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C.8 Risperidone – addition of a restricted square box symbol

MSF strongly supports the proposal from the WHO Collaborating Centre for Research and Training in Mental Health and Service Evaluation to add a restricted square box symbol to risperidone indicating that aripiprazole, olanzapine, paliperidone, and quetiapine are valid therapeutic alternatives, in the Section 24.1 “Medicines used in psychotic disorders” of the WHO Model List of Essential Medicines (EML).

Since 2013, risperidone (solid oral dosage form) is included as the only representative of second-generation antipsychotics (SGAs) in the Section 24.1 “Medicines used in psychotic disorders” of the EML.

In 2009 and 2013, MSF has strongly supported the inclusion of risperidone in the EML, for psychotic disorders including schizophrenia, schizoaffective disorder, mania with psychosis, and depression with psychosis.

In 2009, risperidone has been proposed for inclusion together with clozapine, olanzapine, quetiapine, aripiprazole, ziprasidone. The 2009 Expert Committee has rejected this application because of the incompleteness of the literature review and pricing data.

In 2013, the Expert Committee recommended that risperidone solid oral dosage forms should be added to the Core List of the EML without the square box symbol. The Expert Committee added that “it would welcome further applications for additional second-generation (atypical) antipsychotics, based on careful consideration of suitable alternatives or additions to risperidone”.

As pointed out by the authors, recent meta-analytical evidence shows that most oral SGAs are similarly effective and tolerable in both acute and maintenance treatment of schizophrenia and other chronic psychoses.

After a comprehensive review of the best available evidence for efficacy and tolerability of oral SGAs, the authors selected risperidone (already included in the EML), aripiprazole, olanzapine, paliperidone, quetiapine, asenapine, sertindole and zotepine. Risperidone, aripiprazole, olanzapine, paliperidone and quetiapine are currently available as generics in many countries worldwide, have a favorable cost-effectiveness profile, and are currently approved by the largest national and international regulatory agencies for the treatment of schizophrenia.

The authors concluded that asenapine, sertindole and zotepine are not eligible for inclusion on the EML, due to their unavailability in some countries and/or regulatory issues. Aripiprazole, olanzapine, paliperidone, and quetiapine did not show clinically relevant differences of efficacy and acceptability compared to risperidone for both acute and maintenance treatment and they are therefore considered as valid therapeutic alternatives to risperidone, which should be maintained in the EML with an additional restricted square box.

MSF guidelines recommend risperidone or olanzapine for the treatment of acute or chronic psychosis and acute manic episode, in the event of intolerance or treatment failure with other antipsychotics (preferably using haloperidol for these indications).

MSF has been using risperidone since 2009 and olanzapine since 2017 in its programs.

MSF urges the 24th Expert Committee on the Selection and Use of Essential Medicines from the WHO Collaborating Centre for Research and Training in Mental Health and Service Evaluation to add a restricted square box symbol to risperidone including aripiprazole, olanzapine, paliperidone, and quetiapine as valid therapeutic alternatives, in the Section 24.1 “Medicines used in psychotic disorders” of the WHO Model List of Essential Medicines.



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