The BSE Inquiry / Statement No 476

Mr David Hagger

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BSE INQUIRY

STATEMENT OF DAVID HAGGER

Introduction

1. My name is David Osborne Hagger. I am a retired civil servant. My professional address for matters relating to medicines is Market Towers, 1 Nine Elms Lane, London, SW8 5NQ.

2. I joined the Medicines Division of the Department of Health in 1984 as Head of MB1. This was a grade 5 (Assistant Secretary) post. I had previously occupied a posting at that level on the social security side of the Department of Health and Social Security (DHSS). I remained as Head of MB1 until about February 1990 when, in the course of management changes during the period of establishing the Medicines Control Agency (MCA), I became successively co-ordinator of the newly formed Executive support business, Business E and head of Business B (Abridged Licensing). I retired in September 1994.

3. Since my retirement my only contact with the Department of Health has been as independent chairman of an occasional panel charged with reviewing possible candidates nominated by external bodies after consultation, to recommend to Ministers for appointment to the Committee on Safety of Medicines (CSM) and Medicines Commission. I have been asked to attend panel meetings on approximately five occasions since 1996.

4. In preparing this statement I have relied heavily on the documents supplied to me for that purpose which I prepared or were addressed or copied to me. I have little independent recollection of relevant events and I am therefore unable to provide details of any additional discussions regarding BSE which are not recorded in the documents provided.

Roles and Responsibilities - MB1 1984-1990

5. MB1 had wide-ranging administrative and policy responsibilities covering medicines licensing under European and UK law and related international policy issues and relations with e.g. the World Health Organisation (WHO), and the European Commission. MB1 was divided into three, later four, sections, each headed by a Grade 7 official reporting to me with up to about 70 staff. So far as matters relevant to the Inquiry are concerned, the relevant section was MB1C, which provided the administrative lead on policy for medicines licensing issues for which CSM was the appropriate advisory body. These issues included product licence applications and monitoring reports of adverse drug reactions. MB1C also provided the administrative secretariat services for the CSM and its sub-committees.

6. About 25 staff worked in MB1C. They were predominantly Executive Officers,

Administrative Officers and Administrative Assistants and two Higher Executive Officers. They reported to the Grade 7, who in turn reported to me. The grade 7 exercised a supervisory responsibility in relation to the day to day licensing activities for CSM-related applications and adverse drug reaction monitoring, but in addition he or she was expected to liaise with scientific and/or legal colleagues in considering any wider issues which a particular application or licensed product might create. These could include, for example, legal issues arising out of the Medicines Act, co-ordinating the response to media interest in a particular drug or class of drugs, formulating draft responses to Parliamentary Questions and constituency correspondence from MPs; dealing with licensing issues affecting particular pharmaceutical companies or their trade associations and being ready to make proposals for a possible change of policy to be considered if this seemed appropriate. In addition, the grade 7 was the Secretary to the CSM and had responsibilities in relation to management and staffing issues. During my time, the grade 7s in MB1C were Mr Jeff Grimshaw, Miss Aileen Simkins and Mr Jim Bewley.

7. At some point before March 1987, as I recall, the work and staff of MB1B were transferred to MB2, the administrative branch headed initially by Mr John Sharpe and then by Mr Robertson. In exchange I took over staff and responsibilities from MB2 which included the product licence database with over 50,000 detailed records and about 15,000 changes annually and an information store of well over 2,000 files of technical data. This new section became the new MB1B and was led initially by Mr Jim Bewley and then by Mr Murray Love.

8. As far as I can remember, shortly before the transfer of responsibilities referred to above, MB1 took on responsibility for the Division's IT development. This section, led by Mr Jeff Grimshaw, became MB1D and continued until it was detached to become a branch in its own right, sometime between January-October 1989.

9. As the grade 5, I was reported to by the MB1C grade 7 and accordingly involved in the formulation of the divisional response to any of the wider issues to which product licensing gave rise. In addition, I had the normal branch management responsibilities. I also attended CSM meetings. During my early days I attended most meetings. However, I had reason to contribute only on limited occasions and therefore, as time went on, I attended less frequently. The bulk of my normal work comprised such things as considering courses of action to meet actual or anticipated licensing issues; preparing reports; briefings and occasional submissions for senior officers or ministers; contributing to meetings of the Divisional Management Group; negotiating on proposed European Directives in Brussels; co-ordinating the response to legal claims arising from the licensing or use of medicines; and general direction of the work of the branch led by the administrative Grade 7 section heads. Much of the work necessitated frequent consultations with health and legal professionals and administrative colleagues and sometimes with representatives of pharmaceutical companies and their trade associations. MB1C accounted for roughly 30-40% of my work overall.

10. My own reporting line was to the grade 3, the administrative Head of Division, initially Mr Norman Hale and subsequently Mr Clive Wilson. This was a post at Under Secretary level. The grade 3 in turn reported to a Deputy Secretary (Grade 2), initially Mr Brian Rayner and then Mr Strachan Heppell.

11. It needs to be remembered that there were three separate lines of reporting for physicians, pharmacists and administrative staff. The professional Head of the Medicines Division when I joined was Dr Gerald Jones; he reported to the Deputy Chief Medical Officer (DCMO), then Dr Edward Harris. The DCMO in turn reported to the Chief Medical

Officer (CMO). The pharmacists reported to the Chief Pharmacist. The CMO, DCMO and the Chief Pharmacist were not members of Medicines Division.

12. A particular feature of Medicines Division was the scientific nature of the bulk of its work and the central role of its health professionals. A strong input to much of the briefing was required from colleagues in the Division who were professionally qualified as either physicians, pharmacists or in other scientific specialisms. Legal advice was often needed as well to take account of the statutory requirements of the Medicines Act and European Directives. Good co-ordination was therefore essential and a close working relationship between administrators and professionals in the Division had developed. Drafts were always agreed with those concerned before being submitted and copies of final documents were circulated to all concerned.

13. There were regular (possibly monthly) meetings between the Head of Division and his Deputy, the Deputy CMO and the Chief Pharmacist, which were known as the "Quartet" meetings. I do not recall ever being asked to attend. The CMO tended to become directly involved in the work of the Division where the medicines issues had major public health implications. As well as involvement in BSE, examples I recall of significant CMO involvement were in relation to concerns about junior aspirin and Reye's Syndrome, and concerns about contraceptive pills.

14. My contact with Ministers was mainly written and included briefings and numerous draft replies to Parliamentary Questions. Some contacts were indirect, through Press Office, as issues were raised in the media. From time to time submissions were made setting out options and making recommendations for Ministers to consider, for example on preparing a code of conduct to avoid possible conflict of interests by members of the independent advisory committees or on the line to take in Brussels as proposed new directives were being negotiated. Any material for Ministers would either have been agreed with both the administrative Head of Division, Mr Hale then Mr Wilson, and the Professional Head, Dr Gerald Jones or be in line with their known views and copied to them at the same time.

15. So far as contact with the rest of the Department of Health is concerned, I would liaise with my administrative opposite number in the appropriate division in respect of any issue which affected the wider Department. In the same way, I would naturally discuss matters that affected other departments with colleagues at my level in those departments.

The CSM

16. As indicated above, during the period 1984-1990, I had responsibility for administrative issues relating to the CSM. Although the Secretary to the Committee was the grade 7 in MB1C, I was not responsible for the work of the bulk of the secretariat of the Committee who were professional staff, comprising physicians, pharmacists and scientists. There were two lead medical assessors to the Committee covering licence applications and adverse drug reaction monitoring respectively and a lead pharmaceutical assessor. Meetings would be attended by the independent, expert, scientific members of the Committee, various Medicines Division officials including, the professional head of the Medicines Division, Dr Gerald Jones, principal medical assessors to the CSM, Dr Jefferys and Dr Mann who was succeeded by Dr Wood, the senior pharmaceutical assessors Mr Stewart or Dr Purves and the administrative head of the Medicines Division (initially Mr Hale and subsequently Mr Wilson) as well as a lawyer and the remainder of the professional secretariat. I attended a significant proportion of CSM meetings, mainly to keep myself informed of the issues being considered, although on limited occasions I was able to contribute, for example if issues relating to consistency of policy arose or

with regard to the appropriate procedure to deal with a particular problem.

17. At some point during the period 1984-1990, the "CSM Action Group" was set up to strengthen co-ordination within the Division. Initially I chaired these meetings, which were also attended by two senior physicians (those responsible for adverse drug reactions and for new drug licensing) a senior pharmacist and the CSM Secretary. At these meetings we would discuss items already on the agenda for the forthcoming CSM meeting which might raise difficult regulatory issues. (I would rely heavily on my professional colleagues to alert me to any matter to be discussed by the CSM which they felt might have ramifications beyond the purely scientific.) Even after I became head of Business B, I remained part of the CSM Action Group, although I did not always attend, particularly after Miss Hepburn became the permanent representative of the Abridged Licensing Business. I no longer chaired the meetings; as I remember, the meetings were chaired by the chairman of the CSM at that time and usually took place at lunchtimes immediately before the CSM chairman attended a detailed scientific briefing on the afternoon before the main meeting next day. I did not usually attend the latter briefing meetings.

18. The CSM decided its advice on a corporate basis following discussion in which individual experts would contribute within their own areas of expertise. After meetings, minutes would be agreed in draft by the Secretariat and passed to the Chairman for his approval. The circulation list for approved minutes included me. In general, senior administrators would only get involved following a CSM meeting if it was clear that an issue dealt with there required a Ministerial decision, appeared to have wider implications and/or was likely to become public and attract press interest. In these circumstances both the Head of the Division and the Professional Head would usually have leading roles. Most CSM discussions concerned individual products, specifically licensing of products and the results from the subsequent monitoring of adverse reactions.

19. My involvement with the sub-committees was limited. Like the CSM, the secretariats comprised mainly professionals, although an administrator from MB1C served as secretary to both the Biologicals and the Safety, Efficacy and Adverse Reactions (SEAR) sub committees. Junior administrators entered yellow card data sent by physicians reporting suspected adverse drug reactions and passed the sheets to health professionals for coding and analysis. They also produced a regular performance report to SEAR on progress against time targets for entering these reports. Otherwise, the administrators' main roles so far as the sub-committees were concerned were to ensure that papers for the various sub-committees were copied and distributed and to provide general administrative support. The agendas for the sub-committee meetings were set by the professional secretariat and there was little non-routine action required from the administrators until an issue surfaced at the main committees (CSM, CDSM). I therefore rarely attended meetings of the Biologicals sub-committee, the SEAR sub-committee and the sub-committee for Chemistry Pharmacy and Standards (CPS). The various sub-committees made recommendations to the main committees who were at liberty to disagree with those recommendations or require further consideration. All the chairmen of the various sub-committees were members of the CSM.

20. I also attended one or two meetings of the CSM BSE Working Group, before February 1990. In practice, the impetus behind the Working Group was mainly scientific. MB1C had responsibility for ensuring that the relevant papers were circulated to Working Group members.

<u>Re-Organisation: 1989 to 1990</u>

21. Following acceptance by Ministers of recommendations in the independent Cunliffe-Evans Report on the Control of Medicines in the UK **(M 39 Tab 12)**, it was decided that the Medicines Division would be re-organised as the Medicines Control Agency, a next steps agency, to be headed by a Chief Executive. Dr Keith Jones was appointed as Chief Executive in April 1989 and I reported to him, initially via Mr Wilson.

22. The re-organisation of work under the MCA involved certain changes of organisational structure. Work was to be allocated to separate multi-disciplinary "businesses" known as Businesses A, B, C, D and E. The division of work became known from about August 1989 and began to influence working arrangements from then. In about February 1990, senior staff started to run shadow businesses as precursors to the distinct MCA organisation and I was given a lead co-ordinator role in a team of three running the new executive support business, Business E. At this early stage I recollect it was envisaged Business E would cover a wide area of activity with various "cross-Agency" functions including policy and management of finance (including fees) and IT (including the Medicines Information database). It would also take the lead for policy co-ordination on Agency-wide international issues, the Medicines Commission (for which it was to provide the administrative secretariat) and some other issues, for example, medicines aspects of open government and freedom of information. Its role evolved somewhat in subsequent years. At this time, I would probably have been charged in particular with producing various papers on the organisation and staffing of Business E. Similarly, Dr Jefferys would have taken matters forward with the new Business A which would lead on BSE issues. Mr J Bewley, the Secretary to the CSM and until then in MB1C, also became a member of the Business A management team to provide input on those MB1 subjects which were relevant to A. At that time therefore my earlier administrative responsibility for the CSM ceased and I became involved with other matters.

Roles and Responsibilities-MCA 1990 to 1994

23. On 1st May 1990, my responsibilities altered significantly again when, in a change to what had been anticipated, I became Head of Business B (Abridged Licensing), a grade 4 post, and a member of the new MCA Management Board. This was a Business which consisted of some 110 staff including physicians, pharmacists, other scientists and administrators and which was responsible for abridged product licensing (essentially licensing new products which use active substances already licensed for use in medicines in the UK); variations to existing licences and product licence renewals; parallel imports; radiopharmaceuticals; the licensing work and administrative support associated with the Committee on Review of Medicines (CRM) and the Committee for Dental and Surgical Materials (CDSM); and for policy on alternative medicines. This Business had no scientific responsibility for biological products (for example vaccines), all of which fell within the remit of Business A, the New Drugs Business. My principal remit was to improve the efficiency and timeliness of handling abridged licence applications, the delays in which had become a cause of concern. As head of Business B, I gained some links with the CSM relating to the need for independent professional advice on the abridged licence applications which needed to be put to the CSM. I therefore continued to receive copies of the papers in relation to most meetings of the CSM even though my earlier administrative policy responsibility for the Committee had ceased. Miss Doreen Hepburn, a senior pharmacist and group manager who reported to me, represented the Business as the abridged licensing assessor to the CSM. In addition, Business B provided some clerical support to Business A in its work and also provided the secretary to the CSM BSE Working Group. The Business also had lead responsibilities for the MCA in working with consultants over a prolonged period for the development and introduction

of a new product licensing computer system in the Agency.

24. By the time I became responsible for the CRM in mid-1990 the work of that committee was almost complete and I remember little activity that was relevant to BSE. The CRM ceased to function from March 1991. I relied heavily on another of my group managers, a professional colleague, Dr June Raine for matters relating to the CDSM, for which she was Principal Medical Assessor. She reported to me and would consult frequently and, when a decision was needed on the appropriate line to be taken, we would discuss the various options and reach agreement. The CDSM was wound up in December 1994. Until Regulations implementing the European Directive on Devices came into force in January 1995 the CDSM advised on a number of dental, ophthalmic and surgical products which then became the responsibility of the Medical Devices Directorate (now the Medical Devices Agency). (The third of the group managers reporting to me, who were all appointed during the summer of 1990, was Mr Bewley who became responsible for Variations, Renewals and Parallel Imports.)

25. Inevitably, therefore, under the re-organisations in setting up the MCA I became more detached in relation to the work being done on BSE. For some time, however, I was still copied into the correspondence. The ethos of the Division was such that one continued to provide advisory support if need be to those who might be new to a particular area of responsibility. It has to be said also that the distribution list for correspondence on occasion would take time to catch up with changes in responsibility and I was a familiar name to those involved with the work being done in respect of BSE, both to those inside and outside Medicines Division/MCA.

Chronological account

1988/1989

26. I cannot recall specifically the occasion on which the BSE disease first came to my attention. It would have been in the wider context of the matter becoming known to the Medicines Division generally, and more particularly the CSM getting involved when I would have seen it on agendas and committee papers. At some point during the course of the year 1988/89 I was given the task of co-ordinating briefing on BSE and arranging for consultation of industry. While I do not remember in detail when this issue arose I believe it occurred towards the end of 1988 in association with consideration by the CSM of Southwood's draft report. The first time I was formally brought in to assist with the issues may have been when I received a copy of the CMO's memo of 21 March 1988 alerting Ministers to BSE [17-18] **(YB 88/03.21/3.1-3.2)**. I passed this on to my professional colleagues Dr Gerald Jones, Dr Jefferys and Dr Jenkins as well as Mr Wilson and Miss Simkins (CSM secretary).

27. My attention has been drawn to the minutes of a meeting of the CSM held on 25 February 1988 [6-16] **(YB 88/02.25/1.1-1.6 ; 88/02.25/2.1-2.5)** , at which the recommendations of a meeting of the Biologicals sub-committee held on 6 January 1988 [1-5] **(YB 88/01.06/2.1-2.5)** were considered, and in particular a reference to a product containing bovine brain material. At their meeting, the CSM endorsed the conclusions of the Biologicals sub-committee and advised against the grant of a Clinical Trial Certificate in respect of a product prepared from bovine brain, on the basis that in numerous respects the product did not measure up to relevant standards of safety/quality. Although I attended the meeting of the CSM, I do not now remember their consideration of this product. At the time of the CSM meeting, I do not believe I was aware of the diagnosis of BSE in UK cattle.

28. I was not personally involved in the setting up of the Southwood Working Party. I have seen minutes for the 2 November 1988 meeting of the Biologicals sub-committee [19-21] **(YB 88/11.02/6.1-6.3)** and the papers on BSE that were considered [22-58] **(YB 88/11.02/5.1)**, the papers for the SEAR sub-committee's 4 November 1988 meeting endorsing the Biologicals sub-committee's views [59-61] **(YB 88/11.04/7.1-7.3)**and the minutes of the 17 November 1988 CSM meeting which considered the reports of the Biologicals and SEAR sub-committees [62-63] **(YB 88/11.17/9.1-9.4)**. I received a copy of Professor Asscher's letter to Sir Richard Southwood dated 26 January 1989 [64-65] **(YB 89/01.26/1.1-1.2)**. I would probably have become aware of the antecedent correspondence between them concerning the wording of the guidelines that were to be published but I cannot remember whether or not I received copies contemporaneously with them being sent or if it was later. By February 1989 when draft letters to Licence Holders [66] **(YB 89/02.24/12.3)** were being finalised with other papers in preparation for the CSM's approval that month I was actively involved in the Department's actions to set in motion the steps needed to meet the Report's recommended actions. Dr Jefferys and I were present as observers at the press conference to launch the Southwood Report.

29. The development of the guidelines for industry was progressed jointly by the Veterinary Medicines Directorate and the Medicines Division. This work was carried forward by a meeting on 1 February of a group called the Human and Veterinary Medicines Working Group consisting of representatives from MAFF CVL, the Medicines Division and the Biologicals sub-committee/NIBSC [67-90] **(YB 89/02.01/4.1-4.2)**. I would not have had direct involvement in the scientific investigations, but I would probably have had an opportunity to comment on a late draft and would have been aware of developments as my focus would have been the communication of the guidelines to product licence holders in the form of a letter to be sent under my name [89-90] **(YB 89/2.00/2.4-2.6)**.

30. On 13 February 1989 a meeting was held at our offices at which I was present together with Dr Adams and others including colleagues from MB1 and professional branches [91-93] **(YB 89/02.14/8.1-8.4)**. This was to discuss the CMO's concern to follow up the questions of the safety of medicines in the light of the Southwood Report. As well as planning how to set up and constitute a working group to take matters forward for the CSM (which subsequently became the BSE Working Group chaired by Professor Collee) it was decided that enquiries would be made to identify relevant manufacturers and obtain information about the bovine material contained in children's vaccines, the stocks of these vaccines and how long it would take to switch to other products. The meeting resumed on 14 February when Dr Rotblat described the results of her enquiries about vaccines and further planning of the letters to licence holders was discussed [94-95] **(YB 89/02.15/8.1-8.3)**. I circulated a briefing on 25 February to Mr Cunningham and others in the Department of Health concerned, respectively, with immunisation policy and medical devices [96-97] **(YB 89/2.15/3.1-3.2)**. In the course of the following week I organised the preparation of material for a Question and Answers briefing for ministers and provided an answer on advice being given to doctors and pharmacists [99-103] **(YB 89/02.17/10.1-10.5)**.

31. A meeting of a group called The Human and Veterinary Medicines Briefing Group met on 22 February 1989. It was also chaired by Professor Collee and attended by Professor Asscher and by various other experts including Dr Martin from the Southwood Working Party. Confidential pre-publication copies of the Southwood Report had been made available to the attendees (and CSM Members) prior to the meeting [98] **(YB 89/02.15/9.1)**. I was among a large number of attendees from the Medicines Division and MAFF but the meeting was conducted by the scientific members. Its discussions are

recorded in minutes [104-107] **(YB 89/02.22/11.1-11.4)**. Its role was to review the papers prepared for the CSM meeting the following day and to formulate advice to the CSM as a whole. This was an uncommon way to deal with CSM business (i.e. other than through its established sub-committees) but the BSE issue was unusual in that the CSM was normally concerned with licensing issues for individual products and here it was faced with unusual concerns which could have related to any number of licensed products and had serious implications for the continuing supply of all kinds of medicines, and vaccines in particular. Concerns were expressed about the adverse effect on vaccination programmes if supplies could not be maintained because of the requirements of the guidelines.

32. On 23 February 1989 the CSM held its meeting and I was among those present. Professor Collee presented the views from the previous day's meeting [114-127].**(YB 89/2.23/13.1-13.5)** The CSM approved the guidelines, draft letter to licence holders, the questionnaires and its draft position statement. The same day I sent a minute to Dr McInnis (the CMO's private secretary) reporting on the position of the CSM and the action to be taken subsequent to the meeting, and providing him with the Q&A's [128-138] **(YB 89/02.23/12.1-12.7)**. I cannot recall why it was a minute addressed to Dr McInnis. I seem to recall I had a brief meeting with the CMO that day to discuss the CSM's conclusions and possibly it was to confirm this formally. I noted here that no special action was advised by the CSM on any existing products though the CRM was due to review some old products (i.e. those with product licences of right). Looking back I would have written this on the basis of my understanding of the discussions in the last two days' meetings when existing stocks would have been discussed. (The CSM decisions took into account the points made in paragraphs 5 and 6 of the Secretariat's report to CSM members before the meeting of the need for continuity of supplies and for the question of stocks of existing products to be addressed at a future date in light of the questionnaire replies [108-113] **(YB 89/2.00-2.1-2.6**.)

33. The following day I minuted Mrs Goldhill, Mr Kenneth Clarke's private secretary. From the copy I have seen recently it appears that I or someone else had already provided her with a copy of my minute to Dr McInnis from the day before [139-143] **(YB 89/02.24/12.1-12.5)**. I copied this and the relevant documentation to Mr Davey (private secretary to the Minister of State for Health) and to Mrs Kirk (private secretary to the Parliamentary Secretary for Health). On 6 March I provided a draft reply for the Minister of State (Health), Mr David Mellor, to a Parliamentary Question on BSE and vaccines to which I appended my 23 February report to Dr McInnis [152-164] **(YB 89/03.06/5.1-5.2)**. The CSM's advice and guidance was also outlined in an answer to a Parliamentary Question by Mr McGregor (Minister for Agriculture) on 27 February 1989, which he would have cleared first with the Secretary of State for Health [144-148] **(YB 89/02.27/8.1-8.5)**.

34. On 9/10 March we sent out what I believe were around 4000 letters to licence holders with the questionnaires and guidelines. The tone of the CSM-approved letter to Licence Holders, which described the guidelines as purely precautionary, was consistent with the advice in paragraphs 5.3.3 and 8.2 of the Southwood Report. Similar mailings were sent by the Department of Health's Procurement Directorate in relation to medical devices and appliances. After this the replies to the Licensing Authority's letter would all have been dealt with by MB1B which began to expand its database on bovine and other materials used by the license holders. I was also involved in a debate between professional staff about whether to write as well to companies who submitted Drug Master Files (confidential data packages submitted to the Medicines Division for regulatory purposes

on which commercial partners of the data owner could rely (but not have access to) when seeking their own licensing approved for products with the same compounds): I felt we should require each individual licence holder to be responsible for answering our questionnaires [149-151]. **(YB 89/02.28/9.1 ; 89/03.01/8.1 ; 89/03.02/10.1)** I also followed the plans for appointing the CSM's new BSE Working Party under the Chairmanship of Professor Collee and I requested changes to make its terms of reference clearer in its role as being subordinate to the CSM and not a further stand-alone advisory committee. [166] **(YB 89/03.17/8.1)**

35. On 17 May 1989 I prepared a minute for the Press Office [167-168] **(YB 89/05.17/4.1; 89/05.17/6.1)** which was intended to assist them in briefing ministers on the line to take on medicines for a BBC programme concerning BSE. This was supported by copies of my previous reports. The note of the suggested line to take is missing from the documents I have seen recently. It would probably have referred to the guidelines, the remoteness of risk as advised by Southwood, and the continuing work of the CSM.

36. On 5 June 1989 I sent a minute to the CMO's Private Secretary [169] **(YB 89/06.05/3.1)** reporting on progress. This was unusual for me but I assume I did this as I had minuted him previously and because of the degree of involvement the CMO had in the issues. The minute explained that most responses to questionnaires had been received and were currently being reviewed, and a preliminary scan of the data so far available had not identified any information requiring immediate special action. Further, the MCA were applying the new guidelines to licence applications and renewals. The use of bovine insulin in a small group of mainly elderly patients was noted and it was recognised that alternative products for this group were not considered satisfactory. (I seem to recall that later some of these patients did become quite ill when transferred to other forms of insulin.)

37. I received a copy of Dr Metters' minute to Mr Clarke of 7 June 1989 on further measures MAFF were proposing to take to extend the offal ban [170-172] **(YB 89/06.07/6.1-6.3)**. This advised of the effect this would have of drawing attention to the continued use of bovine material in medicines and brought to Mr Clarke's attention my minute of 5 June 1989. The following day Dr Metters sent a minute to the CMO's private secretary which he described as a follow up minute for officials only and it was copied widely to colleagues in the Medicines Division [173-174] **(YB 89/06.08/7.1-7.2)**.

38. On 9 June Dr Metters similarly updated the CMO on developments [175-186] **(YB 89/06.07/6.1-6.3 ; 89/06.07/7.1-7.2 ; 89/06.05/3.1 ; 89/06.09/5.1-5.4)** . The same day in a minute to Mr Wilson and various other colleagues [187] **(YB 89/06.09/14.1)** I relayed the information about the proposed offal ban and also sought comments on the recommendations on pharmaceutical research issues that had been provided in draft by the Tyrrell Committee. (The report was submitted to Ministers on 13 June 1989.) On 7 September Dr Pickles sent me a minute regarding the Tyrrell report and its implications for medicinal products [196-197] **(YB 89/09.07/3.1-3.2)**. Subsequently there was a fair amount of correspondence between the Departments and their ministers about funding Tyrrell's research proposals. I was not involved in this issue.

39. Questionnaire responses were analysed and outstanding replies were requested so that papers were ready for the BSE Working Party chaired by Professor Collee to consider them at a meeting on 6 September 1989 [188-195] **(YB 89/09.06/10.1-10.8)**. I did not attend but I would have seen the minutes or the recommendations, which would have been available for the CSM's meeting on 28 September 1989 [198-205] **(YB 89/09.28/10.1-10.8)**. (I was not involved in the deliberations over the sourcing of bovine

material for a particular licensed surgical suture because this was the remit of the CDSM which, at that time, fell outside my area of responsibility.) The recommendations of the BSE Working Party were:-

"1. That no licensing action is required at present in regard to products produced from bovine material or using prepared bovine brain in nutrient media and sourced from outside the United Kingdom, the Channel Isles and the Republic of Ireland provided that the country of origin is known to be free of BSE, has competent veterinary advisers and is known to practise good animal husbandry.

2. The Joint CSM/VPC guidelines should apply to all bovine material sourced from UK, Channel Islands and the Republic of Ireland and any other area known to have BSE. Companies which at present cannot comply should be encouraged to do so as soon as possible. The timescale should be agreed with the Licensing Authority for each individual product as appropriate.

3. No licensing action is required at present with respect to products containing material from animals other than cattle.

4. The Licensing Authority should continue to review scientific progress in the field of BSE, so as to be in a position to take licensing action in the future should this be necessary."

The CSM endorsed these recommendations.

40. I discussed the action to be taken following the CSM meeting with Dr Jefferys, Dr Adams and Dr Purves around 13 October as documented in a memo from Dr Jefferys to Mr Love of that date [206] **(YB 90/10.13/6.1)**. We agreed that the further advice of the BSE Working Group was needed and a meeting was planned for January 1990.

41. I later received a copy of a minute dated 14 November from Mr Robertson, who at that time was responsible for administrative issues relating to the CDSM (and therefore for products such as sutures which were considered by the CDSM) to Mr Davey, the private secretary to the Minister for Health and copied to the private secretaries to the other relevant ministers and to the CMO, regarding the possibility of media comment following a scientific conference on BSE to be held at the RSM the following day. The minute reiterated the advice of the Southwood report that the risk to man from medicinal products was theoretical and remote, referred to the CSM/VPC guidelines on manufacturing issued in March 1989 and confirmed that the CSM and MCA were continuing to monitor the position [207-209]. **(YB 89/11.14/13.1-13.3)**

<u>1990</u>

42. I did not attend the January 1990 meeting of the CSM BSE Working Group [210-233] **(YB 90/01.10/7.1-7.7 ; 89/09.06/15.1-15.3)** 221-233 (**L2 Tab 3B)** or the February CSM meeting [234-237] **(YB 90/02.21/10.1-10.8)**; as a result of the MCA reorganisation (see below) my responsibilities had changed and these matters were no longer in my area. I cannot remember whether I would have seen the papers circulated for these meetings. By about February the new shadow businesses had been formed in the MCA, I had become co-ordinator for Business E (which was to take on responsibility for the Medicines Commission and the Medicines database but otherwise had no responsibilities for licensing matters, the CSM or other committees, or BSE) and Mr Bewley, the CSM Secretary, had become part of the management trio for Business A. In the Department's Distribution of Business, however, I continued to be shown as MB1 until October 1990

and so continued to receive some Departmental correspondence. Where I received material that was not for Business E or, later, B I would have passed it on to the appropriate person for action.

43. On 13 March the European Commission gave a decision regarding BSE, banning the export of certain bovine tissues and organs for human consumption and certain other bovine tissues and organs (including foetal calf serum, lymphoid tissue and cell cultures) for uses other than human consumption. Dr Metters subsequently sent a minute to Mr Bewley, copied to me, commenting on the possible effect of this decision on UK pharmaceuticals. He asked whether the CSM BSE Working Party had considered whether licensed products that still used bovine constituents should be asked to transfer to non-UK bovine source material [238] **(YB 90/03.26/6.1)**. Mr Bewley (ex-MB1C but now Business A and Secretary to the CSM) responded to Dr Metters by a minute of 27 April 1990 (copied to various people including me) [244-254] **(YB 90/04.27/5.1-5.4)** which provided an update as to the current position on the few licensed medicines using bovine material sourced from the UK including stocks of vaccines; all new products were required to meet the guidelines. Dr Metters was also informed of the advice of the BSE Working Group. In a further minute of 1 May, Dr Metters indicated that he had noted the recommendations of the Working Group; he commented that even though any risk of transmissions of BSE through vaccination was remote, it would be desirable to replace existing vaccine stocks with New Zealand sourced products as soon as possible **[255] (YB 90/5.1/8.1).** He requested to be kept abreast of developments and would have discussed the issue with CMO if he had considered this appropriate.

44. On 26 April 1990 I attended a CSM meeting [239-243] **(YB 90/04.26/9.1-9.5)** at which a letter from the British Diabetic Association concerning the safety of bovine insulin was considered and a response approved confirming there was no insulin sourced from cattle in the UK or Ireland and that the situation in other countries was being monitored. By this time, I would have been aware of my impending appointment to Business B (Abridged Licensing) and that I would be establishing new links with the CSM.

45. Later in the year the BSE issue was considered by an Agriculture Select Committee in the House of Commons. A memorandum for this Select Committee was prepared by the Department of Health (**YB 90/06.04/18.1-18.8**); I cannot remember now who was responsible for drafting the document but it originated outside MCA and would have involved a major scientific input from the Department's professional staff. Dr Pickles circulated the draft memorandum to relevant sections of the Department of Health including me as I was still shown as an MB1 contact in the Distribution of Business. I asked Mr Love to circulate the section relevant to medicines and to co-ordinate comments from professional and administrative staff within the MCA **[256-265] (YB 90/06.05/20.1 ; 90/05.18/24.1 ; 90/06.04/18.1-18.8).** I do not recall who commented on the draft memorandum but any amendments would have been derived from work carried out by my professional colleagues and confirmed by them as accurate. At around this time I was also provided with a copy of a minute from Mr Love to Mr Hayward of the Department of Health's Information Division which suggested answers to various questions for a proposed BBC Newsnight programme on bovine products; these responses were to be supplied that evening **[266-267] (YB 90/6.14/19.1 – 19.2).** I was also sent a copy of the statement supplied by one company to the BBC in relation to their vaccine products confirming their compliance with the guidelines issued in 1989 **[268-270]** (**YB 90/6.15/22.1 – 22.3).**

46. On 18 June I received a minute from Dr Pickles informing me that Stephen Dorrell, the

Parliamentary Secretary for Health, might be appearing before the Agriculture Select Committee the following week. She also indicated that she and CMO were being questioned that week and asked for an updated question and answer briefing on BSE and medicinal products/devices **[271] (YB 90/06.18/16.1).** I passed a copy of the minute to my professional colleagues and asked Mr Love to co-ordinate the amendment and to consider whether any additional questions and answers should be added to the briefing. A memo from Mr Love to me and various colleagues confirmed that a question and answer briefing was faxed to the CMO's private secretary on 20 June 1990 **[272-275] (YB 90/06.20/19.1-19.4).** The briefing described the medicinal products in which bovine materials were used as active ingredients, dealt specifically with vaccines and stated that *"the working group advised that existing stocks of medicines should be used, as the known benefits of the products measurably outweighed any theoretical risk from BSE"*. Copies of the briefing papers were also sent to Mr Yates, the assistant private secretary to Mr Dorrell, Mrs Shirley-Quirk, the private secretary to Kenneth Clarke, Mr Davey, the private secretary to the Minister for Health, Mrs Baldock, the private secretary to the Minister in the House of Lords with responsibility for health, as well as to the private secretary to the CMO, Dr Metters and my professional colleagues within the MCA. A briefing meeting was arranged for 25 June to be attended by Mr Dorrell, CMO, Dr Metters, Dr Pickles and others. I was not present at this meeting. **[276-277] (YB 90/6.21/12.1 – 12.2)**. The secretariat of the Agriculture Select Committee provided a "questioning line" copied to me on 25 June 1990 **[278-280] (YB90/06.25/18.1)** and a supplemental briefing was prepared by Mr Otley's section (again copied to me) **[281-286] (YB 90/06.26/7.1).** I subsequently provided a further briefing in response to queries raised by Stephen Dorrell's private office, by way of a minute dated 26 June 1990 and copied to the private secretaries to the other Ministers **[287-289] (YB 90/6.26/8.1 – 8.3).** I do not now remember why I provided the further briefing unless it was a hang-over from my time with Business E where the information section was now based; probably this was an example of the cross-business working referred to in paragraph 25 above, during the change over to the reorganised MCA. (The new permanent Head of Business E was appointed from outside the MCA on 1 June.)

47. A Government response to the Select Committee paper was subsequently prepared by MAFF and was sent by John Gummer to Kenneth Clarke by letter dated 1 November 1990. I received a copy and circulated it to my professional colleagues together with a request to one of my professional colleagues, Mrs Shersby, Secretary to the CSM BSE Working Group, to co-ordinate any comments [**335-346] (YB 90/11.01/11.1).**

48. That year the issue of overall management of BSE matters within the Department of Health was considered. I was copied in to the minute from Mr Otley to Dr Pickles dated 2 July 1990 **[290-291] (YB 90/7.2/4.1- 4.2)** which dealt with this.

49. On 4 July 1990 I received a copy of a minute from Dr Metters to Mr Heppell regarding the co-ordination of research into BSE and requesting comments as to suitable expert candidates. This was clearly an issue regarding which I was not qualified to advise and illustrates the way in which minutes were often sent to me as the point of contact in Medicines Division/MCA rather than specifically for my input. I copied this minute to my professional colleagues for their advice **[292-293] (YB90/7.3/7.1-7.2).** I later received a copy of a letter from Stephen Dorrell to John Gummer dealing with the issue. [302] **(YB 90/07.05/2.1)**

50. On 4 July a further meeting of the CSM BSE Working Group was held. I was circulated with a copy of the agenda in advance of the meeting **[294] (YB 90/07.04/13.1)** but I did

not attend. I cannot remember whether I would have seen the papers circulated in advance of the meeting but Dr June Raine would have discussed any issues relevant to the areas of responsibility of Business B with me afterwards. At this stage, the reorganisation of the MCA had taken place and as head of Business B, I had some limited responsibility for clerical support associated with the Working Group (the secretary to the group, Mrs Barbara Shersby was provided by Business B). However, my concern with the issues discussed by the Working Group was limited essentially to those products which came under the aegis of the CDSM and CRM, although Business B was concerned additionally to ensure that matters which might impact generally on its responsibility for abridged product licence applications, variations and renewals were also noted. I have reviewed the minutes of the meeting **[295-301] (YB 90/7.4/1.2 – 1.8)**. The only matter discussed that fell within my area of responsibility was the consideration of a specific bovine-derived suture, but by the date of this meeting, no source material for this suture was obtained from the UK. I note that vaccines were also considered. At this time, biological products (the responsibility of the CSM) would have been dealt with by Business A where the Biologicals secretariat was located. Business A would also have had primary responsibility for the lead in relation to the Working Group although in planning the agenda for such a meeting, Business A would have consulted B.

51. On 10 September 1990 I received a copy of a minute from Dr Pickles to Dr Metters regarding the experimental transmission of the BSE agent to a pig reported by the Tyrrell Committee. Although this experimental transmission was in no way comparable with natural infection, there was obviously a concern about the implications for medicinal products/devices derived from porcine sources. Mrs Shersby, who was also copied with the minute, arranged for it to be circulated to the relevant professionals, Dr Raine (B), Dr Rotblat (A), Dr Purves (A) and Dr Jefferys (A) **(YB90/9.10/7.1 – 7.2) [303-304]**. A subsequent minute from Dr Metters to Dr Keith Jones (again copied to me) indicated that information regarding the pig case should not be passed outside the department until relevant Ministers had decided how they wished it to be handled **[305-307] (YB 90/9.12/2.1;YB90/9.10/7.1-7.2).** Dr Jones later sent a minute to both Dr Jefferys and me stating that he wished to discuss the implications of this matter to determine the line the MCA should take in relation to porcine derived products **[308]. (YB 90/9.14/6.1)** I have not been provided with any documents that record the substance of subsequent discussions and I do not now recall the meeting with Dr Jones regarding this issue. Dr Pickles followed the matter up with several further minutes reporting on the conclusions of the Tyrrell Committee; the advice at that time was that there were no new implications for human health, other than the fact that the question of parenteral medicinal products and implantable devices of porcine origin should be looked at further **[309-327] (YB 90/9.13/4.1-4.9; YB90/9.18/2.12.2; YB90/9.20/14.1-14.2; YB90/9.7/1.1-1.4).** The statement prepared by the Tyrrell Committee, circulated to Ministers and made available in a MAFF press release, made no reference to pharmaceuticals or devices. However, I was involved in arranging for a briefing in relation to pharmaceuticals/devices if this were to be required at the press conference. The line I suggested, which would have been based on advice from my professional colleagues, is set out in a minute dated 21 September 1990 from myself to Dr Metters. *"There are no medicinal products licensed for use on the UK market which make use of UK derived porcine tissues with which any hypothetical "high risk" might be associated. The results of the recent experimental work at the CVL will be carefully examined by the CSM's working group on spongiform encephalopathy at its next meeting [in October]"* **[328] (YB 90/9.21/9.1).** I subsequently sent a minute to Dr Jefferys and my other professional colleagues attaching the various minutes from Dr Pickles and reminding Dr Jefferys that he would wish to make appropriate arrangements for the case of spongiform encephalopathy in a pig to be

considered at the forthcoming meeting of the CSM BSE Working Group in October **[329] (YB 90/9.25/16.1).**

52. At various times concerns had been raised about dural implants of human origin in the context of transmission of CJD. In May 1990 the CDSM had advised that the product licences for 2 products prepared from human cadaveric dura mater should not be renewed on safety grounds. In circumstances where the Biologicals sub-committee was not due to meet, it was decided that the BSE Working Group would consider these products as well as an implant derived from porcine dermis and a licence application for an implant derived from bovine pericardium at the October meeting **[330-332 and 334] (YB 90/09.25/16.1).**

53. At a CPMP meeting held on 11 October, it was decided that a CPMP BSE working party would be set up to monitor the implications of BSE for the circulation of medicinal products within the EC. I was notified of this development by a minute from Dr Jefferys (who was the MCA representative on the CPMP at that time) to Dr Metters, Dr Jones and Dr Pickles, which was copied to me **[333] (YB 90/10.12/5.1).**

54. On 31 October 1990 a meeting of the BSE Working Group was held. I did not attend the meeting although as indicated previously I may have received copies of the papers circulated in advance. However, Dr June Raine did attend the meeting and if any action had been required relevant to the areas of responsibility covered by Business B (for example if a referral to the CDSM was indicated or if an issue arose which would affect our approach to product licence renewals) she would have discussed the matter with me afterwards.

55. On 14 November 1990 Dr Jefferys circulated a minute to a number of people, including Dr Metters, Mr Rayner, Dr Jones, Dr Pickles and myself, regarding his discussions with the Swiss Regulatory Authority in relation to the action being taken with respect to pharmaceuticals in Switzerland following reports of cases of BSE in cows in Switzerland **[347-348] (YB 90/11.14/6.1-6.2)**. He said that the Swiss Authorities had been provided with a copy of the UK Guidelines and that further assistance was being provided by the MCA. I see that Dr Metters notified the CMO of this development.

56. On 21 November 1990 I attended part of a meeting of the CDSM **[349-355] (YB 90/11.21/7.1-7.7).** During this meeting, the advice of the CSM BSE Working Group regarding the four dural implants were considered although I was not present for these items. My colleague, Dr June Raine was present throughout the meeting and would have discussed the recommendations of the CDSM with me afterwards. The Working Group had considered the risks associated with medicinal products using porcine material (including that sourced in the UK) and took the view that no action was required at that time. The Working Group considered four implants of bovine, porcine and human origin. Following its recommendations, the CDSM advised against the grant of renewed product licences for the two human dura products and against the grant of a product licence in respect of the bovine product but agreed to advise the grant of a renewed product licence with respect to the implant derived from pig dermis.

57. On 22 November 1990 I attended a meeting of the CSM at which Professor Collee gave an oral report of the recommendations of the CSM BSE Working Group following their meeting on 31 October **[356-360] (YB 90/11.22/14.1-14.5).** The CSM considered the advice given in respect of the dural implant products and Professor Collee emphasised that the draft minute of the Working Group meeting did not reflect the virtually unanimous conclusions of the Working Group that alternative products should be used.

The CSM also discussed the Working Group's conclusions regarding products derived from porcine sources. They endorsed the recommendations of the Working Group insofar as they affected products within the responsibility of the CSM; and noted the advice given to the CDSM. In addition, the question of stocks of vaccines was also considered; the Working Group had indicated that they were reaching the conclusion that it was no longer appropriate for UK sourced bovine products to be used when they could be replaced with batches processed in accordance with the Guidelines. As stated earlier, my role in relation to vaccines was now very limited and substantive matters would have been dealt with by Business A.

1991

58. By this time my involvement with BSE issues had become quite limited. On 27 March 1991, a fax was sent from the EC Commission expressing concerns about the possible transmission of the BSE/scrapie agent to man through use of certain cosmetic treatments **[361-363] (YB 91/03.27/9.1-9.2).** The fax was copied to me and to Dr Jefferys. I think I felt that cosmetics fell outside the MCA's normal remit. I referred the enquiry to Mr Winstanley (Secretary to the CDSM) because of his earlier responsibility for liaison with the DTI over cosmetics.

59. The next meeting of the BSE Working Group had been provisionally scheduled to take place in July 1991. The meeting was in fact postponed - I was not involved in that decision. I received a copy of a minute from Dr Raine to Dr Jefferys dated 26 April 1991 in which she expressed some concern regarding the postponement of the Working Group meeting in view of the fact that BSE had now been reported in France and there were some licensed surgical sutures derived from French bovine material. **[364] (YB 91/04.26/8.1).** She asked if the CPMP discussions on the subject would assist in identifying the extent of any risk. Dr Purves responded on behalf of Dr Jefferys that the French position was still unclear and particularly that the CPMP discussions on the issue were not well advanced and could provide no clarification at that stage **[365] (YB 91/04.29/5.1).**

1992

60. In view of Dr Raine's continuing concern about the question of French sourced surgical cat gut, a further meeting of the BSE Working Group was arranged for May 1992. However, the meeting did not in fact take place until 8 July. I did not attend the meeting and I am not sure whether I would have received a copy of the papers or minutes. I have not been provided with copies of these documents for the purposes of preparing this statement. My colleague from Business B, Dr June Raine did attend the meeting and she would have reported any relevant issues to me if licensing action had been required **[366-367] (YB 90/7.9/2.1 – 2.2).**

61. On 23 September 1992 I attended part of a meeting of the CSM **(YB 92/09.23/4.1/4.8).** I think it is likely I would have been circulated with copies of the relevant papers in advance of the meeting although I do not remember the substance of any discussions. Concerns were raised at that meeting regarding a possible risk of transmission of the BSE agent in gelatin products. The CSM agreed that the matter would be considered at a later meeting **[368-373] (YB 92/7.31/3.1-3.4).** I do not recall any subsequent discussions regarding this issue.

1993/1994

62. A draft of the General Medical Devices Directive was considered in 1993. There was some concern within the MCA that the requirements for certain medical devices would be substantially relaxed if they came under the Directive as drafted and, for example, that the new legislation would allow the reintroduction of human dura products removed under the Medicines Act. Dr Raine expressed some of these concerns in a minute dated 19 July 1993 to Dr Ludgate and copied to me as well as to many others within the MCA **[374-375] (YB 93/07.19/5.1-5.2).**

63. In March 1994 we received information from the German Federal Health Office that the BGA had published an Announcement on 26 February presenting its safety requirements for medicinal products and cosmetics derived from ruminants **[376-378] (YB 94/03.21/15.1-15.2).**

64. I retired in September 1994 and as far as I can remember dealt with no other relevant issues prior to leaving the Department of Health.

Connections with Interested Bodies

65. I confirm that I have no past or present links with the farming community, renderers, feed stock manufacturers, pet food manufacturers, pharmaceutical companies, local government or relevant trade associations other than those which arose through my work as a Civil Servant.

66. This statement is true to the best of my knowledge, information and belief.

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