethanol (although many different formulations exist). Ethanol above 24% content is regulated as dangerous goods and most hand sanitizers would have at least that amount.

That said, hand sanitizer is recognized as a low risk product and can be transported under a "limited quantity exemption" if transported in small containers (1L-5L depending on their flammability). This exemption provides relief from the requirements of the TDGR as long as ail conditions of the exemption are met. For example, the box containing small bottles of sanitizer cannot weigh more than 30kg and the box must be marked with the limited quantity mark. This exemption applies to road, rail or vessels on a domestic voyage. Other requirements such as shipping documents, safety marks (apart from the limited quantity mark), container testing or certification, training, and reporting are not required.

For air transport, hand sanitizer can also be transported under a limited quantity exemption. However, the requirements under this exemption are much more restrictive. For example, the quantity limits per receptacle are often smaller, there are quantity limits per package, containers must meet testing requirements and training is required.

From: Gordon2, Travis (HC/SC) [mailto:travis.gordon2@canada.ca]
Sent: Wednesday, March 25, 2020 10:11 AM
To: Chan, Marco (IC) <marco.chan@canada.ca>
Cc: Caira, Celine (IC) <celine.caira@canada.ca>; Murdock, Kelly (SPAC/PSPC) <kelly.murdock@canada.ca>; McCloskey, Shane <shane.mccloskey@tc.gc.ca>
Subject: RE: Questions: SAP, oxylator, sanitizer

*Shane — see highlighted text for questions related to transport

Hi Marco,

SAP is not the appropriate route. If they had a practitioner requisition Cepheid's test then it's possible we could get some here, but it is only practitioners in Canada that can make SAP applications. And it seems like they are working on a diagnostic, which is a medical device. However, the MD-SAP program is largely the very same.

If they want to do a clinical trial, I copy some info below. A CT is likely more appropriate for this case and would still allow them to establish a base and enroll patients. I expect our officials would move very quickly. I can also ask officials

to reach out to Cepheid. Easiest is for them to submit a high-level proposal to the med devices email below, copy me, and I'll flag for officials. Though they're likely follow up ASAP anyway.

Details:

For clinical trial sponsors

Companies and researchers with drugs, medical devices, or natural health products that may be effective in treating or diagnosing COVID-19 are encouraged to contact us to facilitate clinical trials.

Clinical trials are studies to find out whether a drug or medical device is safe and effective for people. We can authorize a clinical trial quickly in urgent situations.

Please contact us at:

- trials using pharmaceutical drugs: OCT BEC Enquiries Enquetes@hc-sc.gc.ca
- trials using biologies or radiopharmaceuticals: hc.bgtd.ora.sc@canada.ca
- trials using natural health products: NHPD-CTA.DEC-DPSN@canada.ca
- investigational testing of medical devices: hc.meddevices-instrumentsmed.sc@canada.ca

On oxylators, I'm not familiar. If P/Ts want us to procure it, we will do so. But have not seen orders come through from P/Ts for these. Interesting idea, though based on my quick google search it looks like it's essentially a combo between a bag-valve mask and a portable ventilator. Not sure it is a priority item at this time. It looks like it is primarily used for emergency, short-term use.

On sanitizers,

1) I don't think we've specified a size for procurement. Kelly may have context. But the bulk I've seen are 500-550mL.
2) Yes, sanitizer still requires product approval. But it should be very fast if they follow WHO/FDA guidance. We are also working on guidance for those who want to re-too, highlighting the process and timelines. It's typically about a 24 hr turnaround for licenses, assuming that can meet sanitation and GMP requirements (pretty familiar for food businesses). Our department has also facilitated dialogue between the sanitizer industry and distillers to share expertise. We expect we'll have specific publicly-available guidance available this week.
3) Transport of Dangerous Goods — not sure if sanitizers are covered. Certainly on a regular bottle there are not really strong WHMIS requirements. Adding Shane from Transport who may be able to advise as TC handles the *Transportation of Dangerous Goods Regulations.*

Cheers,
TG

From: Chan, Marco (IC) <marco.chan@canada.ca>
Sent: 2020-03-24 11:09 **PM**
To: Gordon2, Travis (HC/SC) <travis.gordon2@canada.ca>
Cc: Caira, Celine (IC) <ceiine.caira@canada.ca>; Murdock, Kelly (SPAC/PSPC) <kelly.murdock@canada.ca>
Subject: Questions: SAP, oxylator, sanitizer

Hi Travis,

Trying to batch questions so I'm not hitting you up all day long. Happy to jump on the phone briefly if it's easier to talk live.

Firstly, a connection to **Cepheid** (Sunnyvale, CA) is **eager to get a trial going in Canada for COVID test** at point of care (see attached). They want to trial and then manufacture in Canada in case the US imposes export restrictions. **They say there's a need to undergo SAP approval for speed — is this desirable for us or feasible?** They got US FDA Emergency Use Authorization. We should manage expectations.

Secondly, are we **considering the use of "oxylators"?** It was described to me as a significantly simplified ventilator, raised to us by the Director or Cardiology at St. Michael's Hospital in Toronto. Apparently the inventor and producer is Canadian but let the product license lapse (long story), though it continues to be made in Canada and sold abroad. Again, want to set expectations about whether this is a priority item, whether to guide them toward approval,

Lastly, several **sanitizer questions:** (we are overwhelmed with sanitizer offers)

- Do we have **guidance on the container material and size** for hand sanitizer, for our procurement?
- **A sanitizer made per WHO formulation would still need a product approval, correct?**
- Does the Transportation of Dangerous Goods Regulations dictate what kind of containers the sanitizer can be moved in, if you know?

My intent is that we all get smart on some questions, we can share the burden of questions/work— y'all have enough going on at Health!

All the best,
Marco

Marco Chan

Policy Advisor
Office of the Minister of Innovation, Science and Industry
marco.chan@canada.ca / Tel: 819-744-0194 / TTY: 1-866-694-8389