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SUPREME DECREE NO. 3 OF 2010 OF THE MINISTRY OF HEALTH, WHICH APPROVES THE REGULATION OF THE NATIONAL SYSTEM FOR THE CONTROL OF PHARMACEUTICAL PRODUCTS FOR HUMAN USE, IS MODIFIED

On August 21st, 2020, two modifications to Supreme Decree No. 3 of 2010, which approves the Regulation of the National System for the Control of Pharmaceutical Products for Human Use (hereinafter DS 3/10), were published in the official gazette. The first refers to aspects of therapeutic equivalence, while the second relates to several changes in the sanitary registration application procedure of pharmaceutical products.

Regarding the matter of therapeutic equivalence, the modification incorporates a**new article 221 bis**, which refers to the validation of the therapeutic equivalence demonstration, as indicated in said new article below:

"Article 221 bis. - It will be understood that those pharmaceutical products that have certified said condition before any of the High Surveillance Medicine Regulatory Agencies referred to in article 54º C have been demonstrated. In the same way, it will be understood that they have demonstrated their therapeutic equivalence, if said pharmaceutical products have been prequalified by the World Health Organization as such. "

This modification takes effect as of**August 21, 2020**.

On the other hand, regarding the procedure for the pharmaceutical products' sanitary registrations applications, the amendment includes the following changes:

•Article 43: On the application for health registrations, the second paragraph is replaced by the following:

"Said request shall be recorded in a file, written or electronic, which must be ordered according to the format approved by the Director of

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the Institute through a resolution. In the aforementioned file, the documents submitted by the interested parties will be recorded, stating the time and date of presentation, granting a reference number for its entry and follow-up, after payment of the fee corresponding to the first phase of admissibility of the application."

•**Article 46: Regarding the admissibility of the registration procedure, the current article 46 is replaced by the following:**"Upon declaring the admissibility of the registration procedure, the antecedents will be sent to the corresponding agency, according to their nature, for subsequent analysis, separately."
•**Article 49: Regarding the denial of the sanitary registration based on insufficient background information or studies presented**, a period of 6 months is granted to start a new registration process, accompanying the antecedents and necessary corrections to overcome the grounds for denial. The Public Health Institute (ISP) will have a period of 3 months to verify and grant the respective sanitary registration. In this sense, the second and third paragraphs of article 49 are replaced by the following:"In the event that such new records are not presented within the term granted or that, presented in time, are again evaluated as insufficient, the Institute will proceed with the denial of the sanitary registration, by means of a founded resolution that establishes it, which will be notified to the applicant.

Notwithstanding the foregoing and within a period of 6 months after the date of notification of the denial, the applicant may initiate a new registration procedure, accompanying in the application the antecedents, clarifications and corrections that are necessary to overcome the causes of the denial. In this case, the Institute will have a period of 3 months to verify the previous antecedents, evaluate the new ones and, if sufficient, grant the respective sanitary registration."

•**Article 51: Regarding the abbreviated registration procedure**, it is established the possibility that it may be declared ex officio by the ISP or at the request of the interested party.In this regard, the phrase "based on a resolution of the Ministry of Health, founded" is replaced in the first paragraph by the following: "ex officio or at the request of the interested party, founded".

Additionally, a new second paragraph is added, with the following content: "Once the requirements indicated above have been met, the Institute will issue the resolution that approves the application for registration of the abbreviated procedure."

•**Article 52: Regarding the simplified registration procedure**, a maximum period of 5 months is established for the granting of the sanitary registration, through the incorporation of the following new second paragraph:"The total period for the resolution of the application that is processed through the simplified registration procedure will be 5 months from the entry of the application."
•**Article 54: It is modified to incorporate a new accelerated registration procedure**, based on the sanitary registration of medicines granted by High Surveillance Medicines Regulatory Agencies, which approval term may not exceed three months from the receipt of the application, as long as the requirements established in the new numeral 3° to the Fourth Paragraph of Title II indicated below are met.This procedure may not be used for the granting of sanitary registrations of medicines, in the following cases:

• Biological products, unless there is a founded resolution from the Ministry of Health that allows this exception.
• When there are public health reasons regarding a certain pharmaceutical product or category of products, which will be qualified through a founded resolution of the Minister of Health.
• Products for which the sanitary registration has been denied in one or more High Surveillance Regulatory Agencies.

"3º of the accelerated registration procedure.Article 54 A.- Those medicines that are registered in the High Surveillance Medicine Regulatory Agencies may undergo the accelerated registration procedure.

To request the accelerated registration procedure, the applicant must indicate in the application the existence of a sanitary registration or authorization for use granted by any of the Regulatory Agencies indicated in the first paragraph. This must be in the same therapeutic indication whose authorization is requested.

Once the existence of a sanitary registration or authorization of sale in any of the agencies of article 54º C has been certified, fulfilling the requirements of this paragraph, the medicine will be registered by the Institute without further processing.

Article 54 B.- In order to obtain the sanitary registration of the medicine, the applicant who opts for the accelerated registration procedure must present the same supporting information given to the Regulatory Agency that granted the registration, together with the Certificate of Pharmaceutical Product. The review carried out by the

Institute must take into account what has already been analyzed by the respective Agency.

Article 54º C.- The following will be considered Regulatory Agencies of Medicines of High Vigilance:

• Those defined as stringent regulatory authorities in Annex 5 of the "WHO Expert Committee on Specifications for Pharmaceutical Preparations - WHO Technical Report Series, No. 986 - Forty-eighth Report" and its subsequent modifications.
• Those classified as Level IV in the Evaluation System of National Drug Regulatory Authorities of the Pan American Health Organization.

III. Members of the "Pharmaceutical Inspection Co-operation Scheme" (PIC / S).

Article 54 D.- For pharmaceutical products recognized by the Regulatory Agencies specified above, their authorizations and certifications, such as Good Manufacturing Practices (GMP) and bioequivalence studies, will be recognized.

Article 54 E.- Provided that no complements, rectifications, clarifications or amendments by the applicant, accelerated processing may not exceed three months from the receipt of the application with all the information.

Article 54 F.- However, the sanitary registration in accordance with this procedure may only be granted to the extent that it has not been denied in one or more high sanitary surveillance agencies.

Article 54º G.- Biological products will not be able to benefit from this registration procedure. This may be excepted through a founded resolution of the Minister of Health. This resolution may exempt certain biological products or a category of them.

Likewise, this procedure may not be used when there are public health reasons regarding a certain pharmaceutical product or category of products. This circumstance will be qualified through a founded resolution of the Minister of Health."

•**Article 65: Modifications to the sanitary registration related to pharmaceutical product's manufacturer, as well as the manufacturing process, are incorporated** through the new numeral 9, to the first paragraph of article 65:"9. Change of the manufacturer of the pharmaceutical product or of the active principles; as well as

modifications of the production process."
•**Article 69: The modification of the manufacturer is eliminated as a cause for requesting a new sanitary registration.** The above is reflected with the elimination of the following sentence:"unless a change of manufacturer is required, in which case a new registration must be requested".

In this same sense, a new article 69 A is incorporated that establishes the requirements for the authorization of a new product's manufacturer:

"Article 69 A.- In cases where the authorization of a new manufacturer of a medicine is required, keeping the one already authorized, only the background that proves the implementation of the production process through technology transfer and a management system must be submitted to the institute of a similar quality to that previously authorized producer. If the information presented is sufficient, the Institute will assign a new sanitary registration number, keeping the other aspects already previously authorized.

Notwithstanding the foregoing and by means of a well-founded resolution, the Institute may require new antecedents, studies, or apply all or some of the other sanitary registration requirements."

All the aforementioned modifications take effect from**August 21, 2020**.

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