

AMENDMENTS TO THE REGULATORY NORM ON THE ISSUANCE OF TEMPORARY CERTIFICATIONS OF GOOD MANUFACTURING PRACTICES

The Ministry of Public Health and Social Welfare, through the Ministerial Decree 6-2018, published in the Official Newspaper on January 25th, 2018 approved the amendments to the Ministerial Decree Number 134-2016, which contains the Regulatory Norm on the Issuance of Temporary Certifications of Good Manufacturing Practices.

The amendments to such Regulatory Norm include the following:

- **Renewal:** Article 6 is amended regarding the renewal of the health licenses, sanitary records and other related procedures. The renewal can only be granted to those Pharmaceutical Laboratories that obtained the Temporary Certification of Good Manufacturing Practices and submitted a sworn statement in which they commit to fully comply with the chronogram in accordance with the conditions and requirements established in the resolution 339-2014 of COMIECO (LXVII) whose percentage is 80% and **expires on April 25, 2018**. Both documents must be submitted and signed by the establishment's legal representative and technical director. The Pharmaceutical Laboratory that does not fulfill the requirements stated above will be cancelled due to non-compliance.

The Certification of Compliance with Good Manufacturing Practices in the Pharmaceutical Industry will be issued and granted once the applicant complies with all the requirements set forth in the resolution 339-2014 of COMIECO (LXVII) **by April 25, 2019**. This is contingent upon the compliance of the resolution and the Guide to Verification.

- **Evaluation Criteria:** Article 9 is amended regarding the evaluation criteria for the issuance of the Temporary Certification of Good Manufacturing Practices to Pharmaceutical Laboratories in implementation process. In accordance to the Guide to Verification RTCA 11.03.42:07, Pharmaceutical Products, Medicinal Products for Human Use and Good Manufacturing Practices in the Pharmaceutical Industry should comply with the Ministerial Agreement 6-2018 and the deadlines mandated by the resolution 339-2014 of COMIECO (LXVII).
- **Period of Duration:** Article 12 is amended by stating that the Regulatory Norm on the Issuance of Temporary Certifications of Good Manufacturing Practices will have a period of duration from April 25, 2016 to April 25, 2019 as prescribed in the resolution 339-2014 of COMIECO (LXVII).

The above-mentioned amendments came into force on January 26, 2018.

For more information, do not hesitate to contact us.



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