### Summary of evidence and Expert Committee recommendations

The Expert Committee received two applications to include risperidone in the WHO Essential Medicines List, as follows: The Mount Sinai School of Medicine, Program in Global Mental Health, New York, NY, USA, proposed the inclusion of the second-generation antipsychotic risperidone formulations in the core and complementary EML and EMLc. Massachusetts General Hospital, The Chester M. Pierce MD Division of Global Psychiatry, Boston, MA, USA, (Young Professionals Chronic Disease Network) proposed the inclusion of the second-generation antipsychotic risperidone in the core EML. Expert reviews were prepared by Mr Andrew Gray and Dr Kuruvilla Prasad Mathews. Comments were received from Dr Shekar Saxena, Director, Mental Health and Substance Abuse, WHO and Dr Myriam Henkens, International Medical Coordinator, Médecins Sans Frontières.

An application to add risperidone to the EML was first made in 1998. At that time risperidone had been available for only four years and it was still under patent and was expensive. A second application was made in 2009 several years after generic products of risperidone had become available but was rejected because of the incompleteness of the literature review and pricing data. It is estimated that some 41.7 million people need treatment for schizophrenia and related disorders in low- and middle-income countries. The majority of these cases are in Asia (70%) and Africa (16%) (1). Schizophrenia is a significant contributor to the global disease burden, accounting for 1.1% of disability-adjusted life-years lost (2). The Mental Health Gap Action Programme Intervention Guide published by WHO in 2010 (3) has three antipsychotics (haloperidol, chlorpromazine and fluphenazine), all of which are currently in the EML. The intervention guide states that, if the responses to these medications are inadequate, providers may choose to treat patients with a second-generation antipsychotic, if available and affordable. An excerpt from the guide states: “If the response is inadequate to more than one antipsychotic medication using one medicine at a time at adequate dosage for adequate duration ... consider second-generation antipsychotics (with the exception of clozapine), if cost and availability is not a constraint, as an alternative to haloperidol or chlorpromazine.” A 2010 Cochrane review of 23 randomized controlled trials including 4445 patients found risperidone to be more effective than typical antipsychotics in treating schizophrenia and schizoaffective disorder (4). On the basis of pooled data from nine randomized controlled trials, risperidone was more likely than haloperidol to produce clinical improvement in the short and longer term. Another more recent Cochrane review found that...