### Summary of evidence and Expert Committee recommendations

In 2009, the EMLc Subcommittee considered the review of medicines for palliative care commissioned by the Secretariat to ensure that appropriate medicines for the pharmacological management of the most prevalent and distressing symptoms in children with life-threatening and life-limiting conditions worldwide are included in the EMLc. The Subcommittee noted that malignancy and HIV/AIDS were identified as the most common causes of childhood mortality appropriate to palliative care worldwide and that the 10 most frequent symptoms and symptom clusters (fatigue and weakness, pain, anorexia and weight loss, delirium and agitation, breathlessness, nausea and vomiting, constipation, depression, excess respiratory tract secretions and anxiety) had been identified based on available data. The Subcommittee noted that the evidence to support efficacy and safety of medicines used in the management of these symptoms was generally weak and therefore, several recommendations in the proposal were based on experience from clinical practice. To ensure appropriate first- and second-line management of nausea and vomiting due to different pathophysiological mechanisms, the proposal suggested that antiemetics with different mechanisms of action are required. The review proposed the following medicines: cyclizine (tablet: 50 mg; injection: 50 mg/ml), an antihistaminic antimuscarinic antiemetic that is effective for vomiting centre-mediated nausea and vomiting and levomepromazine (tablet: 25 mg; injection: 25 mg/ml) for chemo-receptor trigger zone-mediated nausea and vomiting. Although there is a lack of documented data on efficacy and safety, these two medicines are currently being used for this indication in some developed countries. Availability, especially of levomepromazine, may be a problem in many parts of the world. On balance, given that there is substantially more experience with the use of cyclizine, the Subcommittee recommended that it should be added to the EMLc in the dosage forms recommended specifically for use in palliative care. The Subcommittee considered the general principle of whether medicines listed for palliative care should also have indications of age restrictions. On the one hand, it was noted that for several of the medicines added to the EMLc in this section evidence of efficacy and safety at all ages was not available. Specifically: — cyclizine is not licensed for use in children under 6 years; — docusate sodium is not licensed for use in children under 6 months; — senna is not licensed for use in children under 2 years. The Subcommittee considered that the licensed indications may not always reflect existing evidence, and
also noted the importance of access to these products for children in need of palliative care, and therefore decided not to indicate age restrictions on the use of these products for this purpose.