Baker McKenzie.

The Health Pod

Health Canada and FDA's response to COVID-19 Episode Guide

- Health Canada's response
- FDA's response

Health Canada's response

Health Canada's response to the crisis was swift and responsive and involved three planks:

1. Drug products approved in Canada but are in short supply - any product in shortage that would have significant impact on public health if not addressed, even if not directly related to treatment, prevention or mitigation of COVID-19
   - Allows the expedited importation and distribution of foreign approved drug products to mitigate the shortage of the Canadian approved counterparts
   - Because these products have differences between the Canadian and foreign labels (for example: different indications, dosing regiments, preparation and administration instructions), sponsors have to submit a risk communication plan to support the safe use of the drug
   - Health Canada expects that products will be sourced from foreign buildings already listed on the Canadian sponsor's establishment license
   - Health Canada has approved approx. 25 products through this from US, Germany, Sweden, Switzerland, Latvia, Malta, Turkey and the Philippines among others
2. New drug products not currently approved in Canada but are relevant to the treatment, prevention or mitigation of COVID-19 - products not yet subjected to Health Canada regulatory review
   - The expedited approval of drug products needed in an emergency basis through an extraordinary new use pathway has already been in place for quite some time
   - The review and approval of these products is based on a slimmer clinical data package so patients may have early access to promising new therapies and vaccines while the products remain subject to further efficacy and confirmatory trials
   - New product must possess an acceptable safety profile
3. New medical devices for use in relation to COVID-19 or the addition of a COVID-19 related use to an existing licensed device
   - Canada implemented the expedited importation and importation of medical devices for use in relation to COVID-19 - new previously unlicensed devices and those approved by a trusted foreign regulatory authority
   - Also extended to COVID-19 related use of an existing device already licensed in the country
   - Shortage of ventilators, PPE and disinfectant was experienced when the crisis first hit and an expedited authorization mechanism was established so importation and distribution can occur even when the products do not fully comply with all regulatory requirements

FDA's response

- Emergency Use Authorization (EUA)
  - Allows the use of an approved medical product or the unapproved use of an approved medical product to address COVID-19, such as ventilators and PPE among others
  - To date, the FDA has approved 204 tests under the EUA process, including 167 molecular tests, 35 antibody tests and 2 antigen tests

FDA's response (continued)

- Guidance documents
  - Similar to other countries, clinical trials in general have been impacted as a result of the pandemic
  - FDA issued a guidance where clinical trial sponsors can reach to the regulatory body to discuss what to do to ensure these clinical trials can still be undertaken
- Coronavirus Treatment Acceleration Program (CTAP)
  - Goal to expedite the development of potentially safe and effective life-saving treatments
  - FDA confirms that the COVID-19 vaccine will not be approved too quickly and would need to go through the same rigorous testing as every other vaccine on the market
- Monitoring shortages of drug products and medical devices
  - FDA is working with drug product manufacturers and medical device manufacturers to be aware of any potential shortages ahead of time to decrease the impact of this
- Enforcement activities for products claiming treatment of COVID-19
  - FDA is using their enforcement arm to stop companies making fraudulent claims about products, vaccines or treatments for COVID-19

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