### Summary of evidence and Expert Committee recommendations

The WHO Department of Child and Adolescent Health and Development commissioned a review of the evidence of potential benefit of prophylactic/routine administration of vitamin A to neonates and infants younger than six months, with a view to updating the current recommendations about its use. The proposal to delete the 50 000 IU formulation currently on the EMLc arose from the results of the review. Expert comments were provided by Dr Stuart MacLeod and Dr Robert Petersen. The two reports, (1) provided as confidential drafts to the Subcommittee, were the manuscript version of the systematic review of neonatal vitamin A supplementation (2) and the report to WHO on the benefits and safety of vitamin A supplementation in the first six months of life (3). Both are comprehensive systematic reviews and both found that the existing evidence shows no benefit of routine supplementation in terms of mortality or morbidity in these age groups. The Subcommittee noted that administration of this drug to young infants has been associated with an increased occurrence of bulging fontanelle. Five additional Cochrane Reviews were identified examining administration of vitamin A to other subgroups of children: low birth weight infants, children with cystic fibrosis, children with measles, for prevention of lower respiratory tract infections, and non measles pneumonia in children under seven years of age (4-8). In low-birth-weight children, most studies reported use of intramuscular vitamin A. There was a trend towards benefit in terms of survival and reduced oxygen requirement, but most of the outcomes analysed were not statistically significant. No studies were identified in the review of cystic fibrosis. In the review of treatment of measles, vitamin A was administered at doses of 100 000 or 200 000 IU and was found to reduce mortality. The reviews of non-measles pneumonia and lower respiratory tract infections found no evidence of benefit of vitamin A supplementation in children under seven years of age.
The EMLc Subcommittee considered that there was no clear need for a 50,000 IU oral dose for routine prophylaxis against vitamin A deficiency during the first six months of life. The 50,000 IU dosage form is also not appropriate for routine supplementation in children over six months of age for whom the recommended dose is 100,000 or 200,000 IU. Therefore, the only potential use for the low-dose capsule would be for the outpatient treatment of clinically proven vitamin A deficiency in neonates and infants under six months of age; a condition that is exceedingly rare. The Subcommittee recommended that the 50,000 IU dosage form be deleted from the EMLc.

References:
2. Gogia S, Sachdev H. Neonatal vitamin A supplementation for the prevention of mortality and morbidity in infancy: systematic review of randomized controlled trials 2008. New Delhi, Department of Paediatrics and Clinical Epidemiology, Sitaram Bhartia Institute of Science and Research. (Manuscript under review for publication).