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Recomendation report

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Incorporation of pyrazinamide 150 mg dispersible tablets in the Brazilian National Relation of Essential Medicines (RENAME in Portuguese)

Brasília – DF
2020

Technology: Pyrazinamide 150 mg dispersible tablets.

Indication: Treatment of tuberculosis caused by Mycobacterium tuberculosis in children under the age of 10 years or adults with difficulty swallowing.

Applicant: Department of Pharmaceutical Assistance and Strategic Inputs/Secretariat of Science, Technology and Strategic Inputs/Ministry of Health of Brazil (DAF/SCTIE/MS in Portuguese).

Background: Tuberculosis (TB) is an infectious disease spread through the air when people suffering from active pulmonary TB expel droplets containing Mycobacterium tuberculosis bacilli. In Brazil, TB is considered a public health problem in epidemiological terms, directly related to social issues. Pyrazinamide 30 mg/mL oral suspension, a first-line drug used as one of the basic TB regimens in paediatric patients and adult patients with difficulty swallowing, is part of the National Relation of Essential Medicines (RENAME). The Brazilian Navy Pharmaceutical Laboratory (LFM in Portuguese) is the only one to have obtained authorization for the production and marketing of pyrazinamide in the form of oral suspension. However, in 2018, LFM notified DAF/SCTIE/MS that there had been a change in the quality of this medicine, resulting in the temporary interruption of its production. In order to ensure the continuity of supply in the scope of the Brazilian Public Health System (SUS), the Ministry of Health requested support from the Pan American Health Organization (PAHO) to provide a quotation for the medicine. PAHO informed that there are qualified suppliers for pyrazinamide in the form of dispersible tablets. According to the Brazilian National Tuberculosis Control Program, dispersible tablets are consistent with the treatment needs of children under the age of 10 years, as well as adults with difficulty swallowing. Currently, pyrazinamide 150 mg dispersible tablets are not registered with the Brazilian Health Surveillance Agency (ANVISA). However, according to the legislation in force in Brazil, CONITEC may decide on the incorporation of a technology in the scope of SUS.

Justification for the incorporation: In view of the interruption of the production of pyrazinamide oral suspension by LFM for an undetermined period of time, paediatric patients and adult patients with difficulty swallowing would have no option than to dilute pyrazinamide tablets. The inclusion of pyrazinamide in the form of dispersible tablets would cover the absence of the oral suspension, providing more convenient dosing for patients.

Final Recommendation: The members of CONITEC's plenary session present at the 83th Ordinary Meeting, on November 7th, 2019, decided by a simple majority to recommend the incorporation of pyrazinamide 150 mg dispersible tablets in the RENAME. The representative of the Secretariat of Specialized Health Care of the Ministry of Health abstained in the vote; the representatives of ANVISA and the National Commission on Food (CNA in Portuguese) voted against it. The Deliberation Record No. 492/2019 was signed.

Decision: To incorporate pyrazinamide 150 mg dispersible tablets in the Brazilian National Relation of Essential Medicines (RENAME in Portuguese), in the scope of SUS, according to Ordinance No. 64, published in the Official Gazette of the Federal Executive No. 244, Section 1, page 149, on December 22th, 2020.