

INFORMATIVE NOTE

AGREEMENT FOR THE PROCEDURE OF IMPORTATION OF MEDICINES WITH OR WITHOUT SANITARY REGISTRATION

Regarding the guidelines for the importation of medicines contained in the agreement issued on the day, **DOF: 28/01/2020** the following is highlighted:

- The import is done through the regulatory offices of the SAT
- The authorized organizations to carry out the above-mentioned procedure or by which it could be imported are ISSTE, PEMEX; ISABI, SEDENA, IMSS, SEMAR or CCINSHAE
- It is advisable to analyze the overall need for a single import, because once the medicine has entered, it is mandatory to apply for health registration within 5 days for future imports (only the first entry of goods into the country is exempt from health registration)
- To be able to import, the medicines must come from a country where there are sanitary regulations equivalent to COFEPRIS in Mexico, such as the following authorities; Swiss Agency for Therapeutic Products-Swissmed. European Commission, Food and Drug Administration of the United States of America, Ministry of Health of Canada, Therapeutic Products Administration of Australia, Regulatory Agency of reference of WHO/PAHO, prequalified by the prequalification program for medicines and vaccines of the World Health Organization or regulatory agencies members of the Pharmaceutical Inspection Cooperation Scheme.
- The entry must be by complete batches, no separate vials or unidose are allowed.
- From the amount entered into the country, 4 to 5% is taken to show compliance with national and international standards in regulation of good practices in the elaboration of medicines.

NOTE: the complete process from the application to the customs release is approximately 60 days, we are waiting for the time route that COPRISJAL will help us draw, to see the least possible time to give speed to the process if necessary.