3. Initial response on veterinary medicines

Introduction

3.1 This chapter traces the story of how MAFF reviewed and responded to the implications of BSE for veterinary medicines from the time the disease emerged up to 3 January 1989, when it had its first meeting about this with DH to discuss joint handling.

Use of animal materials prior to the emergence of BSE

3.2 Prior to the emergence of BSE, the use of substances of animal origin in the manufacture of veterinary vaccines had been the subject of general guidance contained in a Medicines Act Leaflet (MAL 67), published in June 1983. We were told this was the most recent of a series of guidance notes influenced by an earlier incident in which scrapie had been disseminated via a louping-ill vaccine, in which brain and spleen tissue from scrapie-infected sheep had been directly incorporated.

3.3 In the section headed ‘a guide to current practice’ MAL 67 said:

Restrictions are placed upon the use of substances of animal origin in order to minimise the risk associated with pathogens which may be present in these materials. Unless there is a risk from a heat-resistant pathogen such as the scrapie agent, no restrictions are placed on substances sterilised by autoclaving provided that the complete mass is held at a minimum of 115°C for at least 15 minutes. Restrictions on the use of substances that cannot be sterilised by autoclaving vary according to the target species, the species of origin, the country of origin and whether the substance undergoes at any stage treatment which will inactivate contaminating agents.

In practice this meant that cattle tissues were used instead of sheep material.

Consideration of BSE in MAFF from January 1987 to March 1989: a chronological account

3.4 In vol. 3: The Early Years, 1986–88 we consider the initial reaction within MAFF to the outbreak of BSE. In this chapter we focus on this initial response as it related to veterinary medicines. Dr Little, Deputy Director of the Central Veterinary

152 YB83/6.00/1.1–1.5
153 S477 Armour para. 8(b)
154 YB83/6.00/1.3
155 YB88/6.21/4.1, YB90/5.24/6.2
Laboratory (CVL), told us that he believed he first heard of BSE in January 1987 from Dr Watson and Dr Shreeve at the CVL and started thinking about its potential to contaminate biological products in about May 1987. He thought that although Mr Kidd and Dr Thornton, heads of the Medicines Unit and the Biological Products and Standards Department (BP&S) respectively, would certainly have been aware of the existence of the disease, they and their teams were likely to have had very little knowledge of BSE at that point. Dr Little told us that knowledge ‘was fairly contained within the research groups’ and ‘people tended to work in specific areas . . . if they did not work within that area, their interest would have been academic rather than immediate and professional’. There was also a desire to keep the information on BSE ‘fairly tight’, which extended to not disseminating even within CVL.

3.5 Mr Kidd told us that by 1987 (although he could not recall exactly when) he first became aware of the existence of BSE through informal and indirect contacts with CVL staff in the Pathology and Epidemiology Departments. He said that progressively during 1987, CVL staff ‘started to discuss informally the potential of BSE to contaminate immunological products’. Certainly he was involved from 15 June onwards when Mr Wilesmith, the CVL epidemiologist investigating the disease, sent him a minute asking about toxicity tests on a veterinary spray used on cattle on three farms where BSE had been identified. At this stage Mr Wilesmith had not ruled out the use of therapeutic pharmaceutical products and vaccines as a possible source of the disease, although by January 1988 he concluded that the use of therapeutic chemicals ‘presented no common factors’ among cases of BSE (see vol. 2: Science).

Meeting of the Biologicals Sub-Committee of the CSM on 9 September 1987

3.6 On 9 September 1987 Dr Little attended a meeting of the CSM/BSC, the agenda of which included consideration of a product in respect of which the risk of CJD transmission was a concern because it was composed of human dura mater (one of the membranes enclosing the brain and spinal cord). Dr Little gained the impression from this meeting that DH was aware of BSE and conveyed that to his MAFF colleagues. The events surrounding this important meeting are discussed in detail in Chapter 4 in the context of our review of the early response to BSE in respect of human medicines.

3.7 Some time after that meeting, and after publication in the Veterinary Record in October 1987 of a paper by Mr Wells on BSE, Dr Little mentioned BSE informally to Professor Armour, chairman of the VPC, in a routine briefing before a VPC meeting. He told us in oral evidence that he could not recall whether...
Mr Wells’s article in the *Veterinary Record*, which was the first published article to confirm that this novel disease was a spongiform encephalopathy, had prompted the discussion. Dr Little informed Professor Armour that MAFF was aware of the potential dangers associated with BSE and that ‘work had commenced within the two departments [MAFF and DH] to put together an assessment’.  

### December 1987 to February 1988

**Biologicals Committee considers BP&S paper**

3.9 In December 1987 Mr Luff provided his paper for consideration by the BC. The paper seems to us to have summarised thinking about BSE within BP&S at CVL at that time, and we quote from it extensively. Mr Luff saw three alternative approaches to containing the threat:

i. Nothing derived from cattle should be permitted unless it had undergone an inactivation process. However, this would ‘effectively stop the use of bovine serum and cell cultures in vaccine production and the use of therapeutic bovine anti-serum. Serum albumin will also be adversely affected.’

ii. Tracing techniques should be adopted to designate acceptable sources for bovine products. However, Mr Luff thought this was an unusable approach because of the changing picture ‘even if sufficient data were available’.

iii. Risks should be assigned to particular products or groups of products and action taken against them as necessary in the light of the knowledge about the scrapie agent in natural and experimental hosts. As a general rule the harvesting of any substance from suspected or confined cases should not be allowed.

3.10 We note here Mr Luff’s concern about animal vaccines and their production methods, which later were to cause so much concern in the case of human medicines. Annex 2 to Chapter 2 explains briefly the ways in which bovine materials are used in vaccine production.

3.11 On the basis that only the third option was viable, Mr Luff examined products that might be contaminated with infectious agents:

- a) **SERUM AND SERUM PRODUCTS**: There is no evidence that serum from scrapie infected animals contains any infectious agent, although many

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169 S477 Armour para. 6; S331 Little 1 p. 3; T99 Little p. 81
170 T99 p. 82
171 S331 Little p. 3
172 T99 p. 83
173 YB87/12.00/1.1–1.3
174 YB87/12.00/1.1–1.3
175 YB87/12.00/1.1–1.3
attempts have been made. It seems reasonable to assume that the use of these substances is not associated with a risk of BSE agent contamination. It may not be unreasonable, though, for manufacturers to use for anti-serum production only animals with the lowest risk of exposure to the BSE agent. At the present time this means those derived from suckler herds not feeding concentrates, and with no history of contact with BSE.

b) OTHER TISSUES: Tissue distribution of scrapie infectivity is uneven. Maximum titres occur in neural and ‘lymphoid’ tissues. Lower amounts occur in placenta, salivary and adrenal glands, pancreas, liver (from work in sheep and goats), lung, kidney, intestine and uterus (from additional work on mice). The use of these tissues should be firmly discouraged. If such use is necessary, then the product should be treated as 1 above. [ie, subjected to an acceptable inactivation process.]

Traces of scrapie agent have also been isolated from muscle late in the incubation period of the disease. This constitutes a smaller risk, given the low titre and short duration of its presence. A single cycle of 126 C for 30 mins is probably adequate treatment for such products, which tend to be the somewhat diverse ‘peptones’ used in bacteriological media and sometimes as freeze-drying stabilisers.

There are two special cases to consider – hormones and similar extracts, and cell cultures.

HORMONES etc. Although the extraction processes involve the use of various organic solvents, which tend to have a deleterious effect on scrapie infectivity, extracts must be considered to be potentially contaminated – indeed Creutzfeldt-Jakob disease has been transmitted by the use of human growth hormone extracted from cadaver pituitaries. It is therefore not possible to regard bovine gland extracts as deserving special consideration; they must be autoclaved as above. Such products are not likely to be effective after such treatment. The use of pituitary extracts for super-ovulation is not apparently controlled under the Medicines Act. This is an anomaly which requires urgent reconsideration.

CELL CULTURES: Primary cell cultures could transmit an unconventional agent mechanically. Their use should not be permitted. Given the probability of vertical transmission, it is not possible to set up ‘SPF’ [specific pathogen free] herds to get around this problem. Cell lines are a different matter. No unconventional agent has been grown in cell culture. It seems reasonable to assume that the agent of BSE will not replicate in cell cultures either. There is also no evidence that whatever constitutes a ‘genome’ in these agents can integrate into host cell genome, so the danger in the use of cell lines is again one of mechanical transmission. With the number of passages required to produce a validated cell line there seems to be no real need to impose any general BSE-related requirements. This is, of course, a theoretical argument. Given that the risk, regardless of its absolute size, will be related to the degree of contamination of the original tissue, the use of cells derived from tissues that could carry a high burden of infectivity (neural and ‘lymphoid’) should not be allowed.
c) SECRETIONS and EXCRETIONS: Scrapie agents have not been isolated from any natural secretions or excretions. This includes saliva, milk, urine and faeces. It seems reasonable to regard these materials as not constituting a BSE-related risk. However, it is assumed that one way that scrapie is spread is through the ingestion of infected placentae, with the agent passing through the gut and being excreted in faeces. It may be possible to question the use of bovine faeces, or at least products derived from them. This has implications for lung worm vaccines. Calves, though, are not major consumers of placentae, and they are maintained in quarantine for a period before use, so there doesn’t seem to be an appreciable risk.

The situation with bile may not be so straightforward. I don’t know that bile has ever been looked at for scrapie infectivity. One could argue that the absence of agent in faeces suggests that it isn’t present in bile, but there must be a considerable dilution effect. It is probably better to err on the safe side and require a single 126°C, 30 min cycle for this substance.

d) OVA and SPERM: The situation here is uncertain, but of no direct concern for biological products in Medicines Act terms. However, the areas of AI and embryo transfer require some investigation.176

3.12 Mr Luff’s paper was briefly discussed at the BC meeting on 6 January 1988177 and an amended version considered at the next BC meeting on 3 February 1988, chaired by Mr Kidd.178 The minutes of this later meeting recorded:

7.4 The paper outlined three options:

1. All vaccines containing bovine products should be heat treated for 2 cycles of 126°C for 30 minutes. This was considered a severe untenable option as it would affect virtually all product licence holders.

2. Vaccine manufacturers would only use bovine products from herds certified as free of clinical disease.

3. All bovine tissues should be assigned to different risk groups and each group would be treated separately . . . The suggested groups were based on work that had been generated using the scrapie agent. There was concern about the use of brain, neural and lymphoid tissue and pituitary. (It was noted with concern that hormone extracts could be manufactured by a veterinary surgeon for administration to animals under his care without any Medicines Act control). Use of these products should be discouraged. Conversely serum products were considered to be of little concern.179

3.13 While some of the Committee thought the second option was satisfactory, others preferred the third. After considerable discussion it was agreed to take no action at that time, but to review the situation again in six months, unless urgent action was required before then. It was also agreed to inform senior MAFF staff of these conclusions and to assess whether certification of clinically disease-free animals was feasible.180
Dr Little told us that over the following months discussions were held with staff of the National Institute for Biological Standards and Control (NIBSC), leading to arrangements by Dr Minor for a meeting at NIBSC, which took place on 16 May 1988. We discuss this meeting in Chapter 4.

June to July 1988

Further consideration by the Biologicals Committee

The BC next considered BSE on 7 June 1988, at which time it noted that the disease was shortly to become notifiable. The Committee agreed that the BP&S paper by Mr Luff should be re-examined and a set of guidelines drawn up for the industry by Mr Geoff Wood, a veterinarian with the CVL. Medicines Unit, BP&S and CVL experts on the disease would meet as soon as possible to discuss guidelines.

No time was lost. The next day Dr Little chaired an ad hoc CVL meeting to discuss the implications of BSE for biological products containing bovine extracted material. Taking scrapie as the model, the high-risk tissues were considered to be brain, spinal cord and lymphoid tissues, although the use of any bovine-derived tissues was considered to be of some risk. The greatest concern of those present was the use of pituitary gland products.

It was agreed that Medicines Unit should prepare a paper to advise Animal Medicines Division on the course of action to be taken. It was also agreed that BP&S should draw up a full list of all the tissues involved in biological products and that Medicines Unit would produce a list for pharmaceutical products. A chart of risk assessment should be made for each of the tissues in relation to the products, together with appropriate treatments for each tissue.

Finally, the meeting recommended that some form of guidance should be given to companies at the next meeting with the trade association for animal medicine manufacturers, the National Office of Animal Health (NOAH), on 11 July.

Immediate action on Pituitary Hormones

As we noted above, concerns about the use of pituitary gland products had been expressed by Mr Luff in his paper and by the BC in February and again in June. Mr Luff had drawn attention to the role of hormones extracted from human pituitary glands in transmitting Creutzfeldt-Jakob disease (CJD) in man. Furthermore, as part of its programme of work reviewing all products with licences of right, MAFF was at this time reviewing products containing hormones with a view to issuing a guidance note.
3.20 One of the concerns was the use of gonadotrophin, extracted from the pituitary gland in the brain and used to stimulate super-ovulation for embryo transfer techniques: see vol. 12: *Livestock Farming*. Sections 9(2) and 55(3) of the Medicines Act\(^{190}\) exempted from its licensing requirements products specially prepared by a veterinary surgeon for administration to an animal or herd under his or her care. Because of this exemption, there arose the possibility that bovine pituitary extract was being used outside Medicines Act controls by individual veterinary surgeons for specific animals.\(^{191}\) As we understand it, the normal practice was to extract material from a pool of pituitary glands collected from abattoirs, by a process unlikely to destroy the BSE agent.\(^{192}\) Mr Wilkes, head of Animal Medicines Division until October 1988, told us that at the time in question the procedure was used only to a very limited degree in the dairy cattle breeding industry.\(^{193}\)

3.21 Following the BC meeting, Dr Little sent a minute to Mr Kyle (Assistant Chief Veterinary Officer (ACVO), Communicable Diseases), asking what action could be taken regarding the preparation of gonadotrophin from pituitary glands.\(^{194}\) Dr Little suggested that other existing medicines legislation might cover the procedure and referred to the Foot and Mouth Disease (Sera and Glandular Products) Order (which required permission from MAFF to use glandular extracts or sera in ruminants\(^{195}\) and EC Directive 81/851/EEC.

3.22 A round of correspondence ensued regarding powers to prevent the administering of gonadotrophin, involving Mr Wilkes, Mr Meldrum (CVO) and Mr Turner in Legal Branch. Mr Kyle thought that the CJD experience made it essential that this potential route of spread be closed.\(^{196}\) The view was taken that animal health legislation would not assist.\(^{197}\) It was suggested that advice be taken from Legal Branch and, failing a solution, voluntary compliance should be sought from veterinary surgeons. Mr Turner confirmed that current legislation could not block the loophole and voluntary cooperation from veterinary surgeons should be sought.\(^{198}\)

**July meeting of the Biologica onal Committee**

3.23 On 5 July 1988 the BC met again. It discussed the matters raised at the 8 June meeting about the implications of BSE for biological products and the draft guidelines prepared by Mr Wood since then. The minutes record:\(^{199}\)

5.3 . . .

1) The greatest concern was over the use of pituitary gland extracts by veterinary surgeons. However, this use was correct within the terms of the Medicines Act (Section 9.2). It had been agreed that individual letters, indicating the hazard of using these products, would be sent to the vets concerned.

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\(^{190}\) L12 p. A19; L12 p. A67
\(^{191}\) S469 Wilkes para. 12; YB88/6.10/1.1
\(^{192}\) YB88/6.13/6.1
\(^{193}\) S469 Wilkes para. 11
\(^{194}\) YB88/6.10/1.1
\(^{195}\) DM01 tab 27
\(^{196}\) YB88/6.13/10.1
\(^{197}\) YB 88/06.13/6.1; 88/06.14/6.1
\(^{198}\) YB88/6.24/13.1
\(^{199}\) YB88/7.05/6.3
2) At least 16 pituitary based products had Product Licences of Right. It was agreed that for these products and those containing extracts of adrenal, pancreas and thyroid glands, letters should be sent to the licence holders asking for further information on the sources of gland, methods of manufacture, etc.\textsuperscript{200}

3) Other hormone based products would be considered under the hormone review for which guidance notes were being prepared.

4) Neural or lymphoid tissue including brain infusion broths, from the UK, were unacceptable unless heated at 136\(^{\circ}\)C for 18 minutes, which would probably render the tissues unusable. Pig or horse brains tissue or non-UK tissues might be acceptable.

5) Foetal calf serum and new born calf serum collected without prior brain penetrative stunning were considered to be acceptable for use.

6) Several treatments were proposed for other tissues including peptone meat broths. The more acceptable method for the tissues, was considered to be heat treatment at 126\(^{\circ}\)C for 2 cycles of 30 minutes each with cooling in between. A higher temperature of 136\(^{\circ}\)C for 18 minutes was considered preferable, but it would probably lead to the treated tissues being unable to support optimal growth.

7) Horse meat was often used for peptone meat broths and this could be used as an alternative to bovine meat.

8) Bile could not be heat treated at 126\(^{\circ}\)C without denaturation. Although bile was not essential the companies considered that it improved growth. It was suggested that a controlled source could be used for bile.

9) All manufacturers who currently use brain material should be asked to consider alternative materials or methods.

\textbf{3.24} The BC agreed that an amended version of the guidance should be tabled at the forthcoming NOAH meeting, and presented to DH and the NIBSC. It was considered that DH should be kept informed of any developments with BSE.

\textbf{3.25} Mr Wood’s revised paper was considered at the MAFF/NOAH meeting, chaired by Dr Little, on 11 July 1988.\textsuperscript{201} The paper proposed the following conditions under which material of bovine origin might be used in biological products.

i. No product from an animal suspected of being, or confirmed to be, affected by BSE was acceptable for any product.

ii. Only serum collected without prior brain-penetrative stunning was acceptable.

iii. Neural and lymphoid tissue was unacceptable unless it was first held at 136\(^{\circ}\)C or was of non-UK origin.

\textsuperscript{200} We were told by MAFF (see DM01 tab 24 para. 13) that only 4 of these 16 products were considered to present a potential risk. Their licences were not renewed, and expired in December 1990, May 1990, July 1990 and April 1991.

\textsuperscript{201} YB88/7.11/12.1–12.4
iv. For other tissues the meeting was asked to consider alternatives for autoclaving (136°C for 18 mins; 126°C for 30 mins; 126°C for two cycles of 30 mins).

v. Milk and milk products were acceptable.

vi. Primary cell cultures were not acceptable.

vii. Cell lines were acceptable if not derived from neural or lymphoid tissues or cells.

viii. Faeces were acceptable if from a controlled herd with no signs of infection and not fed on offal derived concentrates.

ix. Bile was acceptable under the same circumstances as faeces above.

x. Hormones derived from bovine tissues should not be used.

3.26 Those at the meeting recognised that some of these proposals might cause production difficulties for some companies. It was agreed that companies would consider the implications and send comments to BP&S as soon as possible. NOAH undertook to inform members who were not represented at the meeting, as well as to obtain further information from their members on pharmaceutical products that contained bovine material from UK sources. A list of these products was to be sent to Mr Kidd.

3.27 On 12 July 1988 Mr Wood sent Dr Harris, the Deputy Chief Medical Officer (DCMO) at DH, a copy of his paper, following a suggestion from Dr Minor of the NIBSC that he might be interested in the material. He explained that the proposals had been put to NOAH at the meeting on 11 July and that they were awaiting responses from NOAH members.

3.28 The decision following the BC meeting on 8 June 1988 to seek voluntary cooperation from veterinary surgeons on pituitary hormones (see paragraph 3.23) was implemented through a letter from Mr Kidd and Mr Gray published in the Veterinary Record on 16 July. It read:

> The recent paper by Sreenan (VR, June 25, page 624) prompts us to write regarding the use of pituitary derived follicle stimulating hormones of ovine or bovine origin . . .

Apart from the legal position, we also wish to draw attention to the possible transmission of Bovine Spongiform Encephalopathy (BSE) and to the potential hazard of using tissues of brain origin from cattle.

We are particularly concerned where bovine or ovine pituitary tissue is involved in the preparation of follicle stimulating hormone. The potential risk of disseminating the scrapie agent by this means is well established and there is some evidence to suggest that a similar risk of spreading the agent of BSE may be associated with the use of bovine brain tissue.

If brain tissues are necessary at all in the production of any veterinary medicine, species other than sheep and cattle should be employed wherever possible.
3.29 Individual letters were also sent to the veterinary surgeons concerned. 205

**September 1988**

3.30 When the BC met again on 6 September 1988, it noted that some replies from companies using pituitary glands had been received and that the draft guidelines had been sent to NIBSC and to DH. 206

3.31 At a further meeting with the NOAH Liaison Group on 14 September, NOAH had no comments on the draft guidelines, but undertook to provide details of pharmaceutical products containing bovine material. 207 These details do not appear to have been provided by March 1989 when the joint CSM/VPC guidelines were issued, along with a questionnaire asking for equivalent information. The follow-up to the guidelines and questionnaire is discussed in Chapter 6.

**November 1988**

3.32 At the next meeting of NOAH and MAFF, held on 8 November 1988, there was some discussion of the latest BSE situation. 208 The minute of the meeting records:

> It was felt that the publication of the guidelines was required to protect the UK image and demonstrate to the Commission that we had a clear action policy. We remain the only MS 209 to have admitted to recognising the disease so far. 210

3.33 The target date for issue of the guidelines was 1 January 1989, and companies could further discuss if they were encountering problems. 211 Dr Little told us that although some problems with implementing the guidelines were discussed, NOAH was keen to see them published quickly. 212

3.34 Also in November 1988, as part of the hormone review, guidance notes on hormones, which had previously been circulated in draft, were approved by the VPC and issued to manufacturers. 213 These guidance notes included the following passage:

> substances derived from glandular extracts or serum intended for the treatment of ruminants or pigs require authorisation under the Serum and Glandular Products Order, and account should be taken of any risk of contamination with BSE. 214

3.35 This was the first instance we saw in which institutional guidance that dealt with BSE was issued to pharmaceutical manufacturers, apart from the letter in the *Veterinary Record* on 16 July 1988 to which we refer above.
3.36 Dr Adams, Principal Medical Officer in DH Medicines Division and medical assessor to the Committee on the Review of Medicines (CRM), told us that towards the end of 1988 he had various informal conversations with MAFF colleagues about BSE, as he was keen to know more about the disease and any possible implications it might have for human health. He also went to CVL to see Mr Bradley in December 1988, for the same reason. The follow-up to these contacts is described in Chapter 5 below.

3.37 On 23 December 1988 BP&S prepared revised draft guidance for manufacturers of veterinary medicinal products on the selection and treatment of material obtained from cattle in the UK. The covering note circulating it to the VPC said: ‘The document is presented to members essentially for information but it will be helpful to have comments on it, and suggestions from the Committee will whenever possible be incorporated.’ The note added, ‘It is important to progress the guideline as quickly as possible so that it can be distributed to appropriate organisations, and manufacturers using material of bovine origin in their products.’ The draft guidance recommended:

I COLLECTION

1. No product from a BSE affected animal is acceptable for use.

2. Material should be obtained only from BSE-free herds.

3. Brain-penetrative stunning is unacceptable where tissues are collected post mortem.

4. Instruments used to collect samples and holding vessels should either be virgin . . . or be sterilised. After use reusable instruments should be sterilised after cleaning. Disposable materials should be incinerated.

II TISSUES UNSUITABLE FOR USE

1. Primary cell cultures.

2. Endocrine glands including placenta.

3. Spleen and lymphoid tissue.

4. Neural tissue.

III TISSUES AND OTHER MATERIALS SUITABLE FOR USE

It is recommended that wherever possible source animals are calves.

1. Serum. All cellular components must be removed.
2. Fetal calf serum provided great care is taken to avoid contamination by placenta and fetal fluids. All cellular components must be removed.

3. Milk, or products derived from milk collected aseptically from individual cows under three years old.

4. Faeces collected from the rectum.

5. Bile collected aseptically.

6. Cell lines not derived from neural or lymphoid tissues or cells.

7. Sterilised tissues excluding those listed in II.218

3.38 The VPC’s consideration of the note at its January 1989 meeting is dealt with in Chapter 5.

January 1989

3.39 At the beginning of January 1989 the two Departments responsible for medicines licensing, DH and MAFF, at last met to discuss a joint approach to handling the risk from BSE. In the next chapter we review the course of events in DH that had led Medicines Division to instigate that meeting.

Conclusions on MAFF’s initial response

3.40 Before doing so, we discuss the action on veterinary medicines taken by MAFF up to that date. In our view, its response on this throughout that period was timely and appropriate. We consider that it was reasonable not to take positive action until November 1987, by which time some 120 cases of BSE had been reported,219 and that the commissioning of a paper was an appropriate next step. Before that date, information was scanty. Mr Luff’s paper brought together many of the matters and issues that were to provide a foundation for later guidance. The BC considered Mr Luff’s paper in January and February, and agreed to keep the matter under review for the time being. Again, given what was known at the time, we consider that to have been a reasonable and proportionate response.

3.41 By June 1988, it was clear that the epidemic was worsening, and at this stage MAFF stepped up its response on veterinary medicines, with the preparation of an action plan and allocation of specific tasks to different groups. The initial guidelines were promptly drafted and a series of discussions about them with industry initiated. The implications of BSE for parallel action on hormone products were also recognised and addressed.

3.42 All in all, we think this amounted to a considered and orderly approach to the problem. MAFF was able to proceed with such an approach in part because of its early knowledge of the problem and the close workings between those handling medicines licensing and their CVL colleagues.

218 YB89/1.002.1-2.3
219 DM01 tab 17 para. 63
3.43 We note, however, that MAFF action focused entirely on veterinary medicines. Mr Luff’s paper in 1987 had contained information that might have been of considerable interest to Medicines Division officials. It touched on a number of issues that were later to be addressed in connection with human medicines. We return in later chapters to the effects of the very limited communication about BSE that was taking place at this stage between the medicines licensing officials in the two Departments.