Conitec

# Recomendation report

DRUGS

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# Exclusion of rifampicin for chemoprophylaxis for contacts of patients with Hansen´s disease

Brasília – DF
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**Technology**: Rifampicin 300 mg capsule, and 20 mg/mL oral suspension.

**Indication**: Chemoprophylaxis for contacts of patients with Hansen´s disease.

**Applicant**: Secretariat of Health Surveillance of the Ministry of Health of Brazil (SVS/MS).

**Background**: The term often used for chemoprophylaxis and/or immunoprophylaxis is "post-exposure prophylaxis (PEP)". Although this is a simple intervention, operationalising the administration of a single-dose rifampicin in contacts of an index case of leprosy, as another tool for reducing transmission, depends on carefully planning, so as not to affect patients whose contacts should receive PEP. Furthermore, PEP has never been actually included in the routine of Hansen´s disease services in Brazil.

**Clinical Condition**: Hansen´s disease is an infectious disease caused by a bacterium, *Mycobacterium leprae* (Hansen's bacillus) (6), (7), (8). Transmission occurs mainly through the upper airway, by secretions and the air (7), (8), (9), and not by objects used by the patient (1), (8). This disease predominantly affects the skin and peripheral nerves, but it can also affect eyes, mucous membranes and internal organs (6), (8).

**PEP-Hans Project**: The Ordinance No. 32 of the Secretariat of Science, Technology and Strategic Inputs of the Ministry of Health of Brazil (SCTIE/MS), published on June 30th, 2015, made public the decision to incorporate single-dose rifampicin for chemoprophylaxis for contacts of patients with Hansen´s disease, in the scope of the Brazilian Public Health System (SUS), for the purpose of developing the PEP-Hans Project. This project was implemented from 2016 to 2018, in selected municipalities of Mato Grosso, Pernambuco and Tocantins states, since these states are important endemic areas in Brazil. The municipalities included met the eligibility criteria.

**Treatment**: The treatment protocol consisted of rifampicin in a single dose of 600 mg (2 tablets of 300 mg), given to contacts in the second month of the index patient's treatment (approximately 4 weeks after the start of the index patient's treatment); rifampicin 450 mg for children over 5 years of age, and rifampicin 10 to 20 mg/kg for children or adults with body weight below 30 kg.

**Justification for exclusion**: According to the applicant, the technology should be excluded since the PEP-Hans project was completed in 2018, as pointed out in its final report. Further studies are required for the expansion of the use of rifampicin for chemoprophylaxis for contacts of patients with Hansen´s disease, in the scope of SUS. The General Coordination of Disease Elimination Surveillance (CGDE/SVS/MS) has submitted two proposals to the Department of Science and Technology (DECIT/SCTIE/MS): a multicentre study of post-exposure chemoprophylaxis for contacts, and a study of monitoring and evaluation of the contacts who received chemoprophylaxis by the PEP-Hans project.

**Initial Recommendation**: The members of Conitec's plenary session present at the 85th Ordinary Meeting, on February 4th, 2020, unanimously decided to recommend the exclusion of rifampicin for chemoprophylaxis for contacts of patients with Hansen´s disease, in the scope of SUS.

**Public consultation**: A total of 127 contributions were received, 121 of which were technical-scientific contributions, and 6 were experience or opinion contributions. The majority agreed

with Conitec's preliminary recommendation for the exclusion, mainly pointing out the limited evidence of the benefit of chemoprophylaxis, and also the concern about bacterial resistance to rifampicin, which is the only bactericidal drug among the therapeutic arsenal against Hansen´s disease. The Brazilian Society of Dermatology and other health professionals took part in the public consultation, and their comments were properly considered.

**Final Recommendation**: The Conitec's members present at the 87th Ordinary Meeting, on June 3rd, 2020, unanimously decided to recommend the exclusion of rifampicin for chemoprophylaxis for contacts of patients with Hansen´s disease, in the scope of SUS. The Deliberation Record No. 517/2020 was signed.

**Decision**: To exclude rifampicin for chemoprophylaxis for contacts of patients with Hansen´s disease, in the scope of SUS, according to Ordinance No. 18, published in the Official Gazette of the Federal Executive No. 112, Section 1, page 143, on June 15th, 2020.