5. DEBENDOX PAPER 2

5.1 Members considered a proposal from the Licensing Authority to amend the Data Sheet of Debendox (and if necessary the product licence) as follows:

"Many drugs have been suspected of being capable of affecting the normal development of a child in the early stages of pregnancy. Much evidence suggests that in relation to antiemetics such a suspicion is ill-founded but it has to be accepted that for no medicinal product can a teratogenic effect be excluded with absolute certainty. The use of any drug in early pregnancy should therefore be avoided if possible".

They also considered the recommendation of the Adverse Reactions Sub-Committee to amend the data contained in Paper 1 and 5 additional papers relating to the question of the teratogenicity of Debendox which had become available since the Committee considered the matter in April 1980.

5.2 In the light of their discussion Licensing Authority agreed to amend its proposal as follows:

"Although there have been some reports of congenital malformation associated with the administration of Debendox in early pregnancy a causal relationship has not been established.

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

5.3 The Committee endorsed this proposal but recommended that the secretariat should in the first instance approach the company to see if they were willing to amend their data sheet on the lines of this proposal. If however the company were unwilling to do so the Committee instructed the secretary to notify the company under Section 28(1) and Schedule 2 of the Medicines Act 1968 that they may have to advise the Licensing Authority to vary the Licence and product particulars in accordance with the terms of the proposal set out in this paragraph.