

10. MECLOZINE, "DEBENDOX" AND CONGENITAL MALFORMATIONS (PAPER 2)

10.1 This paper had first been considered by the TCT Sub-Committee who had recommended that all available data relative to a possible association of foetal abnormalities with the use of Meclozine and Debendox should be collated and that [REDACTED] opinion should be sought on the matter.

10.2 The Committee noted that Debendox was indicated<sup>only</sup> for vomiting in pregnancy and that they had always taken the line that drugs should not normally be used by pregnant women. They endorsed the views of the Sub-Committee and agreed that <sup>all</sup> necessary information including that on teratology should be sought from the manufacturers and [REDACTED]. They also asked that the views of the Sub-Committee on Adverse Reactions should be sought.

10.3 During the course of the discussion on the matter [REDACTED] was asked to outline an idea which [REDACTED] had mentioned to the Chairman, ie that if there were insufficient evidence to justify removal of a product from the market but some control of prescribing seemed desirable,

it might be possible to achieve this through Section 62 of the Medicines Act 1968. One way might be to make it a requirement for doctors to mark prescriptions they made out for such products to indicate that they were aware of the warnings issued by the Committee. Pharmacists would be obliged not to dispense the prescription if it were not so marked. The Committee expressed interest in this idea but noted that it might be resisted by the profession.

Redacted under  
section 40 of the FOI  
Act