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F.13 - Rifapentine + isoniazid (300 mg + 300 mg tablet)

MSF strongly supports the WHO Global TB Program proposal to include the fixed-dose combination (FDC) rifapentine + isoniazid (300 mg + 300 mg) tablet in the WHO Model List of Essential Medicines, for tuberculosis preventive treatment (TPT).

Currently, the WHO Model List of Essential Medicines includes rifapentine 150 mg tablet (since 2015) and isoniazid 300 mg tablet (since 1997), separately.

According to the 2020 WHO "Consolidated guidelines on tuberculosis: Module 1: Prevention -tuberculosis preventive treatment" and the 2020 WHO "Operational handbook on tuberculosis: Module 1: Prevention -tuberculosis preventive treatment", systematic TPT is recommended for household contacts of bacteriologically confirmed pulmonary tuberculosis patients, for patients living with HIV/AIDS, for patients who have silicosis, receiving dialysis, initiating anti-TNF treatment, and for patients waiting for transplant.

For TPT, 2 options containing rifapentine + isoniazid are recommended: 3-month regimen of weekly rifapentine used in combination with isoniazid (3HP) or 1-month regimen of daily rifapentine used in combination with isoniazid (1HP). According to these 2020 guidelines, the use of 1HP is recommended only for people aged 13 years and above, due to lack of data on appropriate dosing of 1HP for children 12 years and younger (recommendation established on a study restricted to individuals ≥13 years old).

The targets agreed upon by the Member States during the 2018 United Nations High-Level Meeting on TB include improving TPT coverage as an essential component. The commitment is to provide TPT to at least 30 million people between 2018 and 2022, including 6 million people living with HIV, 4 million household contacts children aged under 5 years, and 20 million household contacts older than 5 years. In 2018, TPT has been provided only to around 424 000 people and around 539 000 in 2019 (19 % patients were older than 5 years, 81% were children under 5 years).

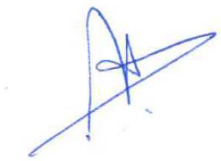
MSF would like to draw the attention of the Expert Committee to the following points:

- The rifapentine + isoniazid (300 mg + 300 mg) FDC formulation will considerably reduce the pill-burden, therefore improving the adherence to tuberculosis preventive treatment. This FDC would allow to reduce the weekly dose for 3HP from 9 or 11 tablets to only 3 tablets. This dosage form is recommended for patients over 14 years old.
- According to the WHO Global TB Program application, the FDC formulation (scored tablet) is marketed by a single manufacturer and a second supplier would be expected to start manufacturing in 2021.
- It is important to include this FDC formulation in the WHO Model List of Essential Medicines to attract additional manufacturers, increase supply security and allow for better competition between manufacturers to reduce price and improve accessibility, particularly in low-and middle-income countries.
- All medicines should always be approved by a stringent regulatory authority (SRA) or WHO-prequalified medicines.

MSF has been using rifapentine in its programs for tuberculosis preventive treatment since 2018. MSF is considering using the rifapentine + isoniazid (300 mg + 300 mg) FDC in its program in 2021 as soon as quality-assured formulations will be available.

In light of these elements, MSF urges the 23rd Expert Committee on the Selection and Use of Essential Medicines to include the fixed-dose combination rifapentine + isoniazid (300 mg + 300 mg) tablet in the core list of the WHO Model List of Essential Medicines, for tuberculosis preventive treatment.

For Médecins Sans Frontières



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