Update from BRDD on COVID-19 on April 7, 2020 – Sowmya Viswanathan notes
Attendees – BRDD, OPIC, CBE, CERB; CARS Biosimilars Canada, CANM, CBF, NMA, CTSG

- Canada has 1/3rd of patients of COVID-19 cases in patients over 60 – highest proportion of hospitalizations – 2/3 and ICU admissions – 60% is over age of 60.
- All Health Canada employees are working from home but set to meet our performance targets – shifting our resources to meet performance targets – more our resources as needed. Focusing quite a bit on COVID-19 essential services – prioritizing those – SAP is also a priority for all indications as well as COVID19 – core review work is considered essential – perform those duties from home
- Impact on submission reviews – have cancelled some onsite evaluations but using other methods. Idea is to not have a negative impact on review – look to receive more information from sponsors to more paper-based review – shouldn't impact how review is conducted or timelines
- Pre-submission is by teleconference now. Some staff have been asked to focus on COVID19 duties. Some policy work has been put on hold – shift staff to focus on COVID19 responses
- If staff is impacted by illness – service standards could suffer – that could have an impact on our service standards – will have a prioritized way to address highest priority first.
- Overview of work that was done – COVID-19 – as of April 6 – 37 special assess requests – test kits, medical devices – over 200 applications for in vitro testing devices – they have authorized 10 applications for test kits and 16 that are other devices
- Drugs – 10 clinical trials – most on small molecules – all of them are listed on the website – and kept up to date – website
- Number of web postings – health products industry – resources, guidance and Q&As.
- Other measures – interim orders – March 18 – expedited review of medical devices – all authorized by interim order – quick tool we can use – put parameters around device and make product available
- March 25 – have an emergency response act B c-13 – equip Health Canada with more information on risks and benefits – use tools such as conditional approvals
- Also allows for amendments to Patent Act – to respond to PH emergency – until Sept 30
- International front – several interactions with FDA, EMA and other regulators – have attended 3 international meetings with this group – vaccines, treatments (non-vaccines), and 3rd took place today on how to leverage real world evidence
- Other international interactions – in clusters, in Australia/Canada/Singapore/Swizterland consortium – exchanged information on regulator activities
- Participating in WHO in research and development footprint –on vaccines – virtual calls with them

Drug Shortages side Regulatory Operations and Enforcement Branch – Drug Shortage Units

- Supply chain issues – pivoting to be more pro-active – reached out to take a more pro-active approach – potential supply issues. Increased demand as result of increased patients being treated – inhalants – increased demand in hospital settings – whether companies can access additional supplies.
- Communication strategy with health care professionals – advocating conservation measures
- Potential shortages in sedatives and muscle relaxants and pain relievers – for patients using ventilators – working with Canadian Society of Hospital Pharmacists and Canadian Care Society and industry – looking to increase availability of supplies in Canada.
- New legislative amendment – new interim order – allow for expedited importation/sales for products that are not authorized in Canada but meet other GMP requirements – sets up notification process.
- Working with all parts of govt. Certain companies are placing restrictions on export – another layer to supply disruptions. Working with Global Affairs Canada to mitigate those conditions and expedite release of supply materials.

Round Table Updates

Biosimilars Canada – Jody Cox

- With international work, we are doing a lot of international work in international biosimilar association – very active in terms of monitoring what's happening in different countries around the world – delays in supply chains and working closely as an organization –
- working with WHO and other agencies as well.
- There have been a lot of good statements coming – G20 statements from Canada. Joint statement of WCO and WTO to allow for free flow of medical supplies – all positive, but need more concrete action.
- Have an opportunity to seeing what has happened in the European context – to avoid some of the problems. Particularly around border closures – they have implemented green lanes (less transportation disruptions).
- Essential worker designation – very pleased to see acknowledgement of pharmaceutical supply chain. To have that available and to keep things moving forward. Transportation is going to continue to be a major issue – ocean freight – seeing things slow down. Twice as long to get here from Europe. Reduction in air freight – has been a struggle to get adequate air freight but cost is becoming more prohibitive – seeing 1500% increase in cost/kg - very difficult for regulated industry to absorb. I
- n terms of PSP suppliers, looking at minimizing disruptions in terms of delivery to patients.
- Watching the federal courts as well. Need for subsequent entry products and the value they bring will be more essential.
- How can we help BRDD to ensure that review targets are met? We have put out a few statements around supply chain and challenges.

CANM – Daniel Levin - Radiopharmaceutical manufacturing –

- Community in Canada hasn't seen too many supply problems –

- more delays in shipment.
- Radiochemicals (increase in duration of shipment affects radiochemicals) – have a limited shelf life.
- If changing the starting material for radiochemical manufacturing, are we talking about the same submission timelines or can they be faster?
- Response from BRDD - For clinical trials, being affected for oncology during this –amendments might be needed. Those are the issues and fears from the community. Posted some guidance on clinical trials – some alternative remote approaches that can be used for patient monitoring. On submissions being expedited, are focusing on COVID-19 are being expedited, but continuing to meet performance standards in other areas.
- Following Society of Nuclear Medicine in US and European Association of Nuclear Medicine– we could forward issues they are raising – signal us of shortages.

CBF – all 4 biomanufacturers are involved in biosimilars and other 2 are innolved with Innovations Medicine Canada – expanding access – a lot of work is happening on the margins and is on the back burner – much of the work is now focued on public health issues rather than biosimilars per say- No comment

NMA – No update at this time Hassan – no comments at this time

CTSG –

- A lot of movement on cell therapy trials focusing on MSCS around the world. There is also interest in immunotherapy approaches globally. Provided an update on how we don't have Canadian stock pile and a bit concerned about importing cells from Europe for some trials that are looking to be initiated in Ottawa and Toronto. Will be seeing some submissions from various groups but also looking at potentially consolidating a pan-Canadian approach.
- Asked about update on CTO guidance for raw material and ancillary agent screening. Liz Anne said that CTO guidelines had been updated and sent directly to source establishments that deal with minimally manipulated autologous cells, tissues organs for homologous use, but acknowledged that this should be sent to others who will use it for allogenic purposes. Liz Anne to send to Sowmya to distribute (not received yet).
- Also provided an update on COVID-19 session at ISCT in May from cell and gene therapy perspectives – important science and discussion and latest abstracts

Next Steps – Follow up call in one month's time to assess impacts on our organization.