REPORT 199

Pentoxifylline 400 mg in combination with antimonial for the treatment of mucosal Tegumentary Leishmaniasis

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EXECUTIVE SUMMARY

**Technology:** Pentoxifylline 400 mg tablet

**Indication:** Mucosal Tegumentary Leishmaniasis.

**Applicant:** Secretariat of Science, Technology and Strategic Inputs (SCTIE) and Secretariat of Health Surveillance (SVS), both from the Ministry of Health.

**Context:** In Brazil, tegumentary leishmaniasis is one of the infectious diseases that are worthy of greater attention, especially due to its high magnitude and the risk of occurring permanent deformities in the affected subjects. It may present in the following clinical forms: cutaneous, disseminated, mucosal or mucocutaneous, and diffuse. In the period from 2009 to 2013, 21,395 cases/year, on average, were recorded, distributed in all Federative Units of Brazil. Some researches have demonstrated success in using pentoxifylline as coadjuvant in the treatment of mucosal leishmaniasis, with a cure outcome in a lower time when compared to conventional treatment.

**Question:** Is there evidence that pentoxifylline is effective and safe in the treatment of patients with mucosal leishmaniasis?

**Scientific evidence:** After a search in scientific literature databases, 4 references on the use of pentoxifylline in the treatment of mucosal leishmaniasis (ML) have been found: 3 systematic reviews and 1 randomized clinical trial. One of the reviews was based on a case series of 10 patients with refractory ML, and the other 2 systematic reviews included the same randomized clinical trial, already selected in the search, with 23 adult patients with ML. Both the case series and the clinical trial were conducted in Bahia and included patients infected with *L. braziliensis*. In both studies, the therapy with pentoxifylline combined with standard treatment with antimonial has led to a higher and more rapid lesion cure rate than the therapy with antimonial alone.

**Budget Impact Assessment:** An annual budget impact of BRL 45,000.00, resulting from pentoxifylline incorporation into SUS for the treatment of mucosal leishmaniasis, has been estimated.

**Recommendation made by CONITEC:** at the 40th ordinary meeting, the plenary session members of CONITEC made a preliminary recommendation favorable to incorporating pentoxifylline for the treatment of mucosal tegumentary leishmaniasis into SUS.