LIFE SCIENCES & HEALTHCARE

CLIENT ALERT

APRIL/2019

ANVISA PUBLISHES NEW RULES FOR PHARMACIES' AND DRUGSTORES' AUTHORIZATIONS

Resolution of the Collegiate Board of Directors ("RDC") No. 275/2019 updating the regulation concerning procedures for granting, changing and canceling the Authorization of Operation ("AFE") and Special Authorization ("AE") of pharmacies and drugstores was published on April 10, 2019. The previous rules, established in the RDC No. 17/2013, were revoked.

According to the National Agency of Sanitary Surveillance ("ANVISA"), this new RDC is the result of the optimization of the procedures for the concession of AFEs and AEs.

In the opinion of Fernando Mendes, director of the Agency, the former format of the regulation for the granting authorizations to pharmacies and drugstores did not contribute to the reduction of risks of the activity or the exercise of sanitary surveillance. The agency expects that RDC No. 275/2019 will contribute to more effective regulation of the sector.

The changes implemented with RDC No 275/2019 involve:

- Redefinition of the documentation required in the process for obtaining such authorizations;
- Realignment of the analysis and decision stages;
- Redefinition of the criteria for publication of concessions or alterations;
- Period of 30 days for ANVISA to decide on applications submitted. In case of non-compliance, it will be possible to grant AFEs and AEs automatically;
- Implementation of a follow-up program and monitoring for official local surveillance, with the elaboration of procedures and risk assessment.

It is important to mention that the automatic concession of AFEs and AEs does not prevent the Agency to analyze the request at any time and to cancel the correspondent authorization in the cases of identification of the noncompliance with the sanitary regulation by the establishment concerned.

Veirano's life sciences & healthcare team is available for additional information.

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