5. Debendox: Paper 3

5.1. This paper sought the Committee's advice on the significance of two animal teratogenicity studies and an application to vary the product licence of right. The two studies were of doxylamine Succinate/ Bendectin in rats and mice, and crab-eating macaque monkeys respectively. The SEAR Sub-Committee at its meeting on 12 February 1982 had recommended that expert opinions should be sought. It had been possible in the interval since SEAR met to obtain the advice of [redacted] and this was reported verbally by [redacted]

5.2. [redacted] considered that no conclusions could be drawn from the studies. In the monkey study, the foetus had probably been sacrificed too early, so that heart development was not complete. The rat and mouse study gave insufficient information; in particular the question of distribution of diaphragmatic hernia between litters, and whether there were sub-mucocutaneous cleft palates. In the light of this advice it was agreed that these studies did not give cause for concern and the Committee saw no reason to alter their previous advice, namely that there was no scientifically acceptable evidence that Debendox caused harm to the foetus. As a precaution it was agreed that the views of one more outside expert should be sought and it was agreed that copies of the studies should be sent to [redacted]

5.3. On the application for variation the Committee endorsed the recommendation of SEAR that consideration of the application should be deferred, and that the company should be asked to provide the full report of the 8-way efficacy study which led to the removal of dicyclomine hydrochloride from the US formulation. The Committee agreedthat this study should be examined initially by [redacted] with a view to assessing the efficacy of the 2-ingredient formulation in relation to the existing product. In the event that this assessment raised doubts about the comparative efficacy of the two ingredient formulation, the matter would be referred back to SEAR.

Redacted under section 40 of the FOI Act