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To: 23rd Expert Committee on Selection and Use of Essential Medicines

Subject: Comments on the Application a24 for the addition of (a) risperidone long-acting injection and (b) paliperidone palmitate 1-month (PP1M) long-acting injection to the EML core list of section 24.1 "Medicines for mental and behavioral disorders >> Medicines used in psychotic disorders", with the indication of maintenance treatment of adults with schizophrenia or related chronic psychotic disorders.

Dear Expert Committee on Selection and Use of Essential Medicines,

Janssen, the innovator Company of risperidone and paliperidone, has reviewed the above-mentioned application and fully supports the addition of long-acting injectables of risperidone and paliperidone to the WHO Model List of Essential Medicines (EML). It is recognized that the application presents a comprehensive case based on the extensive available data to support the inclusion of the risperidone long-acting injection and paliperidone palmitate 1-month long-acting injection (PP1M) to the EML. Our review comments on the application are provided below.

1. Addition of Paliperidone Palmitate Long-Acting Injection

Janssen would like to provide additional relevant information on paliperidone palmitate 3-month long-acting injection (PP3M) to allow for potential EC evaluation of addition of this formulation on the EML. The PP3M formulation is widely available and can provide a valuable option for the maintenance treatment of schizophrenic adult patients who are clinically stable on the 1-monthly paliperidone palmitate injectable product.

- PP1M and PP3M are closely related products and currently approved in 103 and 91 countries, respectively, including the United States, European Union, Japan and African countries like Ghana and South Africa. Achieving stability for at least 4 months of PP1M is required before switching patients to PP3M. Treatment with PP3M involves only 4 injections per year. Since its launch, more than 1.3 million treatment courses of PP3M have been dispensed globally.

- Long-acting formulations are designed to achieve continuous drug delivery over extended periods of time. Paliperidone palmitate 3-month injectable is commercially available as a prefilled syringe not requiring refrigeration and provides treatment advantages of longer cycle duration, longer half-life, and greater protection from relapse after sudden discontinuation. Clinical data suggests that PP3M, on average, protects patients from relapse for a median time of 274 days after a single dose.

- Paliperidone palmitate 3-month injectable assists disadvantaged patients such as those who have limited access to psychiatric care, those who cannot coordinate frequent travel, and those who are homeless or from underserved populations. In addition, PPM3 also offers less frequent visits to the pharmacy, and fewer injections.

- During times of a global pandemic such as COVID-19, PP3M minimizes patients' contact with healthcare professionals and hospital systems and reduces healthcare burden and transmission of communicable disease.

The detailed proposal, together with the clinical efficacy and health economics data, is summarized in the Annex 1: Supportive data to include Paliperidone Palmitate 3-Month Long-Acting Injection for the Maintenance Treatment of Adults with Schizophrenia to the WHO Essential Medicine List. Janssen believes that the provided information can sufficiently support the addition of the PP3M on the WHO EML.

2. Available dosage strengths of Risperidone long-acting injection

RISPERDAL CONSTA is currently licensed in 59 countries. RISPERDAL CONSTA is available in dosage strengths of 25 mg, 37.5 mg, or 50 mg for a maintenance dose. A 12.5 mg dose is used as titration/starting dose only and is currently available in the US and Canada.

Please let us know if you have any additional questions.

Yours sincerely,

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