

CONFIDENTIAL

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BOVINE SPONGIFORM ENCEPHALOPATHY

This minute details the information received on human vaccines in response to telephone enquires, and details of forthcoming expert group meetings during February 1989.

Vaccines

We have contacted all the major vaccine product licence holders whose products are likely to be used in children. Many manufacturers use bovine material. As can be seen, this information is diverse and incomplete. Each company stressed that they could not give an accurate assessment without detailed researches, given the complexity of sourcing/purchasing arrangements.

All the licences are detailed in appendix 1; the overview is as follows:

1. have polio, measles, mumps, rubella, rotavirus vaccines. All use bovine serum from a UK source and bovine commercial product from unknown source. Some agent comes from the USA and New Zealand.
2. gave us most information (see Appendix 2). All their vaccines apart from yellow fever, cholera and typhoid contain bovine material:
 - Oral polio; up to 1988, foetal calf serum was used from UK and New Zealand (pooled); since 1988 foetal calf serum only from New Zealand. Large stocks are held.
 - Rubella; bulk was made before 1979 from foetal calf serum from UK and New Zealand. None has been made as there are some 15 years stock.
 - Diphtheria; UK bovine beef muscle and ox heart is used but since the end of 1988 this has been sourced from Eire. There are 1,250 litres of stock.
 - Tetanus; this involves bovine material from the UK mainly Scottish. There are 21,000 litres of stock.
 - Pertussis; uses bovine material from the UK. There are 63,000 litres of stock.
 - They consider that to switch to a non-UK source will take a minimum of 6-18 months and to switch to a non-bovine source will take a minimum of five years.
3. have measles, mumps, MMR, rubella vaccines. These are sourced from the USA and the company believes that US material only is used.

4. _____ have a measles vaccine using bovine serum from the UK. There are 440,000 units of stock.
- They have also got MMR using bovine serum from the UK.
5. _____ have influenza, rubella, measles, MMR vaccines likely to be used in children. Of those they think that only MMR contains bovine material which is probably a French origin.
6. _____ have diphtheria/tetanus and potasses on clinical trial in the MRC study. These use veal material, some of which has come from the UK and has been made by Wellcome (see above).
7. _____ have influenza vaccines which are made up in egg medium.
8. The Secretary of State has a number of licences. We understand that the inactivated polio vaccine is no longer being used. There is a stock of smallpox vaccine. We have not been able to determine the source material. (Made in sheep very unlikely to contain certain bovine ingredients).
9. _____ have acellular triple vaccine in which material of UK bovine source has been used.

As far as I can see, _____ are the sole supplier of pertussis vaccine which uses bovine casein digest.

You should also be aware that DH has made arrangements for meningococcal vaccine to be available, on a named patient basis, from _____ and _____. Both companies use bovine media in production.

Expert Group Meetings

The Veterinary Products Committee will discuss the proposed draft guidelines and significance thereof to veterinary vaccine products at 2.00pm on Thursday 16 February 1989 with Professor Armo in the Chair. (See appendix for VPC Committee constitution).

The Human & Veterinary Medicines Working Group re BSE will meet on 22 February at 10.00am Market Towers. The meeting will be to provide expert information to CSM on the 23 February in the light of the Southwood report and concerns about vaccines. In addition to Department of Health and MAFF officials, Professor Collee, Dr Schild, Dr Minor, Dr Tyrell from the Biologicals Subcommittee will be present, Dr Kimberlin and Dr Martin and Mr Wilesmith have been invited. Professor Collee will be in the Chair.

The Committee on Safety of Medicines will meet on the 23 February. They will consider advice from the working group, draft guidelines for the industry, a draft letter to product licence holders of human medicines, and recommendations regarding priority actions on particular product groups.

MAFF briefing note is added at Appendix 6.



DR P N ADAMS

Appendix 1

APPENDIX 1

Bovine material
UK source
Some USA + NZ

See Annex

No further material

See Annex

Probably bovine material
Sourced from USA Definite

? no bovine material

Bovine serum - UK - for 5 years

Bovine material - ? French source
} ? No bovine material

Probably Swiss natural ? French

Veal word in Dip Test
(Mollusca survey)
UK bovine

Eggs Atlantic mackerel

?
? Natural stork
Probably bovine ? source [Swiss Manf.]

? Natural stork

?

David Bruce Laker - ? altered

?

? At end source

? No source

- Bovine material ? source

? No source

Probably bovine material ? source

Adelena dip. Tet
- bovine source