MITTELSTAND GLOBAL
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In Latin America, Mexico's pharmaceutical market is second only to Brazil in terms of size. Health care reforms, streamlined regulations and an increasing public sector role make it one of the region's most dynamic markets as well. PharmaUpdate Mexico provides German companies with regular, relevant legislative and regulatory news.

It is a service of the initiative HEALTH MADE IN GERMANY, whose aim is to strengthen Germany's position as a leading global provider of health care products and services.
HEALTH MADE IN GERMANY was initiated by Germany's Ministry for Economic Affairs and Energy (BMWi).

REGULATION OF MEDICAL CANNABIS AND ITS PHARMACOLOGICAL DERIVATIVES IN MEXICO.

On January 12, 2021, the "Regulation of the General Health Law on Sanitary Control for the Production, Research and Medicinal Use of Cannabis and its Pharmacological Derivatives" was published in the Official Gazette of the Federation. The Regulation is exclusively focused on medicinal use and does not cover industrial or recreational uses. The Regulation entered into force the day after its publication.

https://www.dof.gob.mx/2021/SALUD/SALUD_120121.pdf

As mentioned in last month's bulletin, Mexico was awaiting the publication by its government of the guidelines related to the **medicinal use** of cannabis, which was made official in January 2021 and whose main purpose is the regulation, control, promotion and health surveillance of starting materials, pharmacological derivatives and drug products of cannabis, for production, research, manufacturing and medical purposes. Below we mention the most relevant points of the regulation.

The authorities involved in the control and monitoring of the use of cannabis and its pharmacological derivatives are:

- The Ministry of Health, through the Federal Commission for the Protection against Sanitary Risks (COFEPRIS), which will regulate the research, manufacture and medical use of cannabis and its pharmacological derivatives.
- The Ministry of Agriculture and Rural Development, through the National Service for Health, Safety and Agro-food Quality (SENASICA), which will regulate and promote cannabis safety, as well as the

BPI Bundesverband der Pharmazeutischen Industrie e.V.
.B.A.H Bundesverband der Arzneimittel-Hersteller e.V.
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application, verification and certification of systems for reducing risks of physical, chemical and microbiological pollution in primary production.

- The National Seeds' Inspection and Certification Service (SNICS) will regulate the production of certified seeds, the classification of seeds and the commercialization and entry into circulation of all cannabis seeds.
- The Ministry of Economy shall be involved in the determination of import and export tariffs.
- The Ministry of Finance, through the Tax Administration Service (SAT), will verify compliance with goods entering or leaving the country.

The main points of the regulation are the following:

- The regulation of the primary production of cannabis, i.e., the generation of the starting material to be used for pharmacological research and the manufacture of pharmacological derivatives and drug products. Starting material are considered the following: seeds, plants, seedlings and flowers.
- For the sowing of cannabis for research and manufacturing purposes, a permit must be processed before SENASICA, subject to the authorization of the Investigation Protocol by COFEPRIS.
- Sowing, growing, harvesting and producing cannabis should be done in a Confined Permitted Site.
- COFEPRIS should maintain an updated national research inventory where cannabis research centers, participating researchers, scientific publication and surveillance reports generated by research should be recorded.
- Any holder of a sanitary registration (marketing authorization) of drug products containing cannabis must have an independent Quality Control Laboratory with a sanitary license, control book of standards and samples, personnel and own areas, among others.
- All establishments that participate in the manufacturing process or importing, exporting or using starting materials, pharmacological derivatives or drug products of cannabis must have a sanitary license, sanitary responsible, control book authorized by COFEPRIS and a security system for guardianship and custody.
- The manufacture of pharmacological derivatives or drug products of cannabis should be in accordance with the national regulation for psychotropic and controlled products, in particular what is stated in Chapter IV of Title Twelfth of the General Health Law, the Health Products Regulation, Standards NOM-059-SSA1-2015 and NOM-072-SSA1.2012, among others.
- All drugstores and pharmacies authorized to supply drug products of cannabis to the public must have a health license, sanitary responsible and control book, among others.
- Import and Export permits of starting material, molecular complexes, pharmacological derivatives and drug products referred to in the Regulation shall be submitted by electronic means.
- The Ministry of Health, with a favorable opinion of SENASICA, shall issue the import permit for botanical seed starting material for sowing, seedlings for sowing, and plant material for propagation.

- Regarding advertising, only advertising intended for health professionals shall be authorized, advertising directed to the general public is prohibited.

It should be mentioned that the provisional articles of the Regulation state that all administrative provisions which oppose the Regulation shall be repealed, and it gives the Ministry of Agriculture and Rural Development a period of 90 days to carry out the regulatory adjustments necessary for the performance of the duties conferred on the Regulation.

Finally, it is important to comment that unlike the draft legal reform that is being surveyed in Congress (discussed in last month's bulletin) and which would also allow industrial and recreational use of cannabis, this Regulation is exclusively focused on the medicinal use of cannabis.

ADDITIONAL ACTIONS REGARDING THE COVID-19 PANDEMIC.

OXYGEN FOR MEDICINAL USE.

Given the lack of supply generated by supplementary oxygen overdemand, the Ministry of Health published two legal agreements to ensure adequate production and distribution of medical-grade oxygen.

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Among other provisions, COFEPRIS is instructed to: 1) analyze the relevance of reducing the requirements for the granting of the sanitary registration (marketing authorization) required for the production and distribution of oxygen for medicinal use, and 2) settle applications for authorization within a period less than established in the current health regulations.

FOLLOW-UP TO VACCINATION AGAINST COVID-19 IN MEXICO.

Given the delay in the production and distribution of batches corresponding to the first two Covid-19 vaccines authorized in Mexico (Pfizer-BioNTech and AstraZeneca-Oxford University), the Government of Mexico announced the purchase of 24 million doses of the Russian vaccine, Sputnik V.

The announcement at the end of January about the imminent arrival of the first doses of this vaccine caused controversy as, as of the date of the announcement, the results of the phase III clinical trials of the Sputnik V vaccine had not yet been published internationally. Once published in The Lancet, COFEPRIS granted authorization for emergency use. We are waiting for confirmation of the first shipment from Moscow.

On the other hand, COFEPRIS has just granted emergency authorization to the vaccines developed by CanSino Biologics and Sinovac.

Additionally, phase III tests are currently being conducted by Novavax from the United States and CureVac from Germany.

Finally, and in the face of increasing pressure, the Minister of Health published an agreement (https://dof.gob.mx/nota_detalle.php?codigo=5610327&fecha=25/01/2021) aimed for federal entities and private health services in order to allow the purchase of vaccines against Covid-19 on their own. It should be mentioned that vaccines must have been previously authorized by COFEPRIS. However, the states themselves have reported that it will be difficult to achieve doses before 2022, as pharmaceutical companies have informed that all their production is committed for the remainder of 2021.

SANITARY ALERTS.

On January 22, COFEPRIS issued an alert about the illegal marketing of the COVID-19 vaccine by Moderna TX Inc., which is not authorized in Mexico and whose sale constitutes a health risk.

Comunicado_Vacuna_Covid_Moderna_220121.pdf (www.gob.mx)

Also, on February 3rd, an alert was issued informing the population about the illegal sale of the COVID-19 vaccine from the company AstraZeneca, as this company has no agreement with private companies for marketing in Mexico.

https://www.gob.mx/cofepris/es/articulos/cofepris-informa-sobre-la-comercializacion-ilegal-de-la-vacuna-contra-covid-19-de-la-empresa-astrazeneca-s-a-de-c-v?idiom=es

RELATED TO THE PHARMACOPOEIA OF THE UNITED MEXICAN STATES.

An update of the Mexican Official Standard that establishes the guidelines for the structuring of the Pharmacopoeia of the United Mexican States and its Supplements, and for the procedure for its review, updating, editing and dissemination is published.

On January 4, 2021, the Official Mexican Standard *"NOM-001-SSA1-2020, which institutes the structure of the Pharmacopoeia of the United Mexican States and its supplements and the procedure for its review, updating, editing and dissemination"* was published in the Official Gazette of the Federation.

This Standard supersedes the Mexican Official Standard *"NOM-001-SSA1-2010" and* shall enter into force sixty calendar days after its publication.

Changes are included in the "*Terms and Definitions"* section, including the modification of the definitions of health supplies, reference substances and medical devices.

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