



## Committee: Drug control

### Topic 2: Easing testing restrictions for vaccines during a crisis

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#### I. Background Information

In December 2019, the first case of coronavirus occurred in Wuhan China, which was the beginning of an unprecedented situation regarding health care, education, tourism, art, business, and law. Governments all around the world battled with the question of how to approach the emerging situation. After months of regional and international research and development, vaccines started emerging and in December of 2020, the vaccination process had begun.

The most common issue that arises is that about the quality of the vaccine. Many argue that it was created under extreme time pressure and should not yet be distributed due to a lack of testing. Others say that thanks to the intense focus, and financial aid that was put into the research, the vaccine was developed and that the time it took has nothing to do with the quality. For these reasons, the various vaccines are under extreme scrutiny.

In order to be distributed in the European Union, a vaccine must be approved by the European Medicines Agency (EMA). The EMA has stated that “COVID-19 vaccines can only be approved and used if they comply with all the requirements of quality, safety and efficacy set out in the EU pharmaceutical legislation”.<sup>1</sup> Critics of the EMA have come forward saying that the testing process is only slowing the distribution process down and that the restrictions should be eased to fight the pandemic as effectively as possible. On the other hand, some are saying that easing restrictions is ill-advised and that we have no way of knowing how the human body is going to react to the unknown substance in the long run.

Many countries have taken measures to speed up the approval process, such as the United States of America which has implemented the Emergency Use Authorization<sup>2</sup>. This is a mechanism to ease the availability of medical countermeasures during public health emergencies. This may include the use of unapproved medical products or unapproved uses of approved medical products.

The easing of testing restrictions for COVID-19 vaccines is one of the most controversial topics in media today, and to this moment there is no clear policy that is set to be adopted worldwide.

#### II. Questions to consider

- Familiarize yourself with the vaccine approval process.
- Research the different vaccines and their distribution within your country.
- What does the vaccination process look like in your country?
- What policies has your country implemented regarding the vaccines that are being distributed?



- Does your delegation believe that the testing criteria for the vaccine are too strict or not strict enough?
- Should the distribution policy be national or trans-national?

### III. Sources and useful links

<sup>1</sup> European Medicines Agency (EMA)

- <https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/vaccines-covid-19/covid-19-vaccines-development-evaluation-approval-monitoring>

<sup>2</sup> US Food and Drug Administration (FDA)

- <https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained>

How the COVID-19 vaccines work

- [https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/how-they-work.html?CDC\\_AA\\_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fvaccines%2Fabout-vaccines%2Fhow-they-work.html](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/how-they-work.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fvaccines%2Fabout-vaccines%2Fhow-they-work.html)

Vaccine testing process

- <https://www.cdc.gov/vaccines/basics/test-approve.html>