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D.2 Antituberculosis medicines

Deletion from the Core Lists of both the WHO Model List of Essential Medicines and the WHO Model List of Essential Medicines for Children.
Ethambutol 25 mg/ml oral liquid
Isoniazid 50 mg/5 ml oral liquid
Isoniazid 50 mg scored tablet
Pyrazinamide 30 mg/ ml oral liquid
Pyrazinamide 150 mg scored tablet
Isoniazid + Pyrazinamide + Rifampicin 75 mg + 400 mg + 150 mg tablet

Deletion from the Complementary Lists of both the WHO Model List of Essential Medicines and the WHO Model List of Essential Medicines for Children.
Amikacin 100 mg, 500 mg, 1g powder for injection
Amoxicillin/Clavulanic Acid 125 mg + 31.25 mg /5 ml oral liquid
Ethionamide 125 mg tablet
Linezolid Injection for intravenous administration: 2 mg/ml in 300 ml bag
Linezolid 400 mg tablet
Para-aminosalicylic acid 500 mg tablet

Inclusion of Amikacin 250 mg (as sulfate)/ml in 2-ml vial in the Complementary lists of both the WHO Model List of Essential Medicines and the WHO Model List of Essential Medicines for Children.

MSF agrees with all the WHO Global TB Program proposals: the deletion of all the anti-tuberculosis medicines listed above from both the WHO Model List of Essential Medicines (EML) and the WHO Model List of Essential Medicines for Children (EMLc) and the inclusion of injectable amikacin 250 mg/ml in 2 ml vial in the complementary lists of both the EML and the EMLc.

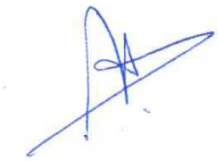
Following the recommendations of the 2017 update of the WHO “Guidelines for treatment of drug-susceptible tuberculosis and patient care”, of the 2020 WHO “Consolidated guidelines on tuberculosis, module 4: treatment – drug-resistant tuberculosis treatment”, and of the 2020 WHO “Operational handbook on tuberculosis”, MSF agrees to delete all the anti-tuberculosis medicines listed above and to include amikacin 250 mg/ml in the complementary lists of both the EML and the EMLc.

All the oral formulations proposed for removal are not child-friendly and MSF supports these removals since child-friendly formulations, preferably dispersible tablets easily dissolved in water or food, are available, reach internationally agreed quality standards, and are listed on both the EMLs.

Amikacin is still recommended for use in longer MDR-TB regimens but classified in Group C medicines (medicines added to complete the regimen and when medicines from Group A and B cannot be used). Considering the need of reconstitution for amikacin powder for injection 100 mg, 500 mg and 1 g, the need to use a large number of vials to reach the required dose with the 100 mg formulation, and no quality-assured formulations of amikacin 1g, the 250 mg/ml in 2 ml vial formulation is the dosage form of choice, in particular for the low- and middle-income countries. Amikacin 250 mg/ml in 2 ml vial is already included in the Access group antibiotics (section 6.2.1), in both the EML and the EMLc.

Therefore, MSF urges the 23rd Expert Committee on the Selection and Use of Essential Medicines to include amikacin 250 mg/ml vial in the complementary lists of both the EML and the EMLc and to delete all the anti-tuberculosis medicines listed in this application from both the EML and EMLc.

For Médecins Sans Frontières



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