

## **New Guidelines for temporary authorizations for health supplies that contribute to the eradication and mitigation of the SARS virus CoV2 (COVID-19) in Mexico.**

Article By:

Gustavo A. Alcocer

Alejandro Luna Fandiño

Armando Arenas

---

These guidelines were published recently in the Official Gazette. The Mexican Federal Commission for the Protection against Sanitary Risks (COFEPRIS) will follow the extraordinary measures in the processes of submission, evaluation and authorization of health supplies and health care establishments, including the temporary certification of good manufacturing practices for establishments that contribute to the eradication and mitigation of the COVID-19.

These guidelines are also focused on the conditions for those establishments interested in the production of medicinal gases (oxygen) or those which would carry out primary conditioning such as filling oxygen tanks (of medical grade) and those applicants to obtain temporary production and / or import authorization and marketing of invasive ventilators, diagnostic tests, concentrators of oxygen, antibacterial gel, sterile masks (mouth covers), thermometers and oximeters.

It is worth highlighting that among the extraordinary measures within this guideline is that COFEPRIS would be able to review of good manufacturing practices for establishments through video conference calls. For the authorization of products (i.e., medicines or devices) a letter indicating the request for authorization of emergency use is required.

COFEPRIS shall respond any application under these guidelines in a term 10 (ten) working days counted from the time of submission of an application.

The authorizations issued under these Guidelines are of a temporary nature. In other words, if the holder of the authorization intends to continue conducting the activities, a further application should be filed within a period that does not exceed 24 months after the submission date of the emergency authorization.

In conclusion, these guidelines seek to streamline requirements and facilitate the eventual approval of products or authorizations for establishments that will contribute to the eradication and mitigation of

the COVID-19. Also, the timeline is being reduced in order to expedite the granting of the corresponding authorization.

© 2005-2025 OLIVARES Y COMPAÑIA S.C.

---

National Law Review, Volume XI, Number 117

Source URL: <https://natlawreview.com/article/new-guidelines-temporary-authorizations-health-supplies-contribute-to-eradication>