

COMMERCIAL IN CONFIDENCE

BSE - CURRENT POSITION WITH VETERINARY LICENCED PRODUCTS (MA.1968)

There are three areas of particular concern, vaccines (including emergency vaccines), pharmaceuticals which are covered by MA licences and unlicensed hormonal products produced under exemptions claimed under (Section 9(2) Medicines Act).

1) Vaccines The B P & S Department report that the draft guidelines (Appendix I) have been sent to NOAH, NIBSC and the DHSS for comment. Two companies so far have replied, but discussions are underway with others and serum suppliers are also being contacted - Oxoid is coming on 5.10.88. to clarify the situation. Communication has been also made with Emergency vaccine manufacturers. The impression is that vaccine companies are working hard to exclude bovine and ovine ingredients of UK origin.

2) Pharmaceuticals Appendix 2 summarises the actions taken. Essentially hormone products and products containing potential ingredients of concern, ie liver, pancreas were identified. To ensure that all companies are aware of the BSE problem. It will be necessary to insert a note in MAIL.

Pharmaceuticals are viewed as a lower risk than vaccines.

3) Unlicensed F.S.H. Production

Appendix 3 gives a list of veterinary surgeons and others who were thought to produce follicle stimulating hormone from bovine/ovine pituitaries and whether they actually do so. The Medicines Unit has written to the Veterinary Record (July 1988) and to each veterinary surgeon (23.8.88). on the subject of avoiding the use of bovine/ovine tissue. From Appendix 3 it can be seen that in only 1 case is bovine material used, in 1 case there is a question mark and another no answer can be obtained. Dr R Brittain has not been traced.

Conclusion - The most important action to take is to write to all veterinary companies re BSE and also to circulate the Universities and Institutes with advice which will help them in formulating products for possible licensing.

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MEDICINES UNIT
6.10.88.

88/10.06/5.1

Dr Little

cc Mr Gray
Mr Gooding

Mr Gooding - you will wish to see the results of action so far. I think the next steps are to agree (if not already the BSE guidelines for pharmaceuticals) and write to Licences with an article in the MAIL on pgs X & Y. If you are content I

file from left of clinic next steps with re. general statement in NB to be shown suffice. 12.10.88 if any home medicine guidelines now available you will. This