Roles and Rules of Some Regulatory Agencies around the World during COVID-19 Pandemic

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Authors’ contributions

This work was carried out in collaboration between both authors. Author ABS managed the literature searches, synthesized the results, and wrote many sections of the manuscript. Author FT designed the study, wrote the protocol, participated in literature searches, and wrote many sections of the manuscript. All authors read and approved the final manuscript.

ABSTRACT

Objective: Collecting and synthesizing relevant data on COVID-19 from official sources of some different regulatory agencies around the world.

Methods: The information and actions related to responding to the COVID-19 situation were collected from the websites of some regulatory agencies, including the US Food and Drug Administration (FDA), the European Medicines Agency (EMA), Health Canada (HC), Swiss Agency for Therapeutic Products (Swissmedic), and the Australian Therapeutic Goods Administration (TGA).

Results: All the regulatory agencies help in expediting the development of COVID-19 treatments and medical devices. These agencies also developed an international regulatory collaboration to develop cure models for the pandemic. While some of the agencies conduct the COVID-19 testing,
like the US FDA, the others do not. The agencies also differ in their approaches towards resolving the pandemic. FDA and EMA are more aggressive in a way that they prioritize more testing and hospitalization coverage. However, as of the 22nd of June 2021, the FDA authorized the highest number (388) of diagnostic COVID-19 test kits followed by TGA (128), and EMA (88).

Conclusions: Although the regulatory agencies differ in their approaches towards resolving pandemic COVID-19, all regulatory agencies help in expediting the development of COVID-19 treatments and medical devices.

Keywords: FDA; EMA; Health Canada; swissmedic; therapeutic goods Administration; COVID.

1. INTRODUCTION

According to the World Health Organization (WHO) [1], COVID-19 is a brand-new strand of coronavirus that was discovered when an outbreak started in Wuhan, China in December 2019. During the earlier months of 2020, the virus became a global pandemic. As per WHO’s June 22nd situation report [2], the number of weekly infected individuals has globally reached more than 2.5 million while the death toll is more than 64,000 deaths. While not generally considered fatal, the disease may be more dangerous to a certain class including senior citizens and those with underlying conditions like high blood pressure and diabetes [3]. Because COVID-19 is highly communicable, several countries have issued lockdown orders to keep citizens safe and prevent the further spread of the virus.

In some territories, the lockdown orders have been effective for months already. Because of the threat of being infected and strict stay-at-home regulations, the masses started to feel peritraumatic psychological distress of varying degrees [4]. At some point, some are experiencing heightened symptoms of anxiety and depression. To appease the mental and psychological chaos, people's morale should be boosted. A study [5] suggests that since mobile technology is easily accessible for many, individuals should take advantage of online psychoeducation and intervention that typically promotes cognitive behavior therapy (CBT) and mindfulness-based therapy (MBT).

The pandemic is a confusing time for many. As different things happen at once, many individuals and institutions are simultaneously releasing information but not all are science-backed and reliable. A group of researchers [6] urge governments and their instrumentalities to be the official source to raise awareness and eventually clear out all misconceptions. The psychological impact of uncertainty and fear can damage the public. Holding unto that sentiment, the authors of this paper collects and synthesizes relevant data on COVID-19 from official sources of different territories. To be specific, this paper summarizes the roles of some regulatory agencies around the world dealing with COVID-10 outbreaks. These regulatory agencies include the United States Food and Drug Administration (FDA), the European Union’s European Medicines Agency (EMA), Canada’s Health Canada (HC), Switzerland’s Swiss Agency for Therapeutic Products (Swissmedic), and Australia’s Therapeutic Goods Administration (TGA).

2. METHODS

The information, actions, number of diagnostic tests related to responding to the COVID-19 situation were collected from the websites of some regulatory agencies, including the US FDA, EMA, HC, Swiss Swissmedic, and TGA. Similarities and differences were identified and discussed.

3. RESULTS

3.1 Agency’s Roles

3.1.1 Food and drug administration (FDA)

During the COVID-19 pandemic, the US FDA regulates medical products that aid the federal government's response, increases the stock of testing kits, therapeutics, and personal protective equipment, monitors the food supply for both humans and animals, and confiscates fake products [7]. The FDA continues ensuring timely availability of COVID-19 diagnostic tests. In addition, the FDA provides continuous updates related to tests that should be used or not used under the Emergency Use Authorizations (EUAs) [7]. The agency also provides technical support to accelerate response efforts [8].
3.1.2 European medicines agency (EMA)

EMA's role during COVID-19 pandemic is to “expedite the development of effective medicines and vaccines to fight and prevent the spread of COVID-19" [9,10]. In the European Union, EMA created a COVID-19 pandemic task force that reviews potential COVID-19 medicines, supports clinical trials, provides scientific advice for the Scientific Advice Working Party, and ensures the cooperation of stakeholders within the European Union and other international participants [9,10].

3.1.3 Health Canada (HC)

HC ensures Canadians’ public health and safety by coordinating with federal, provincial, and international institutions to improve testing rates and periods, providing reliable information as soon as possible, evaluating the workplace areas, and issuing occupational health advice for public service employees [11-14].

3.1.4 Swiss agency for therapeutic products (swissmedic)

Switzerland’s Swissmedic holds the national authority to approve and supervise medicines and other therapeutic products, confirm research progress on COVID-19, confiscate illegal medicinal products, settle claims over therapeutic properties, procure medical devices for supplies in healthcare institutions, and examine complaints on non-conforming medical devices [15-17].

3.1.5 Therapeutic goods administration (TGA)

TGA's role in handling the COVID-19 pandemic includes publishing the latest information on COVID-19, conducting, and regulating clinical trials, maintaining records of COVID-19 test results, and managing COVID-19 point-of-care test activities [18,19]. As of March 2021, there were 36 COVID-19 tests under review by the TGA [18]. For those that turn positive for COVID-19, the TGA guides such patients on what to do [20].

3.2 Agency’s Rules

3.2.1 Food and drug administration (FDA)

To speed up pharmaceutical and medical device innovation, FDA created the special emergency program Coronavirus Treatment Acceleration Program (CTAP) [21]. With CTAP, protocol reviews are to be finished within 24 hours of submission, and single-patient expanded access requests reviews in 3 hours [21]. As of the 14th of June 2021, over 100 ventilators and accessories are authorized by the FDA under EUAs [7].

The FDA continues working closely with regulatory agencies to hasten quality assessments for products and devices to treat COVID-19 patients [22]. In June 2021, a policy recommendation was released, by the FDA, to “address the vulnerabilities in US pharmaceutical supply chains” [7]. These recommendations have been accepted by the US President [7].

3.2.2 European medicines agency (EMA)

EMA released a guideline [23] to accelerate the development of support and evaluation processes to treat COVID-19 treatments by creating vaccines. Under this guideline, EMA will have a rapid formal review process that will include rapid scientific advice, rapid pediatric investigation plan and compliance check, rolling review, expedited marketing authorization, and the easier release of medicinal products that may only be available at the national level. As of June 2021, there are four COVID-19 vaccines under rolling review [24].

3.2.3 Health Canada (HC)

Canada's Minister of Health released the Interim Order Respecting the Importation and Sale of Medical Devices for Use about COVID-19 [25]. With this interim order, there will be a maximized and expedited production of COVID-19 medical devices and medicines. Also, through another protocol [26], HC has expedited the production and distribution of alcohol-based hand sanitizers.

3.2.4 Swiss agency for therapeutic products (swissmedic)

To deal with the COVID-19 outbreak, COVID-19 Ordinance 2 [27] was implemented. Under Articles 4m and 4n of this rule, Swissmedic is allowed to import non-authorized medicinal products for COVID-19 and place the same on the market temporarily, and, Swissmedic places COVID-19 medical devices on the market despite the lack of a conformity assessment procedure.

3.2.5 Therapeutic goods administration (TGA)

To encourage the production of medical devices concerning the treatment of COVID-19, the TGA
expedites the medical device application process [28]. Medical devices covered under this hastened registration process are test kits and other diagnostic test materials [29].

3.3 Similarities

All the featured agencies help in expediting the development of COVID-19 treatments and medical devices. All of which are also government instrumentalities with extended authorities to shorten and hasten their medicine or product development process to bring potential solutions to the market. Fig. 1 shows the total number of COVID-19 test kits approved by some regulatory agencies in 2020 and 2021 [31-35]. These and other agencies also developed an international regulatory collaboration [36] to develop cure models for the pandemic.

3.4 DIFFERENCES

While some of the agencies conduct the COVID-19 testing, like the US FDA, the others do not. The agencies also differ in their approaches towards resolving the pandemic. FDA and EMA are more aggressive in a way that they prioritize more testing and hospitalization coverage. This is likely because they have a higher number of casualties. The other agencies are more collaborative in the sense that they encourage private participation through less strict production standards and regulations. In addition, the featured agencies identify what testing kits are safe for public consumption. As of the 22nd of June 2021, the US FDA authorized the highest number (388) of diagnostic COVID-19 compared to other regulatory agencies like TGA (128 diagnostic tests), and EMA (88 diagnostic tests) (Table 1).

4. DISCUSSION

The agencies are acting according to the risks and assets of their countries. Table 3 shows the total number of COVID-19 cases, deaths, and recovered cases in different countries. In countries where the number of COVID-19 patients is high, the regulations are often more intensive but careful. Also, despite the difference in each country’s interests, it is obvious that everybody is united to resolve the existing global pandemic.

Table 1. COVID-19 Test Kits Approved for Public Consumption

<table>
<thead>
<tr>
<th>Agency (Country)</th>
<th>Number of Approved Kits (As of June 22, 2021)</th>
<th>Manufacturers</th>
<th>Date of Approval (Latest Releases)</th>
<th>Device Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA (US)</td>
<td>388a</td>
<td>Siemens Healthcare Diagnostics</td>
<td>June 17, 2021a</td>
<td>IgG, CLIA, Semi-quantitativea</td>
</tr>
<tr>
<td></td>
<td></td>
<td>BioFire Defense</td>
<td>June 17, 2021a</td>
<td>Moleculara</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Kaiser Permanente Mid-Atlantic States</td>
<td>June 17, 2021a</td>
<td>Moleculara</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WREN Laboratories</td>
<td>June 17, 2021a</td>
<td>Moleculara</td>
</tr>
<tr>
<td></td>
<td></td>
<td>MobileDetect Bio</td>
<td>June 17, 2021a</td>
<td>Moleculara</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Roche Molecular Systems</td>
<td>June 17, 2021a</td>
<td>Moleculara</td>
</tr>
<tr>
<td>EMA (European Union)</td>
<td>88b</td>
<td>AAZ-LMB</td>
<td>May 11, 2021b</td>
<td>Antigenb</td>
</tr>
<tr>
<td>HC (Canada)</td>
<td>75c</td>
<td>Sd Biosensor</td>
<td>June 21, 2021c</td>
<td>Antigenc</td>
</tr>
<tr>
<td>TGA (Australia)</td>
<td>128d</td>
<td>RapiGEN</td>
<td>May 12, 2021d</td>
<td>Antigend</td>
</tr>
</tbody>
</table>

a Data adapted from FDA [30, 31, 32]
b Data adapted from Health Security Committee, European Commission [33]
c Data adapted from HC [34]
d Data adapted from TGA [35]

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Fig. 1. Total Number of COVID-19 Test Kits Approved by Some Regulatory Agencies in 2020 and 2021

Table 2. Total Number of COVID-19 Cases, Deaths, and Recovered Cases in Different Countries (November 24, 2021) [37-41]

<table>
<thead>
<tr>
<th>Country</th>
<th>COVID-19 Cases</th>
<th>Deaths</th>
<th>Recovered Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>34,450,186</td>
<td>618,337</td>
<td>28,846,609</td>
</tr>
<tr>
<td>Canada</td>
<td>1,411,328</td>
<td>26,185</td>
<td>1,375,608</td>
</tr>
<tr>
<td>EU</td>
<td>180,574,546</td>
<td>3,911,357</td>
<td>165,263,088</td>
</tr>
<tr>
<td>Australia</td>
<td>30,404</td>
<td>910</td>
<td>29,307</td>
</tr>
<tr>
<td>Switzerland</td>
<td>702,398</td>
<td>10,878</td>
<td>679,259</td>
</tr>
</tbody>
</table>

Table 3. Total number of warning letters, reports, and abuse complaints issued by the FDA [7]

<table>
<thead>
<tr>
<th>Number of Warning Letters Sent to Sellers</th>
<th>Number of Reports Sent to Online Marketplaces</th>
<th>Number of Abuse Complaints Sent to Domain Registrars</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 231</td>
<td>&gt; 310</td>
<td>&gt; 299</td>
</tr>
</tbody>
</table>

COVID-19 was first discovered in China. China is the most severely affected country and a country where the control measures are relatively effective. As a representative country, the measures adopted by China’s regulatory agencies can have reference value. More importantly, China’s actions and rules may be much differentiated from those of the West. The contrast can be fairly strong. A previous study focused on the Chinese guidelines related to COVID-19 to provide critical references for other countries that fight COVID-19 pandemic [42]. This previous study identified a total of 100 Chinese guidelines that covers almost all aspect of COVID-19 [42]. Chinese organizations (e.g., China’s National Health Commission), physicians, and researchers continue to generate massive source of information (i.e., guidelines and scientific publications) focused on COVID-19. This information is evolving as the pandemic continues to unfold.

4.1 Information Dissemination

The featured agencies served as information hotspots for developments regarding COVID-19 [8, 9, 12, 16, 18]. Aside from producing high-quality and accurate content, their websites are constantly updated. To make sure that their information is verified, some of the websites even cross-refer to the WHO and the Centers for Disease Control and Prevention. The agencies understood that the release of prompt news will help people to act smarter.

4.2 Multi-level Approaches

The multi-tiered approach by the agencies [7, 11] keeps the efforts against COVID-19 grounded. With the cooperation of local and national governments, the flow of information, finances, and other resources will be quicker. In this
fashion, more people are working. Consequently, more goals are achieved within a shorter period.

4.3 Faster Manufacturing Approval

One key strategy among the mentioned agencies is the shortening of the manufacturing process by being less strict about approval [17, 22, 25, 26, 27-29]. In a way, each of the countries' governments is lightening the burden that inventors have when trying to put a product on the market. With higher demands for a cure and helpful medical devices, doing so is the best option.

4.4 Mass Importation

Importation is a common trend among the mentioned agencies [25, 27]. Kits, sanitizers, alcohol-based products, and medicines are being shipped from one country to another. Again, this signifies international cooperation. Countries are becoming open to local and international discoveries to hasten the formulation of COVID-19 medicines and the invention of more accurate test devices. Also, with importation, countries will be able to take advantage of other countries' technology and raw materials.

4.5 Benefits

The roles that the FDA, EMA, HC, Swissmedics, and the TGA play are beneficial to the people living in the countries where they operate. In general, these agencies ensure that the health and well-being of their people are secured and protected. This is especially true during an epidemic or pandemic, like the current COVID-19 situation.

4.5.1 FDA in the US

The FDA makes sure that human and veterinary drugs and medical products and devices are safe, effective, and secure by regulating their manufacturing, marketing, and distribution. Thousands of proactive websites and social media reviews lead to issuing many warning letters and reports [7]. Table 3 shows the number of warning letters, reports, and abuse complaints issued by the FDA as of June 14, 2021 [7].

As of June 2021, there are 388 authorized COVID-19 diagnostic tests and three authorized COVID-19 vaccines. In addition, there are over 620 drug development programs in the planning process [7, 21]. Besides this, the FDA also helps speed up innovations that will make medicines and other medical products not only more effective and safer but also more affordable [43]. Considering the current situation, effective but cheaper medicines and other medical products can help the people in the US.

4.5.2 EMA in the European Union

The EMA is an essential agency of the European Union. Same with the FDA, it is also responsible for maintaining the health of its people. More particularly, it assesses, supervises, and monitors medicines long before they are sold in pharmacies and hospitals. It also continues to assess, supervise, and monitor medicines even when they are already made available in the market by looking out for any unexpected side effects [44]. As of now, there are four authorized COVID-19 vaccines for use in the European Union [24].

4.5.3 HC in Canada

The HC does not only focus on ensuring that the medicines and medical products are safe and effective, but it also assesses, monitors, and ensures health in the environment and the workplace [45]. This is equally important in today's situation. Despite the pandemic, many people still need to go to work and buy food. The HC evaluates the workplace areas to contain the spread of the virus. As of June 2021, there are four COVID-19 vaccines authorized by HC [46].

4.5.4 Swissmedics in Switzerland

The COVID-19 pandemic is making people anxious. Unfortunately, many people are taking advantage of the current situation. Fake pharmaceuticals are being supplied, which is putting lives at risk [47]. Swissmedics is responsible for the authorization and supervision of therapeutic products. In line with its role, it confiscates illegal medicinal products [48]. As of June 2021, there are three COVID-19 vaccines approved by Swissmedic and one vaccine pending in the approval process [49].

4.5.5 TGA in Australia

The TGA keeps its people informed by publishing the latest information on COVID-19, including the records of the test results [50]. This reminds people not to be complacent. Aside from this, the TGA also relieves the worries of its people. It
ensures that those who tested positive for the virus will not be alone. As of the 8th of June 2021, TGA provided provisional registrations for two COVID-19 vaccines [51].

5. CONCLUSION

Although the regulatory agencies differ in their approaches towards resolving pandemic COVID-19, all regulatory agencies help in expediting the development of COVID-19 treatments and medical devices. As COVID-19 is an unprecedented situation and many changes occurred rapidly, follow-up research is needed to provide future updates.

DISCLAIMER

Authors have declared that no competing interests exist. The products used for this research are commonly and predominantly use products in our area of research and country. There is no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by the personal efforts of the authors.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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