



Healthcare - Regulatory Affairs

Regulatory affairs at INVIMA- Newsletter -COVID 19

Within the context of the national government's health emergency declaration, the National Institute for Drugs and Foods Surveillance ("INVIMA") has set into motion a group of safety measures to face the rapid growth of COVID 19's pandemic in Colombia. We list these decisions below:

I. What are the sanitary steps Invima has taken concerning the COVID 19 pandemic?

1. Invima declared all COVID19 protection items and products, such as medications and medical devices, as *non-available vitals*.

This declaration means that companies can import products such as masks, medications, sanitizer gel, disinfecting skin preparations, without a prior Invima sanitary registration to sell them in Colombia.

These measures will extend as long as Invima can rebalance the product's supply.

You may download the relevant information below. From the specialized revision board for drugs memorandums [N°. 01/18/2020](#) and the dedicated revision board for medical devices and in-vitro diagnostics reagents memorandum [N°. 2 11/3/2020](#), especially, section 3.16.

2. Invima also reduced the timing to acquire importation approval for this products, from six (6) days to one (1) working day. It also arranged a straight-forward communications channel to share information related to COVID 19 pandemic.

3. Invima also classified medication and medical devices that might suffer from the pandemic, as outlined below:

- i. **First-line medications:** directly associated with the treatment and palliative care of coronavirus patients, used according to medical indications.
- ii. **Complementary medications and medical devices:** Health officers and professionals use them in the treatment of moderate and acutely severe COVID19 cases.
- iii. **Sensible medication and medical devices:** Health officers and professionals use them in the treatment of different medical conditions other than COVID19, which in turn, the sanitary emergency

might affect them. Probably, due to lack of access and supply, importation, raw sources, manufacturing, etc.

4. Invima classified as “priority” the approval of sanitary registrations or renovations for medication products listed in pharmacological and medical devices rules as IIb and III risk levels. For the Invima, these products are essential for the prevention and diagnosis of COVID19.

5. Invima issued notice 1000-096-20 of 24/3/2020, through which, it clarifies which individuals within the Food Industry can freely move according to the legal exceptions of the nation-wide quarantine.

a) The following persons are within these exceptions:

- Workers or affiliates to animal collection, butchering, deboning, and conditioning companies, as well as, manufacturing plants of derivatives from meat and all other food-producing companies (Section 3.10 Decree 457/2020).
- The exception also applies to staff members who handle the transport of unusable non-for-consumption subproducts, like skins, bones, feathers, animal fat, among others (Section 2.25 Decree 457/2020).
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b) The notice also restated some sanitary requirements for the food industry:

- Animal collection, butchering, deboning, and conditioning companies ought to follow a [guide](#) the Health Ministry and Invima prepared regarding their production processes.
- Companies must ensure all transport of animals to collection facilities. Transporters must carry the [Internal Mobilization Sanitary Guide](#) (GSMI) from the National Agropecuary Institute (ICA)

6. Invima issued a quick-review strategy for clinical research projects related to COVID19 medications.

Invima established specific requirements for the presentation of initial grade protocols contributing to achieving information on possible treatment alternatives for COVID19.

To study the protocols, Invima’s clinical research task group will review each protocol within the following five days to its submission. You may access the requirements in this [link](#)

II. ***How the current COVID 19 pandemic impact ongoing proceedings and new submissions to Invima?***

As of writing, Invima has not suspended legal deadlines in ongoing requests and proceedings. However, to avoid gatherings and place to place transport, starting on Monday, March 30th, 2020, Invima's User Attention Offices will not receive in-person requests. INVIMA will handle all applications and other requests via its online website.

Requests and proceedings concerning the COVID19 pandemic will have more priority than other ongoing proceedings. This measure aims to secure so needed sanitary authorizations in the shortest possible time.

III. Powers the Health Ministry granted to Invima for as long the sanitary emergency lasts.

Through Decree 476/2020, the National Health Ministry granted to INVIMA the power to designate as *non-available vitals* products medicines intended to the prevention and treatment of COVID-19 without need to verify the lack of the product supply.

This executive decision also permits INVIMA to designate as *non-available vitals* products: diagnosis reagents, cosmetics, phytotherapeutic preparations, hygiene products and personal hygiene products needed for the prevention, diagnosis and treatment of COVID19, without the obtention of a previous approval from the corresponding Specialized Revision Board.

The decree also allows INVIMA to perform an expedited review of new sanitary licenses applications and of the renewal of medicines, phytotherapeutic products and medical devices sanitary licenses. This process would apply to products needed for the prevention, diagnosis and treatment of COVID-19, which are currently low in stock nationwide. INVIMA can also accept the Good Manufacturing Practices (GPM) issued by PIC-S agencies (Pharmaceutical Inspection Co-operation Scheme).

The decision also waives the apostille or consular requirements for documents in proceedings related to sanitary licenses applications and associated processes for products needed to prevent, diagnose and treat COVID-19.

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