DM-RM-7905-2020.- MINISTRY OF HEALTH. San José at eight o'clock on December 3, two thousand and twenty.

ADMINISTRATIVE RESOLUTION OF AUTHORIZATION OF USE OF VACCINES AGAINST COVID-19 BASED ON THE RECOGNITION OF THE MARKETING AUTHORIZATION OR AUTHORIZATION OF EMERGENCY USE OF STRICT REGULATORY AUTHORITIES OR PRE-QUALIFIED BY THE WORLD HEALTH ORGANIZATION.

RESULTS:

I. That, in accordance with the Political Constitution, in its articles 21 and 50, the right to life and The health of people is a fundamental right, as well as the well-being of the population, which become legal assets of public interest and, given this, the State has the inexorable obligation to ensure their protection. Derived from this duty of protection, there is a need to adopt and generate immediate safeguard measures when such legal assets are threatened or endangered, following the constitutional mandate stipulated in numeral 140 subsections 6) and 8) of the Basic Text.

II. That it is an essential function of the State to ensure the health of the population, corresponding to the Executive Power through the Ministry of Health, the definition of the national health policy, the training, planning and coordination of all public and private activities related to health , as well as the execution of those activities that correspond to it according to the law, Due to the functions entrusted to the Ministry of Health, public health surveillance must be carried out and the health situation of the population must be evaluated when they are at risk.

III. That according to articles 4, 6, 7, 337, 338, 340, 341 of the General Health Law, Law No. 5395 of October 30, 1973 and ordinal 2 subsection b) and 57 of the Organic Law of the Ministry of Health, Law NO 5412 of November 08, 1973, health regulations are of public order. Given this, the Ministry of Health as the competent authority may order and take special measures to avoid risk or damage to people's health, or that these are spread or aggravated, as well as to inhibit the continuation or recurrence of the violation of individuals. Said legal norms that establish the competence of the Ministry of Health in matters of health, consecrate the power of empire in matters of health, which empowers it to dictate all the technical measures that are necessary to face and resolve states of health emergency.

IV. That the public authorities are obliged to apply the precautionary principle in health matters in the sense that they must take the necessary preventive measures to avoid serious or irreparable damage to the health of the inhabitants.

V. That since January 2020, the health authorities have activated the protocols to face the international health epidemiological alert due to the outbreak of the new coronavirus in China. The alert of the World Health Organization (WHO) of January 30, 2020,

It was generated after a new type of coronavirus was detected in the city of Wuhan in the Hubei Province of China, which has caused infections and deaths worldwide.

SAW. That on March 6, 2020, the first case of COVID-19 was confirmed in Costa Rica, after the results obtained at the Costa Rican Institute for Research and Teaching in Nutrition and Health.

VII. That on March 8, 2020, given the increase in confirmed cases, the Ministry of Health and the National Commission for Risk Prevention and Emergency Attention determined the need to raise the current health alert for COVID-19 to yellow alert.

VII. That on March 9, 2020, the Executive Branch established the Inter-institutional care and coordination measures in the face of the Coronavirus (COVID-19) health alert through guideline No. 073 - S - MTSS, instructing all ministerial bodies and institutions of the Decentralized Public Administration, to implement temporarily and to the extent possible throughout the week, the teleworking modality in their respective institutions, as a complementary and necessary measure in the face of the coronavirus alert, through expedited procedures.

IX. That on March 11, 2020, the World Health Organization elevated the public health emergency situation caused by COVI D-19 to an international pandemic given the rapid evolution of the events, on a national and international scale, which requires the timely adoption of immediate and effective measures to deal with these extraordinary circumstances of an unprecedented health crisis of enormous magnitude, both due to the very high number of people affected and the extraordinary risk to their lives and rights.

X. That through Executive Decree No. 42227 - MP — S a state of national emergency is declared throughout the territory of the Republic of Costa Rica, due to the health emergency situation caused by the disease caused by COVID-19.

CONSIDERING:

I. That it is imperative to apply immediate measures to prevent and care for the health emergency due to COVID-19, as well as to guarantee effective compliance with the protocols of the Ministry of Health and jointly, take preventive measures that contribute to the proper management of the problem that it is experiencing. our country, as well as the measures to minimize the risk in the emergence of a very high number of simultaneous transmission chains or that can occur in a short period of time, generated in the same place where a high volume of people converge or transit, with greater attention where there is contact with people who come from different parts of the world, which represents an increase factor in the advance of the outbreak by COVID-19, causing an eventual saturation of health services that can make it impossible to

timely care for those who may become seriously ill (people with risk factors such as high blood pressure, diabetes mellitus, immune system problems, chronic lung diseases, chronic cardiovascular diseases or older adults).

II. That, in the framework of the national health emergency and the growth in the number of people affected by COVID-19 to date and the need for citizens to collaborate by staying at home and staying away from public places, extreme precautionary measures must be taken. protection and prevention in the spaces managed by the Ministry of Health, specifically in the Health Governing Areas.

III. That in accordance with the obligation of effective protection of the aforementioned constitutional rights, the duty of protection and prevention imposed by the state of national emergency COVID-19, the need to adopt and generate immediate safeguard measures is sustained when such legal assets are in threat or danger, following the mandate stipulated in numeral 140 subsections 6) and 8) of our Political Constitution.

IV. That some Companies-Manufacturers-Importers of the vaccine against COVID-19 with bilateral agreements signed with government institutions or belonging to the COVAX mechanism, have offered the country the sale of vaccines against SARS-COV2 to prevent COVID-19 infection in the Humans.

V. That the government of Costa Rica will receive the doses of the aforementioned vaccines after the authorization of the Ministry of Health, for which there could be coverage to grant two applications to just over three million people.

SAW. That the deliveries of the vaccines would be made progressively in 2021, starting in the first quarter of that year, subject to clinical success and local regulatory approval.

VII. That for what is indicated here it is considered timely and necessary that the Ministry of Health proceed to expedite the procedures for the Authorization of use of the Vaccines against COVID-19 based on the recognition of the marketing authorization or authorization of use

in emergency of Strict Regulatory Authorities or prequalified by the WHO.

THEREFORE,

THE MINISTER OF HEALTH

RESOLVES:

In accordance with the foregoing, and based on the attributions and in the exercise of the powers conferred by articles 50, 140 subsections 6), 8) and 20) and 146 of the Political Constitution, 23 subsection m), 25 subsection 2), 28 section 2 subparagraph h), 66, 83, 99, 102, 107, 147, 148, 149, 227, 361, 362, 363, 364, 365, 366, 367, 368, 369, 370, 371 and 348 of Law No. 5395 of October 30, 1973 "General Health Law; 2, 6 and 57 of Law No. 5412 of November 8, 1973 "Organic Law of the Ministry of

Health"; and Law No. 8811 of July 18, 2001 "National Law on Vaccination and Epidemiology", and due to the national emergency situation caused by the COVID-19 disease declared via Executive Decree No. 42227-MP-S of March 16, 2020, effective as of that date, the following measures are adopted for the Authorization of use of Vaccines against COVID-19 based on the recognition of the marketing authorization or emergency use authorization of Strict Regulatory Authorities1 or prequalified by WHO.

FIRST: Requirements that the interested parties must present:

The interested party must send to the Directorate for the Regulation of Products of Sanitary Interest to the email drpis.correspondencia@misalud.go.cr with a copy to andrea.badilla@misalud.go.cr the following requirements:

to. Authorization request letter signed by the legal representative of the responsible laboratory, or failing that, by the importer of the product.

b. Certified copy of the Emergency Use Authorization or Sale authorization certificate (Free Sale Certificate or Pharmaceutical Product Certificate) issued by a Strict Regulatory Authority (1) or prequalified by WHO. In the event that you only have the Emergency Use Authorization, you must submit a sworn statement by the legal representative of the responsible laboratory where you agree, once the sales authorization certificate has been obtained, to submit the sanitary registration process for the vaccine. before the Ministry of Health. In the event that the certified copy is issued abroad, it can benefit from ministerial resolution No. DM-RM-2934-2020 on "Provisions regarding the procedures for registration, renewal and post-registration changes of products of health interest on the platform Register it", for the subject of the apostille or consularization.
Remember that it must be accompanied by the official translation into Spanish.

c. Sworn statement issued by the legal representative of the responsible laboratory confirming that the product or pharmaceutical forms offered to the Ministry of Health correspond in every way (for example, the qualitative and quantitative formula, the facilities where finished pharmaceutical products are manufactured and active pharmaceutical ingredients, stability, summary of product characteristics and labeling) to the product approved by the Strict Regulatory Authority or prequalified by the WHO. In the case of a product that uses an alternative manufacturing chain to which the Emergency Use Authorization or sales authorization certificate issued by a Strict Regulatory Authority was granted, you must present a certified copy of the

[1] In attention to the document "Use of decisions of other regulatory authorities to authorize the emergency use of medicines and other health technologies in a pandemic (for example, COVID-19)" available at https://iris.paho.org/handle/10665.2/52037, It is clarified that the list of "Strict Regulatory Authorities" is adopted, made up of the founding members of the International Council on the Harmonization of the Technical Requirements of Pharmaceutical Substances for Human Use, that is, the authorities of Australia, Canada, the United States, Iceland, Japan, Liechtenstein, Norway, the United Kingdom, Switzerland and the European Union.

Certificate of Authorization from a Regulatory Authority of Reference2 level 4 of OPS and comparative quality information between the product approved by the strict Regulatory Authority and the product with the proposed manufacturing chain. In the event that the certified copy is issued abroad, it can benefit from the ministerial resolution DM-RM 2934-2020 on "Provisions regarding the procedures for registration, renewal and post-registration changes of products of health interest on the Register it platform", for the issue of the apostille or consularization. Remember that it must be accompanied by the official translation into Spanish.

d. Drug Information Monograph or its equivalent and package insert or prescribing information approved by the referring authority. If it is in a language other than Spanish, the corresponding translation into Spanish must be provided. and. Specifications for the release of the finished product and the description of the methods analytical.

F. List of all facilities involved in the manufacturing process.

g. Certified copy of the Certificate of Good Manufacturing Practices of all laboratories involved in the manufacturing process of the active ingredient and finished product accepted by the strict or reference regulatory authority. In the event that the certified copy is issued abroad, it can benefit from resolution DM-RM-2934-2020 on "Provisions regarding the procedures for registration, renewal and post-registration changes of products of health interest on the Register it platform", for the issue of the apostille or consularization. Remember that it must be accompanied by the official translation into Spanish.

h. Labels of the container / primary, secondary packaging and insert in original or their projects in PDF format and all information leaflets as the product will be marketed. The labels must come in Spanish or, if it is in different languages, at least one must be in Spanish. In the information on the label or primary packaging, as minimum information, you must indicate the name of the product, the name of the active ingredient, the route of administration, the batch number, the expiration date, the name or logo that identifies the responsible laboratory. The secondary packaging must include the information requested for the label or primary packaging, in addition to the special conditions for its storage or handling, warnings and precautions. In the case of products that require reconstitution, it must include a prospectus or instructions on how to carry out the reconstitution in Spanish.

i. Copy of the risk management plan (PGR) with the summary in Spanish and the pharmacovigilance plan (in Spanish) approved by the reference authority, which includes a formal note with the character of a sworn statement in which it undertakes to present the Periodic Report of the Evaluation of Risks and Benefits (PBRER, for its acronym in English), or failing that, the Periodic Safety Report (IPS), when they are ready and notify any Event Supposedly Attributable to vaccination and Immunization (ESAVI) to the center

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[2] In response to the document available at https://iris.paho.org/handle/10665.2/52037, it is clarified that the list of Regional Reference Regulatory Authorities is adopted, that is, the authorities of Argentina, Brazil, Canada, Chile , Colombia, Cuba, United States and Mexico.

National Pharmacovigilance through the Noti-FACEDRA digital platform through the link: www.notificacentroamerica.net

J. Anything related to suspected substandard or counterfeit quality issues should be send to the email denuncias.drpis@misalud.go.cr.

SECOND: Instruct the Directorate for the Regulation of Products of Sanitary Interest for the implementation of this Ministerial Resolution.

THIRD: Valid as of this date.

COMMUNICATE AND PUBLISH ON THE WEBSITE OF THE MINISTRY OF HEALTH

Dr. Daniel Salas Peraza
HEALTH MINISTER

VB Director ai **Product Regulation Directorate of Sanitary Interest**	**VB Director ai** **Directorate of Legal Affairs**