

Belliveau, Sébastien

From: MacKnight, Aisling (HC/SC) <aisling.macknight@canada.ca>
Sent: May 12, 2020 9:14 AM
To: Belliveau, Sébastien; Khalil, Samantha
Cc: Gordon2, Travis (HC/SC)
Subject: RE: HC Approval stats - May 11
Attachments: MDEL numbers May 11.docx

Updated version attached – new numbers came in this morning

Aisling MacKnight
(613) 327-2803

From: MacKnight, Aisling (HC/SC)
Sent: 2020-05-12 6:52 AM
To: sebastien.belliveau (sebastien.belliveau@pmo-cpm.gc.ca) <sebastien.belliveau@pmo-cpm.gc.ca>; 'Khalil, Samantha' <Samantha.Khalil@pmo-cpm.gc.ca>
Cc: Travis Gordon2 (HC/SC) (travis.gordon2@canada.ca) <travis.gordon2@canada.ca>
Subject: HC Approval stats - May 11

Morning both,

Sharing our latest figures on HC approvals under the interim order. Let us know if you have any questions.

Thanks,
Ash

Aisling MacKnight
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HC APPROVALS: May 11

MEDICAL DEVICES

As of **May 11**, Health Canada has authorized a **total of 152** medical devices under the *Interim order*.

- **17** test kits
- **134** non-diagnostic devices (non-IVDD devices):
 - **8** N95 masks
 - **39** surgical masks
 - **38** face shields
 - **4** ventilators
 - **9** gloves
 - **4** sterilizers
 - **32** Others (thermometers, airway management, beds, swabs, isolation kits, ventilator accessories, AI for diagnosis, test reagents, monitors, software, sterilizer solution, glucose monitoring, Spirometer, Bipap, CPAP helmets, infusion pumps and a thermal camera).
- Health Canada is **currently reviewing**:
 - **37** applications for **test kits**
 - **585** applications for **non-diagnostic devices**

HAND SANITIZERS & DISINFECTANTS

As of **May 11**, Health Canada has authorized:

- **70** disinfectants
- **1,993** new hand sanitizer products
- **1,436** new site licences for over-the-counter drugs and natural health products.

INTERIM ORDER ON DRUG AND MEDICAL DEVICE SHORTAGES (imports):

- As of **May 11**, Health Canada has added **51 total medical devices** to the *List of Medical Devices for Exceptional Import and Sale* under the Interim Order.¹
 - Ventilator: 1
 - Masks: 34
 - N95 respirator: 2
 - Gowns (including apron, sleeve): 8
 - Protective suit/coverall: 2
 - Face shield: 1
 - Gloves: 3
- As of **May 11**, Health Canada has added a **total of 33 drugs** to the *List of Drugs for Exceptional Import and Sale* under the Interim Order.²

MEDICAL DEVICE ESTABLISHMENT LICENCES (MDELs)

- As of **May 11**, total MDELs issued under the interim order: **973**
- Total MDEL applications remaining in the queue: **50**

¹ Once added to the list, importers with medical device establishment licenses are permitted to import the products after notifying Health Canada 5 days in advance.

² Companies with a drug establishment license may import drugs on the *List of Drugs for Exceptional Import and Sale* after notifying Health Canada 5 days in advance of importation.