

8. DEBENDOX (TABLED PAPER 7)

8.1 This paper was a follow-up to that considered by the Committee at its meeting in November. Since that meeting, the Secretariat had had discussions with the company, in the light of which the licensing authority had modified its proposed data sheet amendments.

8.2 The Committee endorsed the modified proposals and agreed that the following paragraphs be inserted in the data sheet;

"There have been a large number of epidemiological studies of Debendox. Although there have been some reports of congenital malformations associated with its administration in early pregnancy, a causal relationship has not been established".

"For no medicinal product can a small risk of a teratogenic effect be excluded with absolute certainty and so the use of any drug in early pregnancy should be avoided if at all possible".

8.3 It was agreed that if the advice of the Committee was unacceptable to the company, the Secretary should advise the company of the proposal to vary the product licence and product particulars in accordance with Sections 28 and 29 and Schedule 2 of the Medicines Act 1968.