MAÑÓN QUINTANA abogados

Mexico City, Mexico, June 3, 2021

Various provisions of the Mexican Regulations for Health Supplies have been amended, added and repealed.

Dear clients and friends,

On May 31, the *Decree amending, adding and repealing several provisions of the Regulations for Health Supplies* (the "*Decree*") was published in the Federal Official Gazette. Please find the most relevant aspects of these amendments detailed below:

1. Labeling of medicines intended exclusively for public health institutions

The Decree expands the requirements originally established in the Regulations for Health Supplies (the "Regulation") with respect to health supplies intended exclusively for public health institutions, establishing that:

a. The primary or secondary label of health supplies exclusive for public institutions must be differentiated from that intended for the private sector.
b. The labeling must comply with the requirements established by the Regulations themselves as well as applicable Mexican Official Standards.
c. The label must include the text "not for sale" or "property of the Health Sector".
d. The labeling must contain the code of the National Compendium of Health Supplies on its secondary packaging (or primary packaging in the absence of secondary packaging).

2. English as a second language to integrate dossiers

a. The Decree allows the submission in English of information to be included in the registration dossier for health supplies. This avoids the need for translations by an expert translator, making the time required to submit documents to COFEPRIS more efficient.

3. Biotechnological biocompatible medicines

a. The information required for the processing of health registrations of biocompatible biotechnological drugs is developed in greater detail, to include preclinical and clinical studies of biocompatibility, immunogenicity, and adverse event reports, subject to the opinion of the New Molecules Committee.
b. The indications approved for the reference biotechnological drug will be authorized provided that the biocompatible is presented in the same pharmaceutical formulation and dosage, and that the mechanism of action or pharmacodynamic effect is the same as the reference drug.
c. The registration of a biocompatible product with respect to a biotechnological product protected by a patent may be requested within eight years prior to the expiration of such patent, to carry out the corresponding studies, tests, and experimental production. The registration will be granted only at the end of the patent term.
d. The Ministry of Health, based on the opinion of the New Molecules Committee, may exempt the interested party from submitting in vitro studies.

e. The characteristics with which reports of preclinical studies in animals must comply are developed in greater detail.
f. The Ministry of Health, with the opinion of the New Molecules Committee, may request a report on comparative pharmacokinetic studies to demonstrate pharmacokinetic biocompatibility.
g. The specific requirements for the approval of each biocompatible biotechnological drug will be determined by the Ministry of Health considering the opinion of the New Molecules Committee.
h. In the event that the Pharmacopoeia and its supplements do not have relevant information, guides or national monographs, the Secretariat may resort to international guides for the evaluation of biocompatibility tests.
i. When an applicant for registration of a biocompatible biotechnological drug has based its application on clinical studies of origin, it must submit clinical studies conducted in Mexico at the time of requesting an extension.
j. The use of a biotechnological drug in other clinical indications may be approved, as long as there is scientific justification supported by clinical studies.

4. Deadlines for modifications to marketing authorizations

a. The Decree establishes that COFEPRIS will have a term of 45 working days for technical modifications and 20 working days for administrative modifications of marketing authorizations.
b. If this Agency does not resolve the matter within the established term, it will be considered as a constructive assent.
c. The official notice authorizing the modification shall establish the term that the holder of the registry shall have to exhaust inventories, which may not exceed 240 working days.

5. Assignment of registrations

a. The new holder must notify COFEPRIS of the transfer of rights of a marketing authorization within a term no longer than 30 working days from the date of transfer, accompanying the documents that demonstrate the transfer and the project of labels identifying the new holder.

6. First extension of marketing authorizations for national medicines

a. The requirements for the first extension of the marketing authorization of medicines have been simplified.
b. In case of major modifications that have an impact on the pharmacokinetics of the drugs, a technical report issued by the Interchangeability Units must be submitted to justify it.
c. For the granting of extensions in the marketing authorization of drugs, compliance with good manufacturing practices will be verified.
d. Extension requests will not be an additional procedure to verify the authorized conditions, only to verify that the changes made do not impact the quality, efficacy, and safety of the drug.

7. First extension of marketing authorizations for foreign drugs

a. It is necessary to have a legal representative domiciled in Mexico.
b. Certificate of good manufacturing practices of the drug issued by the competent authority will need to be filed

c. Requests for extension must be submitted 150 calendar days before the expiration date of the registration and COFEPRIS will have 120 calendar days to resolve the request. In case the respective resolution is not issued within the established term, it will be understood that the request was accepted.

8. First extension of marketing authorizations for medical devices

a. The requirements for the first extension of the sanitary registration have been simplified.
b. For foreign medical devices, a certificate of good manufacturing practices issued by a national regulatory agency recognized by the Ministry of Health will be required.
c. Extension requests will not be an additional procedure to verify the authorized conditions, only to verify that the changes made do not impact the quality, efficacy, and safety of the drug.

9. Deadlines for the first extension for drugs and medical devices

a. Requests for the first extension for drugs and medical devices must be submitted 150 calendar days prior to the date on which the registration expires.
b. COFEPRIS will have 120 calendar days to resolve the request. In case the respective resolution is not issued within the established term, it will be understood that the application was granted.

10. Second and subsequent extensions of drugs and medical devices

a. Requests for second and subsequent extensions for drugs and medical devices must be submitted 150 calendar days prior to the date on which the registration expires.
b. The certificate issued by COFEPRIS as acknowledgement of receipt of the application submitted, must keep the same alphanumeric code, and will have the effect of extending the marketing authorization.
c. If the applications are not submitted within the period established for such purpose, the marketing authorization will lose its validity and a new registration must be requested.
d. Second and subsequent extensions may be requested once the specific format for this procedure is published.

11. Relevant deadlines

a. COFEPRIS has 180 working days from June 1 to make the necessary regulatory adjustments to comply with the Decree, including the format for second and subsequent extensions.
b. The public sector will have 180 calendar days to start requiring the new labeling for products destined for public health institutions.
c. Drug manufacturers or establishments will have 120 calendar days to use up packaging materials and finished products that do not comply with the new labeling provisions applicable to products for sale to the public sector.

MAÑÓN QUINTANA abogados

12. Applications in process

The extension requests in process will be attended until their conclusion in terms of the provisions in force at the time of their filing.

In the hope that this communication proves useful, the lawyers of Mañón Quintana are at your service to with regards to any questions related to the scope of this document.

Atentamente,

Antonio Mañon
antonio.manon@mqsc.mx

Gerardo Quintana-Pineda
gerardo.quintana@mqsc.mx

Jorge Rosales-Fernandez
jorge.rosales@mqsc.mx

Dario Jandette Fuentes
dario.jandette@mqsc.mx

Santiago J. Nuñez-Chaim
santiago.nunez@mqsc.mx

Julio J. Copo-Terres
julio.copo@mqsc.mx

Antonio Barrera-Rios
antonio.barrera@mqsc.mx

Alberto Quintana-Pineda
alberto.quintana@mqsc.mx

Gerardo Sanchez
gerardo.sanchez@mqsc.mx

Enock Perez-Arias
enock.perez@mqsc.mx

Beatriz Gonzalez-Alanis
beatriz.gonzalez@mqsc.mx

Paulina Ruiz
paulina.ruiz@mqsc.mx

Sofia Philippe
sofia.philippe@mqsc.mx

Fernando Salinas
fernando.salinas@mqsc.mx

Nuria Ledezma
nuria.ledezma@mqsc.mx

Bruno Saab
bruno.saab@mqsc.mx

Hugo Oseguera
hugo.oseguera@mqsc.mx

Fernanda Hernandez
fernanda.hernandez@mqsc.mx

Paulina Martin-Gonzalez
paulina.martin@mqsc.mx