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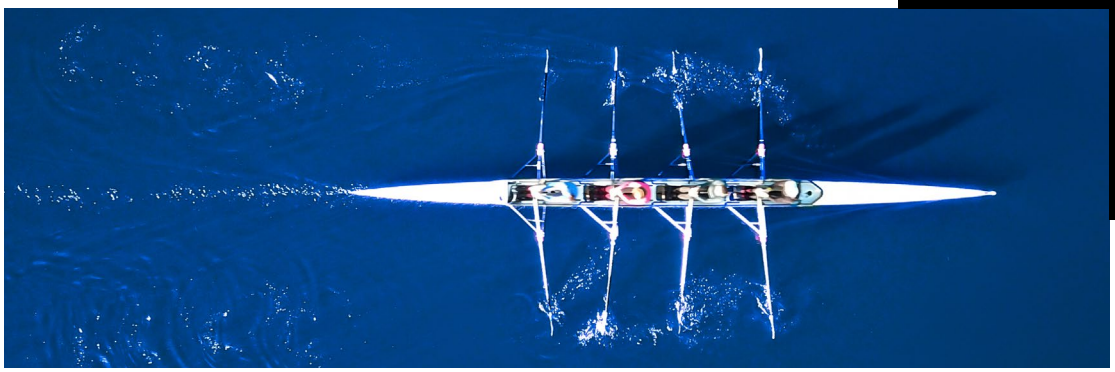

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ANGOLA

NEWS

HOSPITAL HEALTH AND PHARMACEUTICALS

Licensing to Engage in Pharmaceutical Activity

Presidential Decree 41/24 of 29 January – **Regulations on Licensing to Engage in Pharmaceutical Activity** ("RLEAF") was recently published to establish the rules and procedures for licensing to engage in pharmaceutical activity. It also repeals Articles 8, 9, 11, 13, 47 and 49 of the Regulations on Engaging in Pharmaceutical Activity, approved by Presidential Decree 191/10, approved by Presidential Decree 191/10, approved by Presidential Decree 191/10 of 1 September, and Presidential Decree 202/21 of 26 August.

The RLEAF applies to all natural and legal persons in the private sector who carry out pharmaceutical activities in Angola, through the following establishments: *(i)* pharmacies; *(ii)* retailers of herbal medicine; *(iii)* retailers of cosmetics; *(iv)* retailers of health products; *(v)* distributors of medicines or health technologies, and *(vi)* importers of medicines or health technologies.

These are the main changes:

- Simplification of the documentation required for the purposes of the licensing process, with some previously required documents no longer being required;
- Establishment of a maximum legal period of 30 (thirty) days, from the date of the interested party's application and once the establishment has been completed, for an inspection of the establishment to be carried out;
- Establishment of a maximum legal period of 3 (three) working days for the Regulatory Agency for Medicines and Health Technologies ("ARMED") to grant the interested party the authorisation to open and operate the pharmaceutical establishment, once the inspection has been completed and a favourable opinion has been issued by the integrated Technical Commission;
- Establishment of the exclusivity and non-transferability of the authorisation, except in cases of transfer and assignment of commercial operation of the establishment, which must be communicated to ARMED for licensing purposes.
- Reinforcement of the rules on administrative offence for offences committed under the RLEAF.

In general, these changes are aimed at speeding up the procedures for granting authorisations to carry out pharmaceutical activities, in line with the guidelines established under the SIMPLIFICA 2.0 project, approved by Presidential Decree 182/22 of 22 July.

The law entered into force on the date of its publication. ■

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