

- 2.1 The Committee were not reassured by the additional data submitted by the company with regard to:-
- i. the clinical value of this type of preparation;
 - ii. the efficacy of the product itself, as presented, which it was proposed to market;
 - iii. the efficacy of this type of preparation in the wide range of indications requested in the application.

The animal and clinical data presented for the product it was proposed to market were considered to be inadequate.

- 2.2 The Committee were not reassured that the proposals made by the company to reduce the risk of transmission of non-A non-B hepatitis would be sufficient to render the product safe for use in the wide range of indications proposed. If the product were shown to be efficacious in a severe, life-threatening indication, the degree of risk might be considered acceptable for such use only. Clear warnings would be required in the Data Sheet and product literature.

The Company do not wish to administer the product by means of a spraying device.

- 2.3 The Committee were not reassured by the additional data submitted by the company with regard to the risk of sensitisation to bovine antigens.

3. ADVICE

On the evidence before it and having considered the information submitted by the Company, the Committee advised that on grounds related to safety and efficacy the Product Licence applied for should be refused.

4. REASONS FOR ADVICE

- 4.1 The clinical value of the product had not been established.
- 4.2 The efficacy of the product had not been demonstrated.
- 4.3 The efficacy of the product for the indications had not been demonstrated.
- 4.4 Inadequate animal and clinical data had been provided.
- 4.5 Inadequate data had been provided to establish the safety in use of the product from the risk of hepatitis.
- 4.6 Inadequate data had been provided to establish that the product was safe from the risk of sensitisation to bovine antigens during use.

6. COMMENT TO APPLICANT (ARISING FROM COMMENT TO LICENSING AUTHORITY)

Inadequate information had been supplied on thrombin by the manufacturer (MILES LABORATORIES).

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