

A.24 - Paliperidone palmitate (prolonged release suspension for injection 25 mg, 50 mg, 75 mg, 100 mg, 150 mg) and Risperidone (powder and solvent for prolonged-release suspension for injection 12.5 mg, 25 mg, 37.5 mg, 50 mg).

MSF welcomes the WHO Collaborating Centre for Research and Training in Mental Health and Service Evaluation rigorous and comprehensive review proposing the inclusion of the long acting injectable (LAI) formulations of paliperidone and risperidone, in the WHO Model List of Essential Medicines (section 24.1 Medicines used in psychotic disorders), for maintenance treatment of adults with schizophrenia or related chronic psychotic disorders.

Currently, the WHO Model List of Essential Medicines (EML) includes only fluphenazine decanoate/enantate with a square box (□), as representative of the group of first-generation long-acting antipsychotics, which includes haloperidol decanoate, zuclopenthixol decanoate, perphenazine enanthate, pipotiazine palmitate, bromperidol decanoate, and flupenthixol decanoate. The EML includes also oral risperidone since 2013.

Paliperidone long-acting and risperidone long-acting are two second generation LAIs; paliperidone (9-hydroxy-risperidone) is the main active metabolite of risperidone. Paliperidone must be administered by intramuscular injection 1 time a month, as risperidone must be administered by the same route, but 2 times a month.

The 2020 Inter-Agency Standing Committee's Guidance on Operational considerations for Multisectoral Mental Health and Psychosocial Support Programmes during the COVID-19 Pandemic recommends to “develop a clear strategy for the administration of long-acting antipsychotic medication. This may involve changing the interval of administration to avoid travel during periods of high contagion risk, or administering the medication during home visits instead of at the health facility”.

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

- When the acceptability, efficacy and tolerance of a second generation oral antipsychotic are ascertained for a patient, switching to a second generation LAI is the safer option.
- The prescription of 2nd generation LAI should take into account patient choice as an important aspect of the treatment.

- In low- and -middle income countries, regular clinical follow-up is not easily established and maintained, and the bi-monthly or monthly administration of LAIs can allow optimal medical care for maintenance treatment. Reduced risk of missing daily intake of pills, increasing individual treatment options, better adherence to treatment and ease of control of drug dosage are the main advantages presenting by LAIs.
- While paliperidone long-acting is available in prefilled syringe and can be stored at room temperature (77°F, 25°C) with permitted excursions between 15°C and 30°C (59°F to 86°F), risperidone long-acting requires a reconstitution and cold chain with refrigerated storage (36°- 46°F; 2°- 8°C). If cold chain is not available, risperidone long-acting can be stored at room temperatures not exceeding 77°F (25°C) for no more than 7 days prior to administration. In some low-and middle incomes settings and in humanitarian contexts, these logistical constraints and the need for trained health caregivers may seriously impede the use of long-acting risperidone. In light of these elements, MSF strongly supports the addition of paliperidone with a square box (□), as representative of the group of second-generation LAIs.
- MSF has been using two LAIs in its programs: fluphenazine deacanoate since 2015 and also haloperidol decanoate since 2017. MSF has been using oral risperidone in its programs since 2009 and supported the application for the inclusion of oral risperidone in the EML in 2013.
- The LAI formulation of paliperidone is mainly registered in high regulated countries. Its inclusion in the EML, with a square box (□), will serve as a basis for National Essential Medicines lists and therefore will attract additional manufacturers, will facilitate importations, will alert manufacturers about the need for local registrations, will better allow for competition between manufacturers in order to reduce price and improve accessibility, particularly in low-and middle-income countries, and will give a strong signal to manufacturers, generic producers, country programs, international donors, and health regulatory authorities.

In light of these elements, MSF urges the 23rd Expert Committee on the Selection and Use of Essential Medicines to include paliperidone long-acting with a square box (□), as representative of the group of second-generation LAIs in the WHO Model List of Essential Medicines, for maintenance treatment of adults with schizophrenia or related chronic psychotic disorders.

For Médecins Sans Frontières



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