7. Human and veterinary medicines and cosmetics

Introduction

7.1 Many medicines, medical devices and cosmetics are produced using material from, or derived from, animals, including bovines. Volume 7: Medicines and Cosmetics, explains why these products were significant in the BSE story.

7.2 This chapter describes the responsibilities and systems, both statutory and non-statutory, for controlling medicines, medical devices and cosmetics, and the workings of these in practice in the period leading up to the emergence of BSE. This was the context in which policy makers had to consider the possible impact of BSE and what action, if any, to take.

7.3 The legislative framework differentiated between ‘medicinal products’ and ‘medical devices’ and these are dealt with separately in this chapter.

Medicinal products: responsibilities

Introduction

7.4 The Medicines Act 1968 and European Directives together established a framework of responsibilities and controls for human and veterinary medicinal products. The relevant legislation changed between 1985 and 1996 as a result of the gradual introduction of EC measures, connected with the Single Market, which added to and modified the Medicines Act 1968. The basic framework, however, remained the same.

7.5 The Medicines Act 1968 set out a system under which a Licensing Authority, advised by a Commission and Committees, was responsible for the licensing of human and veterinary medicinal products according to standards set out in the Act and Regulations made under it. The Licensing Authority’s key concern was with ensuring the safety, quality and efficacy of medicinal products.416

7.6 European regulation of medicinal products had a framework similar to that of the Medicines Act, with control and regulation being achieved through a licensing system. It had two aspects: a decentralised system whereby each Member State provided a licensing regime for medicinal products within its jurisdiction; and, from 1993, a centralised system allowing for EU-wide licences, which were administered by the European Medicines Evaluation Agency (EMEA). European Regulation of medicinal products is outlined in more detail later in this chapter.

416 Safety relates to a medicine’s actual or potential harmful effects; quality to its development and manufacture; and efficacy to its beneficial effect on the patient. (DH01 tab 6 para. 2)
7.7 Until 1995, the Medicines Act 1968 and regulations made under it were the primary instruments through which the UK performed its European obligations in relation to medicinal products.

The UK Licensing Authority

7.8 As noted above, under the Medicines Act 1968 responsibility for the grant, renewal, variation, suspension and revocation of licences was given to the Licensing Authority. This comprised ‘the Health Ministers’ and ‘the Agriculture Ministers’ – ie, the Secretary of State for Health, the Minister of Agriculture, Fisheries and Food and the corresponding Ministers in Northern Ireland, Scotland and Wales417 – although any one of them acting alone was permitted to perform its functions.418

7.9 In practice, the functions of the Licensing Authority in relation to medicines for human use in the UK were, throughout the period 1985–96, performed by the Secretary of State for Health.419 Similarly, the functions of the Licensing Authority in relation to medicines for animals were performed by the Minister of Agriculture, Fisheries and Food.

7.10 During the period covered by this Report, the human medicines licensing functions of the Secretary of State for Health were delegated to officials working in the Medicines Division of the Department of Health (DH) or, after April 1989, officials working for the Medicines Control Agency (MCA). This arrangement was, however, subject to the normal legal principles relating to the extent to which ministerial functions may be delegated.420 Similar arrangements were in place in the Ministry of Agriculture, Fisheries and Food (MAFF). This meant that product licences were in practice granted by officials, not by the Minister.

7.11 The Licensing Authority received advice from a number of statutory bodies, most importantly the Medicines Commission and Committees known as section 4 committees (see below).

Advice to the Licensing Authority

Medicines Commission

7.12 Section 2 of the Medicines Act 1968421 provided for the establishment of the Medicines Commission to advise the Ministers making up the Licensing Authority on matters relating to the execution of the Act or the exercise of any power conferred by it or otherwise relating to medicinal products, where either

i. the Commission considered it expedient; or

ii. it was requested by the Minister or Ministers to do so.422
Responsibilities for Human and Animal Health

There were to be no fewer than eight members of the Commission, including at least one person having ‘wide and recent’ experience of each of the following:

i. the practice of medicine (other than veterinary medicine);
ii. the practice of veterinary medicine;
iii. the practice of pharmacy;
iv. chemistry other than pharmaceutical chemistry; and
v. the pharmaceutical industry. 423

7.13 The Medicines Commission was also required to recommend to Ministers the number, functions and membership of committees to be set up under section 4 of the Medicines Act (known as ‘section 4 committees’), 424 and

... it also had an important role in one of the stages of the appeal mechanism in respect of licences for medicinal products. 425 It was also required to send Ministers an annual report on the performance of its functions. 426

Section 4 committees

7.14 Section 4 committees were established by Ministers to consider particular classes of substances or articles covered by the Act, for the purpose of:

(a) giving advice with respect to the safety, quality or efficacy or with respect to all or any two of those matters; and

(b) promoting the collection and investigation [of] information relating to adverse reactions, for the purpose of enabling such advice to be given. 427

7.15 Members of section 4 committees were appointed by Ministers having regard to recommendations made by the Medicines Commission as to their number, function and membership. 428 Each Committee was required to send an annual report on the performance of its functions to the Commission and the Ministers. 429

7.16 During the relevant period, there were five section 4 committees:

i. Committee on Safety of Medicines (CSM);
ii. Veterinary Products Committee (VPC);
iii. Committee on Dental and Surgical Materials (CDSM);
iv. Committee on the Review of Medicines (CRM); and

423 L12 p. A11 section 2(3)
424 L12 p. A12 section 4(1)
425 T71 p. 16
426 L12 p. A13 section 5(2)
427 L12 pp. A12–13 section 4(3)
428 L12 pp. A11–13 sections 3(2), 4(1), 4(5)
429 L12 p. A13 section 5(3)
7.17 A section 4 committee could, with the approval of the Ministers, appoint one or more specialist subcommittees to supply information on all aspects of medicines including chemistry, pharmacy, biologicals, safety and efficacy. The various subcommittees could report to any of the section 4 committees, depending on the nature of the problem they were considering, and there was in practice a great deal of cross-membership between the various committees and subcommittees. Recommendations made by subcommittees had to be passed on to the relevant section 4 committee and endorsed before officials could act on them. Committee and subcommittee members were part-time independent experts who were paid a nominal fee.

7.18 Dr David Jefferys, a Principal Medical Officer in Medicines Division of DH and then in the Medicines Control Agency, told the Inquiry that:

The Section 4 committees, particularly the Committee on the Safety of Medicines, have a very heavy workload. As a result, the CSM recommended many years ago that a number of advisory subcommittees, such as the Biologicals subcommittee, should be set up.

The subcommittees tend to devote more time to scrutinising the details of issues raised for their consideration whilst the Section 4 committees adopt a more general overview. The subcommittees are generally scheduled to meet approximately two weeks before the meeting of whichever Section 4 committee will ultimately consider the relevant issues.

In practice, there is a considerable overlap between the membership of the Section 4 committees and the membership of their subcommittees. This means that it is not necessary for all disciplines to be represented on a Section 4 committee provided that the relevant expertise is available in the subcommittees. In addition the CSM can ask the Licensing Authority to appoint further experts as ‘members for the day’ to provide additional expertise.

7.19 The Committee on Safety of Medicines (CSM) was established by the Medicines (Committee on Safety of Medicines) Order 1970 to advise on the safety, quality and efficacy of medicinal products for human use. It had overall responsibility for advising Ministers on the safety, quality and efficacy of human medicines. It was also required to promote the collection and investigation of information relating to adverse reactions, to enable such advice to be given. During the period covered by this Report, the CSM met once a month; such meetings lasted for one or two days. The Inquiry was told that the Chairman bore ultimate responsibility for the advice given.

7.20 In relation to BSE, the CSM had two key subcommittees: the Sub-Committee on Biologicals, often known as the Biologicals Sub-Committee or BSC, and the BSE Working Group. The BSC’s role was to advise the CSM in relation to medicinal products of a biological nature – ie, non-synthetic drugs such as vaccines.

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430 S190 Jones para. 5
431 771 p. 25
432 S419 Jefferys paras 16–18
433 L13 tab F p. 7
434 S441 Asscher para. 8
435 S441 Asscher para. 5
blood products, etc. The BSE Working Group, on the other hand, was an *ad hoc* committee specifically set up to deal with BSE. Its role was to advise the section 4 committees on the possible hazards to man of human medicinal products, with special reference to BSE.

7.21 **The Veterinary Products Committee (VPC)** was established in 1970 to advise on safety, quality and efficacy in relation to the veterinary use of medicinal products. The VPC also promoted the collection of information relating to suspected adverse reactions to enable such advice to be given. It advised on applications for test licences and product licences for individual veterinary products, and general policy, including guidelines for registration of veterinary medicines.

7.22 **The Committee on Dental and Surgical Materials (CDSM)** was established by the Medicines (Committee on Dental and Surgical Materials) Order 1975 to advise on the safety, quality and efficacy, for human or animal use, of substances and articles for dental and surgical use, to which the Medicines Act applied and which fell outside of the expertise of the CSM or the VPC. It was also responsible for substances and fluids for use with contact lenses. It had a role, too, in promoting the collection and investigation of information on adverse reactions for the purpose of giving advice. The CDSM was disbanded in 1994.

7.23 **The Committee on the Review of Medicines (CRM)** was established in 1975 under the Medicines Act 1968 to advise on the safety, quality and efficacy of substances and articles that were on the market before the Act came into force and which had been granted ‘licences of right’ under section 25 of the Act (see below). This amounted to some 30,000 products, the review of which began in 1975. Once its work was completed in 1991, the CRM was disbanded.

7.24 **The British Pharmacopoeia Commission (BPC)** was responsible for preparing new editions of the *British Pharmacopoeia* and the *British Pharmacopoeia (Veterinary)* and for keeping these up to date. The British Pharmacopoeias provide authoritative standards for the quality of substances, preparations and articles used in medicine and pharmacy. The BPC was also responsible for maintaining liaison with the European Pharmacopoeia Commission and, under section 100 of the Medicines Act, for the preparation of a list of British-approved names suitable for use as the names of substances and articles. The BPC had no role in relation to BSE.

**Chief Medical Officer and Chief Veterinary Officer**

7.25 Other advice to Ministers in relation to human and veterinary medicines came from the Chief Medical Officer (CMO) and the Chief Veterinary Officer (CVO). *Government and Public Administration* describes the role and responsibilities of each of these officers.

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436 S423 Collee para. 30; S190 Jones para. 5
437 S423 Collee para. 30
438 M67 tab 1
439 L13 tab F p. 26 Medicines (Committee on Dental and Surgical Materials)(Revocation) Order 1994 SI 1994(3120). The implementation of Council Directive 93/42/EEC (OJ L169, 12.7.93, p. 1) concerning medical devices meant that most of the substances and articles referred to were no longer covered by the Act. In the case of those remaining, the statutory functions of the CDSM fell to another s 4 committee or to the Medicines Commission.
440 By means of the Medicines (Committee on the Review of Medicines) Order 1975 S.I. 1975/1006
7.26 Briefly, the CMO, a Grade 1A official, was:

. . . the principal adviser on medical and public health matters, not only to Ministers in the Department of Health but to the Ministers in other government departments and to the Government as a whole.443

7.27 The CMO also had ultimate line-management responsibility for the medical and scientific staff in DH until April 1995.

7.28 Mr Stephen Dorrell, Secretary of State for Health from July 1995 to May 1997, told the Inquiry about the relationship between the advisory Committees and the Chief Medical Officer:

The Chief Medical Officer in that context is an independent source of advice, if you like, to the Secretary of State, or to Ministers to the Licensing Authority, on how they should react to advice that comes from the CSM. But it is, I think – it certainly did not happen in my time that the CMO expressed a different view from the CSM. I think it is extremely unlikely that he would do that, much more likely that if he felt that action needed to be taken, he would act by changing the machinery rather than by commenting on the advice that came out of the machinery.444

7.29 In this context, the Inquiry was also told that while CSM was not responsible under the relevant legislation to the CMO,445 the practice on all sensitive public health issues was to minute the CMO at the same time as minuting Ministers.446

7.30 The CVO, a Grade 3+ official, was the chief adviser on veterinary policy for Great Britain as a whole.447

Other UK Committees

7.31 The Joint Committee on Vaccination and Immunisation (JCVI), a non-departmental public body, was established under the NHS Act 1977 as a Standing Advisory Committee.448 Its terms of reference were:

To advise the Secretaries of State for Health, Scotland, Wales and Northern Ireland on matters relating to the prevention of communicable disease through immunisation.449

7.32 Professor Alexander Campbell, chairman of the JCVI between April 1989 and May 1996, outlined its role:

The JCVI is an independent committee of experts which gives advice on vaccines and vaccine strategy to the Department of Health. For example, the JCVI makes recommendations on routine childhood and adult immunisation and particular vaccine campaigns which might be required from time to time.
Although the committee deals primarily with issues relating to the vaccination of children, it also gives advice on all other issues involving vaccines, such as the protection of travellers. The committee is responsible for a publication entitled ‘Immunisation Against Infectious Disease’ . . .

The committee is made up of a number of experts from different fields, in areas such as virology, microbiology, paediatrics, general practice, epidemiology, infectious disease, community health and neurology. In addition, Consultants from the PHLS and members of the National Institute for Biological Standards and Control (NIBSC) usually attend meetings. Experts in a particular field can also be invited to attend as appropriate.

### 7.33 The National Institute for Biological Standards and Control (NIBSC)

The National Institute for Biological Standards and Control (NIBSC) had the object of securing high standards of quality, safety, efficacy and consistency of biological substances used in medicine. It was a specialist, laboratory-based organisation whose work fell into three main categories:

1. carrying out controls (the testing of the purity and potency of biological medicines prior to their release, on behalf of DH and the MCA and for the EU under European medicines legislation);
2. producing standards (ie, the preparation and evaluation of International and British Standards and Reference Preparations); and
3. research and development (to inform and enable the control and standards activities).

The NIBSC also had European and World Health Organisation (WHO) functions, and operated as a WHO International Laboratory for Biological Standards. It was overseen by the National Biological Standards Board, established by the Biological Standards Act 1975, and exercised the day-to-day functions of the Board on its behalf.

### Executive functions in relation to medicinal products

#### Human medicines

The executive arm of government responsible for operating the licensing regime for human medicinal products was the Medicines Division of DH and its successor, the Medicines Control Agency (MCA), which became an Executive Agency on 11 July 1991. These bodies carried out the functions of the Licensing Authority in relation to human medicines; ie, the operation of the licensing regime and safeguarding the public health by ensuring that medicines on the UK market met appropriate standards of safety, quality and efficacy. Medicines Division and the MCA provided secretariats for the Medicines Commission and the section 4 committees other than the VPC. They also had responsibilities for monitoring and enforcement in relation to medicinal product licences. The structure and operation
of Medicines Division and the MCA are described further in Chapter 2 of vol. 7: Medicines and Cosmetics.

7.36 The recommendation to transform Medicines Division into the MCA came from the Evans–Cunliffe Report in 1987, which was a comprehensive study of the control of human medicines in the UK.\textsuperscript{453} The main conclusions of this report\textsuperscript{454} were that there were problems within the Medicines Division at that time which needed to be addressed:

Our study suggests that the UK approach to the control of medicines is sound, and the legislative framework satisfactory. Thanks to the contribution of assessors and advisory committees, its intellectual and judgmental qualities stand high. Medicines Division of DHSS has coped quite well with rising workload over a number of years, but is now showing signs of overload with increasing delays and minor documentary errors. There is chronic difficulty in recruiting the best professional staff, and computing support is antediluvian. The complex organisational structure prevents effective management, and overall the Division is unduly constrained from without and lacks resilience within.\textsuperscript{455}

7.37 Officials in Medicines Division played an important role in the operation of the section 4 committees and their subcommittees. The secretariat of the committee would set the agenda for meetings. The subjects for discussion would generally arise from consideration of licence applications within the Division/Agency. Officials would bear in mind the need for recommendations from subcommittees to come forward to the main committee meetings. Officials were also responsible for preparing the many professional papers for the committee members to read for the meetings. At the meetings themselves, officials would generally not take an active role. However, they were responsible for actioning the advice of the committee and communicating it to others as necessary. This might involve briefing Ministers.\textsuperscript{456}

7.38 The Inquiry was told by Professor Asscher, chairman of the CSM, that:

\[ \ldots \text{[T]he Chairman of the CSM played no part in and had no responsibility for setting the agenda for CSM meetings. The first knowledge that members of CSM had about the issues that were due to be considered at meetings came from reading their blue bags for that meeting. However, it was my practice to receive the blue bags for each of the CSM’s subcommittees and, as a result, I would at a slightly earlier stage have had some idea what issues would be coming up at the next CSM meeting. However, I would not be in a position, at that stage, to influence the agenda for the CSM meeting; nor would I need to because every item considered by a CSM subcommittee is also considered at the following meeting of the CSM. I did, however, on first assuming the chairmanship of the CSM, bring my influence to bear on subcommittee chairmen to minimise the number of hearings (presentations by industry) at CSM meetings by the introduction of pre-hearing procedures. This resulted in a considerable saving of committee time.} \]\textsuperscript{457}
7.39 In respect of the CSM Biologicals Sub-Committee, the Inquiry was told by its chairman Professor Collee:

After the meeting there was a Chairman’s debriefing session with officials. This would last about half an hour and was used to prepare a draft of the minutes with officials. I often amended the draft minutes. The purpose of the debriefing meetings was to ensure that officials fully understood the committee’s advice and had accurately minuted that advice. The actual implementation of advice was carried out by officials.\(^{458}\)

**Veterinary medicines**

7.40 Within MAFF, there were until 1989 three bodies involved in the regulation of veterinary medicines. The Animal Health Division III/Animal Medicines Division, part of the Animal Health Group, was responsible for policy matters relating to veterinary medicines. The Medicines Unit at the Central Veterinary Laboratory (CVL) was responsible for the assessment of non-biological products and provided the administrative staff who formed the secretariat of the VPC. The Biological Products and Standards Department (BP&S), also part of CVL, was responsible for the assessment of applications for immunological veterinary medicines and inspections of their manufacturing premises.

7.41 On 1 April 1989, the Animal Medicines Division merged with the Medicines Unit and part of the Biological Products and Standards Department to form the Veterinary Medicines Directorate (VMD), which became an Executive Agency on 2 April 1990. The VMD was responsible for all aspects of licensing and control of animal medicines and medicated feedstuffs, for monitoring and controlling veterinary residues in animal products, and for monitoring suspected adverse reactions.\(^{459}\) The structure and operation of the bodies in MAFF responsible for veterinary medicines and the VMD are outlined further in Chapter 2 of vol. 7: *Medicines and Cosmetics*.

7.42 The establishment of the VMD had been recommended in a report in early 1988 entitled *Review of Animal Medicines Licensing*,\(^ {460}\) which was prepared shortly after the Evans–Cunliffe Report on the licensing arrangements for human medicines. Its conclusions are set out in more detail in vol. 7: *Medicines and Cosmetics*. In summary, it emphasised that there was little criticism of the general concept and indeed of the general correctness of decisions but considerable criticism of the operation of the system.\(^ {461}\)

7.43 It recommended better use of information technology; simplification of procedures and removal of unnecessary work; better communications between applicants and the licensing operation; improvements in staff recruitment, remuneration and management; and improved organisational structures.\(^ {462}\)

7.44 The secretariat of the VPC was provided by the Medicines Unit at the Central Veterinary Laboratory and then by the VMD. It set the agenda, provided papers and

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\(^{458}\) S423 Collee para. 24

\(^{459}\) DM01 tab 14 p. 3; S499 Rutter para. 4

\(^{460}\) M11D tab 18

\(^{461}\) M11D tab 18 p. 14 para. 3.1

\(^{462}\) M11D tab 18 pp. 30–35
produced minutes of meetings, just as Medicines Division/MCA did for the committees considering human medicines.

### 7.45 Professor Armour, chairman of the VPC, told the Inquiry:

Of the licence applications received by the Medicines Unit/VMD, the VPC was asked to advise on approximately 30%. These were all novel substances or those where there might be a perceived problem. Otherwise, applications were dealt with by the Medicines Unit, CVL and later the VMD and a list of processed applications was provided to the VPC for information. All applications containing novel substances were seen in detail, as were all recommended for refusal. General policy matters were all presented for review and advice. At quarterly intervals a paper on all reported adverse reactions to licensed veterinary medicines was presented to VPC.\(^{463}\)

### 7.46 The assessment work of the +VMD was supported by two non-statutory committees of officials, the Scientific Secretariat (for pharmaceutical products) and the Biologicals Committee (for immunological products).\(^{464}\) The meetings of these committees were attended only by officials and not by members of the VPC.\(^{465}\) Mr Alastair Kidd, Director of Licensing at the VMD, explained their operation:

At monthly meetings the Biologicals Committee and Scientific Secretariat considered licence applications for veterinary biological and pharmaceutical products respectively and the assessment reports of BP&S and Medicines Unit staff. The Scientific Secretariat of the VPC drew its members from a variety of sources including the Medicines Division of the Department of Health, and toxicologists from the Department of Health and from the Chemical Division of Porton Down. As far as the Biologicals Committee was concerned, the Department of Health was not represented and any contact with the Department of Health was on an informal basis. However, as technical documents were invariably submitted to the VPC, Department of Health officials were fully informed through their presence at VPC meetings and were able to comment or pass papers on to appropriate colleagues. The Biologicals Committee/Scientific Secretariat subsequently made recommendations as to whether a product authorisation should be granted or not. The comments of the appropriate committee were incorporated into the reports prior to assessment of licence applications by the VPC.\(^{466}\)

### European responsibilities for medicinal products

#### The European Medicines Evaluation Agency

### 7.47 The centralised European licensing system was administered by the European Medicines Evaluation Agency (EMEA), which was set up in 1993 at the same time as the system for which it was responsible.\(^{467}\) The EMEA consisted of the Committee for Proprietary Medicinal Products (CPMP), the Committee for

\(^{463}\) S477 Armour para. 5(ii)

\(^{464}\) S499 Rutter para. 13

\(^{465}\) S477 Armour para. 5(ii)

\(^{466}\) S515 Kidd para. 9

\(^{467}\) L16 tab 1 pp. 22–27 (Council Resolution EEC 2309/93 articles 49–66)
Veterinary Medicinal Products (CVMP), a secretariat, an executive director and a management board.\textsuperscript{468}

**The CPMP and the CVMP**

7.48 The CPMP was initially established in 1975 by Council Directive 75/319/EEC to advise the European Commission on issues of safety, quality and efficacy in relation to human medicinal products.\textsuperscript{469} It did so in much the same way as the CSM advises the Licensing Authority in the UK.\textsuperscript{470}

7.49 A corresponding body for veterinary medicines, the CVMP, was set up in 1981 by Council Directive 81/851/EEC. It performs the same functions in respect of veterinary medicines as the CPMP performs for human medicines.\textsuperscript{471} As noted above, both of these committees now come under the umbrella of the EMEA.

7.50 These scientific committees, comprising two appropriately qualified members nominated by each Member State,\textsuperscript{472} were the mechanisms through which Member States had input into the licensing process.\textsuperscript{473} The members of the committees were required to ensure that there was appropriate coordination between the tasks of the EMEA and the work of the licensing authorities of individual Member States and their consultative bodies.

7.51 The CPMP and CVMP were able to establish working parties and expert groups to assist them.\textsuperscript{474} Dr John Purves of the UK Medicines Control Agency was a member of the *ad hoc* Working Party on Biotechnology/Pharmacy reporting to the CPMP, and Dr Geoffrey Schild of the NIBSC was chairman of this same group from 1986 until 1991.\textsuperscript{475} Dr A Lee of the Veterinary Medicines Directorate was the UK member of the Immunologicals Working Party of the CVMP.\textsuperscript{476}

7.52 In relation to BSE, both the CPMP and the CVMP issued guidelines entitled ‘Minimising the Risk of Transmitting Agents Causing Spongiform Encephalopathy via Medicinal Products’ in 1992 and 1993 respectively.\textsuperscript{477} These are considered further in Chapter 6 of vol. 7: *Medicines and Cosmetics*.

**Medicinal products: the licensing regime**

**Products covered under the Act**

7.53 The Medicines Act 1968 imposed licensing requirements on dealing in and manufacture of ‘medicinal products’,\textsuperscript{478} which were defined as substances or articles, not being instruments, apparatus or appliances, for use wholly or mainly by being administered to human beings or animals for medicinal purposes.\textsuperscript{479}

\textsuperscript{468} L16 tab 1 pp. 22–23
\textsuperscript{469} L16 tab 1 p. 95
\textsuperscript{470} S535 Purves para. 25
\textsuperscript{471} L16 tab1 pp. 14–22
\textsuperscript{472} L16 tab 1 p. 24 article 52 para. 1
\textsuperscript{473} DH01 tab 6 para. 11
\textsuperscript{474} L16 tab 1 p. 23 article 50 para. 2
\textsuperscript{475} S535 Purves para. 25; S575 Schild para. 21
\textsuperscript{476} S499 Rutter para. 21
\textsuperscript{477} YB91/12.11/3.1–3.10; M74 tab 4A
\textsuperscript{478} L12 pp. A15–19 sections 7 and 8
\textsuperscript{479} L12 p. A139 section 130(1)
‘Medicinal purposes’ included treating or preventing disease, diagnosing disease or ascertaining the existence, degree or extent of a physiological condition, and otherwise preventing or interfering with the normal operation of a physiological function.480

7.54 The Medicines Act and Regulations made under it also placed licensing requirements on certain other substances that fell outside the definition of a medicinal product. These included: surgical ligatures; sutures; contact lenses; intra-uterine contraceptive devices; and a wide range of substances, such as heparin, that are used as ingredients in the manufacture of medicinal products.481

7.55 Medical devices, being instruments, apparatus or appliances, did not fall within the definition of medicinal products and are discussed separately later in this chapter.

7.56 Various products fell on the borderlines between foods and medicinal products, between medical devices and medicinal products, or between cosmetics and medicinal products, for example, vitamin supplements. There were Regulations governing whether such products were to be treated as medicinal products or not.482 A key factor was whether they were sold ‘with indications’, ie, specifying their use in treating a particular condition. They were also assessed with regard to their ingredients and function, and presentation to the public through labelling, packaging, advertising and promotion.

7.57 Certain products and substances, which did fall within the definition of medicinal products, were nonetheless excluded from the licensing requirements of the Act. Generally, they were covered under other regulatory regimes. The sale of medicinal products intended for human use as foods or cosmetics was excluded, subject to certain very specific qualifications.483 Also excluded were: medicines made, or imported, for particular patients, sometimes referred to as ‘specials’; herbal remedies under certain specified circumstances; and, from 1994, homeopathic medicinal products granted a certificate of registration.484

**Licensing medicinal products**

**Licences**

7.58 The Medicines Act 1968 prohibited:

i. the sale, supply or export;

ii. manufacture; or

iii. wholesale distribution

of a medicinal product, except in accordance with:

i. a ‘product licence’;

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480 L12 p. A140 section 130(2)
481 L15 tab R: Orders made pursuant to sections 104 and 105 of the Medicines Act 1968
482 For example, the Medicines (Exemption from Licences) (Foods and Cosmetics) Order 1971 SI 1971/1410 (L13 tab G pp. G26–28)
483 L13 tab G p. 27 article 2(1)
484 L12 sections 13, 12, 7(2A)
ii. a ‘manufacturer’s licence’; or
iii. a ‘wholesale dealer’s licence’.

The Inquiry was primarily concerned with product licences, since it was products that contained bovine material which were relevant to the BSE story.

7.59 Before the introduction of this licensing regime, manufacturers of medicines had been able to market products without having to satisfy an independent body as to their safety, quality and efficacy. However, from 1 September 1971, when the relevant provisions of the Act came into force, all medicines had to be licensed before they could be sold or supplied in the UK.\(^{485}\)

7.60 The licensing application provisions did not affect those engaged in selling, supplying, manufacturing, or assembling medicinal products that were on the market as at 1 September 1971. Such people could apply instead for a ‘licence of right’. They would then be entitled to the grant of a product licence, subject to certain conditions.\(^{486}\) The closing date for applications for a licence of right was 1 July 1972.\(^{487}\) The transitional provisions in the Medicines Act, with two exceptions, expired on 1 September 1972.\(^{488}\)

7.61 A review of the safety, quality and efficacy of medicinal products granted product licences of right (PLRs) became mandatory when the UK joined the EC in 1973, with the review to be completed by 1990.\(^{489}\) The CRM was set up in 1975 to review human medicinal products and the VPC carried out a parallel review of veterinary medicinal products.

**Making and processing of licence applications**

7.62 Applications for product licences were governed by the Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Regulations 1971.\(^{490}\) In relation to human medicines, these were superseded by the Medicines (Applications for Grant of Product Licences – Products for Human Use) Regulations 1993.\(^{491}\) In essence, with an application for a product licence the applicant was required to submit the following data in full:

- Qualitative and quantitative particulars of the constituents of the product;
- Description of the method of preparation;
- Therapeutic indications/contra-indications and side effects;
- Posology (dosage), pharmaceutical form, method and route of administration and expected shelf-life;
- Description of the control methods employed by the manufacturer;

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\(^{485}\) S498 Lawson para. 8
\(^{486}\) L12 section 16 and sections 25–27. The conditions were that the licence granted did not extend to any medicinal products other than those already on the market or being imported
\(^{487}\) L13 p. E41 the Medicines (Termination of Transitional Exemptions) (No. 3) Order 1975
\(^{488}\) S498 Lawson para. 9
\(^{490}\) L13 tab H p. 1
\(^{491}\) L13 tab H p. 40A
Results of the physico-chemical, biological or microbiological tests, pharmacological and toxicological tests and clinical trials; and

Pre-clinical and clinical data.  

7.63 Results of clinical trials were an important part of any product licence application. Clinical trials on humans or animals were investigations involving the administration of a medicinal product to one or more patients to assess its safety and efficacy. Where the clinical trials for a particular medicinal product had been carried out in the UK, the trials themselves required an authorisation from the licensing authority. A Clinical Trial Certificate (CTC) for trials on humans or an Animal Test Certificate (ATC) for trials on animals could be issued where the licensing authority had consented – subject to the provisions of the certificate – to a clinical trial of a particular medicinal product. However, the Licensing Authority could exempt a medicinal product from having to undergo clinical trials, by issuing a Clinical Trial Exemption Certificate (CTX).

7.64 When a licence application was submitted, the administrative divisions responsible for medicines within MAFF and DH, respectively, would first establish that the application was complete. When all the required information had been received, the application would be assessed by the medical and scientific experts within the Departments or, in the case of products to be licensed under the EC system, by assessors from two Member States nominated by the EMEA.

7.65 In assessing applications for product licences, particular consideration was given to the product’s safety, quality and efficacy. Manufacturer’s licence applications were assessed taking particular account of

i. the operations proposed to be carried out under the licence;
ii. premises;
iii. equipment;
iv. the qualifications of those responsible for supervision; and
v. record-keeping arrangements.

An initial inspection lasting about three days was carried out to assess whether the manufacturer had the appropriate staff, facilities, systems and organisation to manufacture medicinal products consistently to the required quality.

7.66 Wholesale dealers were licensed with particular regard to the premises, equipment and record-keeping to be used for storage and distribution.

Granting new licences

7.67 In dealing with an application for the grant of a product licence, the Licensing Authority was obliged to take into consideration several factors, including 'the

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492 DH01 tab 6 para. 15
494 L12 pp. A39–51sections 31–39; the particulars required in an application for a CTC or ATC are set out in schedules 2 and 3 of the Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Regulations 1971 (L13 tab H pp. 26, 29)
495 DH01 tab 12 para. 20
496 L12 pp. A19–A19, sections 7, 8, 19(6)
safety of medicinal products of each description to which the application relates’.497
Having done so, the Licensing Authority could:

i. grant a licence containing such provisions as it considered appropriate;

or

ii. if, having regard to the provisions of the Act and any Community obligation, it considered it necessary or expedient to do so, refuse to grant a licence.498

7.68 If the Licensing Authority was minded to refuse a licence on the grounds of the product’s safety, quality or efficacy, it had first to consult the appropriate section 4 committee or (if there was no such committee) the Medicines Commission.499

7.69 In other cases, officials exercised their discretion about whether to refer the application to the section 4 committee. If the application was ‘simple and satisfactory’, it might be granted a product licence at that stage. Such ‘simple’ applications might involve products that were substantially the same as existing products that had been granted licences. Dr Purves of the MCA told the Inquiry that:

... Any new developments where there was not a precedent for action taken by the Licensing Authority, would have been taken to the expert committees for their advice.500

7.70 However, even in cases where the section 4 committee had given advice, it was the Licensing Authority itself, not the committee, that was responsible for determining the application in question.

7.71 The Inquiry heard that decisions regarding the granting of licences were generally not referred to Ministers. When giving oral evidence, Mrs Edwina Currie, Parliamentary Under-Secretary for Health between 1986 and 1988, was asked:

Q: ... medicinal products are licensed under the Medicines Act and there is a licensing authority so that basically you leave it to them. Would that be a fair way of putting it?

She responded:

A: That would be right; but also it reflected considerable confidence in the way that system worked. It worked very well.501

7.72 Mrs Virginia Bottomley, Secretary of State for Health between 1992 and 1995 told the Inquiry:

The process of the licensing of medicines was the territory of a number of highly qualified and highly regarded experts in that team. They, I think quite jealously, preserved that territory. Matters would be raised with Ministers if they were likely to cause public concern, if there was an issue that – if there was a problem, essentially, if the authority of the Minister was necessary.

497 L12 p. A26 section 19(1)(a)
498 L12 pp. A27–A28 section 20(1)
499 L12 p. A28 section 20(3)
500 S535 Purves p. 5 para. 13
501 T84 pp. 44–45
But for the most part they sought, I think, to consume their own smoke and deliver their objectives.\textsuperscript{502}

**Existing licences: renewal, suspension, revocation and variation**

**7.73** Product licences were not granted indefinitely. They expired either five years after they were granted or last renewed, or at the end of any shorter period if specified in the licence.\textsuperscript{503} The licence holder could then apply for the licence to be renewed for a further period of five years. In such cases, the Licensing Authority could:

i. renew the licence, with or without modifications;

ii. grant a new licence containing such provisions as the Licensing Authority considered appropriate; or

iii. if, having regard to the provisions of the Act, it considered it necessary or expedient to do so, refuse to renew the licence or grant a new licence.\textsuperscript{504}

**7.74** Before refusing to renew a licence on any grounds relating to ‘the safety, quality or efficacy of medicinal products’, the Licensing Authority was again obliged to consult the appropriate section 4 committee or (if there was no such committee) the Medicines Commission.\textsuperscript{505}

**7.75** Under section 28 of the 1968 Act, the Licensing Authority also had power to suspend, revoke or vary the provisions of a product licence on certain specified grounds. These included:

(b) that any of the provisions of the licence has to a material extent been contravened by the holder of the licence or by a person procured by him to manufacture or assemble medicinal products of a description to which the licence relates;

\ldots

(g) that medicinal products of any description to which the licence relates can no longer be regarded as products which can safely be administered for the purposes indicated in the licence, or can no longer be regarded as efficacious for those purposes; and

(h) that the specification and standards to which medicinal products of any such description are manufactured can no longer be regarded as satisfactory.\textsuperscript{506}

The Act did not specify the kinds of variation that might be made.

**7.76** Except for suspension in a case of urgency, if the Licensing Authority proposed to suspend, revoke or vary a product licence on the grounds set out in
paragraphs (g) or (h) of section 28(3), they had first to consult the appropriate section 4 committee or, if there was none, the Medicines Commission. Schedule 2 of the Act gave the licence holder a right to be heard and a right of appeal where the Licensing Authority proposed to revoke, suspend or vary a licence.

7.77 Where it appeared to the Licensing Authority that in the interests of safety it was necessary to suspend a licence with immediate effect, then it might do so for a period of up to three months. In such cases, it had to report the suspension to the appropriate section 4 committee, and the usual consultation and notification procedures were then brought into play, as appropriate.

**Monitoring, inspection and enforcement**

**Introduction**

7.78 Responsibility for monitoring, inspection and enforcement of the Medicines Act fell to the executive bodies responsible for medicinal product; ie, the MCA in relation to human medicines and the VMD for veterinary medicines. Some of the avenues through which these tasks were carried out are summarised below.

7.79 After a product had received a licence, these bodies monitored its use throughout its life through ‘pharmacovigilance’ – ie, the process of monitoring a medicinal product on the market. This included: monitoring of adverse drug reactions; inspection of manufacturing sites; quality analysis of samples of marketed products; and enforcement of standards.

7.80 Under the European system, pharmacovigilance, inspection and enforcement activities remained the responsibility of Member States.

**Adverse reactions**

7.81 One of the ways in which the safety of medicinal products that had been licensed was monitored was through the reporting of adverse reactions to the MCA or the VMD. This was achieved through the ‘Yellow Card Scheme’, under which doctors, coroners, dentists, pharmacists and vets reported suspected adverse reactions on a voluntary basis, and the pharmaceutical industry reported them under statutory obligations.

7.82 For human medicines, these adverse reactions were recorded in what is now known as the Adverse Drug Reactions On-Line Information Tracking (ADROIT) database. ADROIT recorded against each product details of active ingredients, excipients, and reports of suspected adverse reactions. Such reports were reviewed on a weekly basis to assess the causal relationship between the products and reported reactions and to identify possible risk factors contributing to the occurrence of reactions – for example, age or underlying disease. It is now possible, if an ingredient can be implicated in a suspected adverse reaction, to interrogate...
ADROIT or the Product Licence User System (PLUS)\textsuperscript{512} to identify other products using such material. When a material is used in the manufacturing process but is not present in the finished product, it is not recorded in either ADROIT or PLUS.

7.83 For veterinary medicines, reports of adverse reactions were recorded in the Suspected Adverse Reactions Scheme (SARS) database. Potentially serious reactions were reviewed monthly, and quarterly reports of all suspected reactions were provided to the VPC. Searches of the system could provide details of other similar authorised products and their ingredients.

7.84 The MCA also operated a Medicines Testing Scheme under which products already on the market were subjected to analytical quality examination. It also operated a 24-hour per day Defective Medicines Report Centre so that action could be taken in respect of faulty batches of medicines reaching the market.\textsuperscript{513}

**Inspections**

7.85 Inspections were carried out to ensure that manufacturers had the appropriate staff, facilities, systems and organisation to manufacture medicinal products consistently to the required quality. An inspection was conducted initially to assess an applicant for a manufacturer’s licence and thereafter every two years to ensure continued compliance with good manufacturing practice (GMP). An inspection lasted on average three days and examined a selection of the premises, processes, procedures and records chosen by the inspector to enable him or her to come to a view on the general compliance with GMP.\textsuperscript{514}

7.86 An inspection could also look at other licensing concerns such as compliance with individual product specifications or processes. However, the primary responsibility for ensuring that an individual product was made in accordance with its licence lay with the manufacturer.\textsuperscript{515} A manufacturer was required to have at its disposal a qualified person who was personally responsible for ensuring that medicinal products produced by the manufacturer complied with the product licence and relevant laws.\textsuperscript{516} Inspections included an assessment of the systems used by the manufacturer to meet these responsibilities and of the manner in which the qualified person discharged his or her specified duties.\textsuperscript{517}

**Enforcement**

7.87 Where issues relating to product standards, manufacturing standards and storage requirements arose, the primary tool for achieving compliance available to the Licensing Authority was the risk or possibility of the relevant licence being withdrawn.\textsuperscript{518}

7.88 Where a product did not comply with the terms of the licence issued, action could be taken by the Licensing Authority to remove it from the market. For example, the licence could be suspended or revoked. There was no express power
of recall in the Act but, if a licence was suspended or revoked, it would be an offence
to supply the product and therefore in practice existing stocks could not be used.

7.89 As well as the Licensing Authority’s powers to take licensing action in relation
to medicinal products, there were powers of enforcement under Part VIII of the
1968 Act in respect of breaches of various provisions of the Act relating to the sale
of medicinal products to consumers. Enforcement was the duty of the Secretaries of
State for Health and for Scotland, and of the Health Minister in Wales and the
Minister of Health and Social Services for Northern Ireland. However, some
duties fell to the Pharmaceutical Society or local authorities or both, concurrently
with the appropriate Minister. The enforcement powers available to Ministers or
the Pharmaceutical Society or local authorities included rights of entry and
powers to inspect, take samples and seize goods and documents.

Non-statutory controls

7.90 As well as the powers of refusal, suspension, amendment or revocation of a
product licence, non-regulatory forms of action were also available to the Licensing
Authority. Dr Jefferys of the MCA told the Inquiry:

It is important for the Inquiry to understand the distinction between formal
regulatory action, such as suspending or revoking a product licence, and
informal action, such as the issuing of non-binding guidelines or
recommendations. The regulation of medicinal products is effected through
a complicated legal framework. This legal framework guides everything that
the Licensing Authority and its advisory committees do. Indeed a lawyer
attends each meeting of the CSM to advise the Chairman on legal issues. In
order to suspend a product licence, which is very rare, a paper has to go to
the CSM setting out a risk-benefit analysis of the product in question and the
matter then has to go to Ministers. In order to revoke a licence, the Licensing
Authority has to make out a case that the risk-benefit ratio for the product
concerned is such that it is unsafe (this is a difficult task given that, when the
product had been granted a licence it would, by definition, have been found
to have proven efficacy). In both such cases the burden of proof is on the
Licensing Authority to make out its case. This means that no formal action
can be taken against medicinal products unless there is an evidential basis for
doing so.

By contrast, informal action, such as the issuing of guidelines or
recommendations, depends upon the co-operation of pharmaceutical
companies. Such an approach has the added advantage that it invariably
produces a quicker result because it involves neither appeals nor legal
processes. In the case of BSE, the pharmaceutical companies were happy to
co-operate.

References

519 L12 pp A117–A121 sections 108(1), 109(1), 110(1)
520 In England and Wales, London Borough Councils, metropolitan District Councils and non-metropolitan County Councils; in
Scotland, District Councils, and in Northern Ireland, District Councils
521 L12 pp. A117–A121 sections 108(2), 109(2), 110(2)
522 L2 p. A122 section 111
523 L12 pp. A123-A124 section 112
524 S419 Jefferys pp. 16-17 paras. 43–44
7.91 In relation to BSE, joint CSM/VPC guidelines were issued to manufacturers of medicinal products in March 1989. The implementation and effectiveness of these guidelines are discussed in vol. 7: *Medicines and Cosmetics*.

**Restrictions on disclosure of information**

7.92 Under section 118 of the Medicines Act it is an offence to disclose any information about manufacturing processes or trade secrets obtained by or supplied in pursuance of the Act, or obtained in premises by virtue of the Act’s entry powers, unless the disclosure is made in the performance of duties.

**EC regulation and its implementation into UK law**

**Decentralised system**

7.93 European regulation of medicinal products was introduced with the adoption of Council Directive 65/65/EEC. The system was based on the grant of a marketing authorisation by the competent authority of the Member State in question (ie, a decentralised system). It provided that no proprietary medicinal product within the scope of the Directive could be placed on the market in a Member State unless the competent authority of that Member State had issued an authorisation. Subsequent Directives introduced licensing requirements for medicinal product manufacturers and wholesalers.

7.94 Directive 65/65/EEC applied to proprietary medicinal products, defined in Article 1(1) as ‘Any ready prepared medicinal product placed on the market under a special name and in a special pack’. From 1 January 1992 the scope of the EC scheme was widened by Directive 89/341/EEC to apply to all industrially-produced medicinal products.

7.95 As noted above, the Medicines Act 1968 and Regulations made under it were the primary instruments through which the UK performed its European obligations under this decentralised system. When the UK joined the EC, the Medicines Act was already in force and no new legislation was introduced to implement Directive 65/65/EEC. The competent authority of the UK for the purposes of the Directive 65/65/EEC was the Licensing Authority; the ‘marketing authorisation’ was the product licence; and applications were dealt with under the mechanisms of the Medicines Act 1968, consistently with the relevant EC rules. The Medicines Act covered many of the areas in which new EC regulation was introduced and amendments were often minor.

**Centralised system**

7.96 In addition to the decentralised system, Council Regulation 2309/93 introduced a central Community procedure for authorisation and supervision of medicinal products.
human and veterinary medicinal products. This provided a single marketing 
authorisation to market a product in all Member States of the European Union and 
was administered by the European Medicines Evaluation Agency (EMEA).

Currently, the procedure is compulsory for products listed in part A of the Annex to 
the Regulation, which include technologically-advanced medicinal products and 
veterinary medicinal products intended for use as performance enhancers, growth 
promoters or to increase yield. The procedure is optional for the novel medicinal 
products listed in part B of the Annex; for instance, products developed by 
innovative biotechnological processes, products containing new active substances 
not authorised in any Member State, and new products derived from human 
blood.531

UK implementation of European legislation

7.97 Comprehensive provision was made to implement the EC legislation on 
medicinal products into UK law in 1994. Effective from 1 January 1995, the 
Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 and 
the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 
provided for applications for marketing authorisations to be made and considered 
by the Licensing Authority, in accordance with the relevant Community 
provisions.532 Consequently, the Medicines Act provisions relating to licences for 
individual products applied only to a residual category of products which required 
UK product licences but did not require licences for the purposes of Community 
law.

Medical devices

Responsibilities

7.98 Until 1990, the regulation of medical devices was the responsibility of the 
Supplies Technology Division of the NHS Procurement Directorate. From 1 August 
1990, this passed to the Medical Devices Directorate, which was re-organised into 
the Medical Devices Agency (MDA), an Executive Agency of DH established in 
September 1994. It had responsibility on behalf of the Secretary of State for Health 
for taking all reasonable steps to ensure that medical devices in the UK were of safe 
design and met appropriate standards of safety, quality and performance and that 
these standards complied with the relevant Directives of the EU. This involved:

i. ensuring compliance with relevant regulations;

ii. evaluating adverse incident reports received from manufacturers and 
    users;

iii. assessing notifications for clinical investigations; and

iv. designating and monitoring independent accreditation bodies (Notified 
    Bodies) used to check manufacturer’s claims of conformity for all but 
    the lowest risk devices.533

531 L16 tab 1 p. 30
532 L15 tab U; M11D tab 15 p. 3
533 DH01 tab 11 p. 2
Statutory controls

7.99 Medical devices were excluded from the licensing system governing medicinal products. They were covered by the general product safety regime of the Consumer Protection Act 1987. This Act, which is described in more detail in the section on Cosmetics below, provided powers to prohibit the supply of consumer goods, defined as ‘goods . . . ordinarily intended for private use or consumption’, and to remove unsafe products. The Act contained enforcement powers for the Regulations made under it. There was also European legislation.

7.100 From 1992 onwards, several sets of Regulations were introduced under the Consumer Protection Act, including some providing specifically for medical devices. The Active Implantable Medical Devices Directive 90/385/EEC was implemented in the UK by the Active Implantable Medical Devices Regulations 1992. These Regulations applied to active implants (ie, relying on a source of power other than that generated by the human body or gravity), totally or partially introduced into the human body and intended to remain there, including pacemakers. Separate regulation of most other medical devices began with the Medical Devices Directive 93/42/EEC, as implemented in the UK by the Medical Devices Regulations 1994. These Regulations provided that medical devices placed on the market must comply with certain essential requirements in relation to safety and performance.

7.101 Manufacturers had a statutory responsibility to report serious adverse incidents involving medical devices. The Regulations also provided for a vigilance system whereby information concerning serious incidents in the UK had to be notified by the MDA to the EU and other Member States, so that any necessary action could be taken at European level. Member States had the power to withdraw from their market any product considered to be a danger to public health. From 1994, medical devices were also subject to the General Product Safety Regulations 1994, under which offences might be committed by the marketing of unsafe goods.

7.102 Powers under the Consumer Protection Act were exercisable by the Secretary of State for Health. The Secretary of State was also the responsible authority for enforcing the EC Directives on medical devices in the UK, acting through the MDA, although local authority Trading Standards Departments had some enforcement responsibilities for medical devices that were also consumer goods.

Non-statutory controls

7.103 In addition to the general product safety legislative regime outlined above, the MDA and its predecessors ran a voluntary registration scheme – the Manufacturers’ Registration Scheme (MRS) – under which manufacturers could apply for assessment of their quality systems for the manufacture of medical devices, and subsequent registration. The manufacturing practices and quality systems of those who chose to register were evaluated and audited. The MRS was
run down gradually as the product-specific statutory provisions for the regulation of medical devices described above were introduced, and the scheme was ended in 1998.

7.104 Although voluntary, this registration scheme served as a control. Purchasers, mainly the NHS, were advised to buy medical devices and equipment only from MRS-registered manufacturers. The Inquiry was told that the MDA believed that this advice was followed in the vast majority of cases. Further, manufacturers would be removed from the MRS if their systems and practices failed to meet the requirements of the scheme.

7.105 Another control was a reporting system, operated by the MDA, to encourage manufacturers and users to notify details of any adverse incidents involving medical devices. On the basis of reports received, the MDA issued safety and hazard notices to users of medical devices to alert them to any potential problems or safety issues.

7.106 In addition, the MDA operated other information controls including surveys, issuing guidance, performing audits and maintaining other contacts with the industry.

Cosmetics

Responsibilities

7.107 The Department of Trade and Industry (DTI) had policy responsibility for the safety of cosmetics in the UK. Within DTI, overall responsibility for the safety of cosmetics, as for other consumer products, lay with the Consumer Safety Unit (CSU). Within the CSU, the Chemical Hazards Section (CHS) had day-to-day responsibility for cosmetics.

7.108 Although DTI had overall regulatory responsibility for cosmetics, DH also played a role as DTI’s advisers on toxicity. The relevant Division in DH was MED TEP (Medical Toxicology Environmental Protection), later HEFM (Health Aspects of Environment and Food Medical), which gave advice when necessary.

7.109 Mr Richard Roscoe, Head of CHS from 1983 to 1992, told the Inquiry that whenever CHS was alerted to the presence of a potentially ‘risky’ ingredient in a particular cosmetic product they would refer the matter to DH. Upon receipt of advice from DH, CHS would then decide on a course of action. According to Mr Roscoe, DTI would always act on this advice ‘unless there were very strong reasons for not doing so’.

539 DH01 tab 19 p. 3 para. 5(b)
541 DH01 tab 13 paras 12–15, 18–22
542 S471 Roscoe paras 5, 12
543 S471 Roscoe para. 15
544 Also known as MED TEH (Medical Toxicology and Environmental Health)
545 S436 Fielder para. 1
546 S471 Roscoe para. 15
547 S471 Roscoe para. 18
The Cosmetic, Toiletry and Perfumery Association (CTPA) was the representative body for the UK cosmetics industry and the channel through which DTI distributed cautionary guidance on BSE to cosmetics manufacturers. In written evidence to the Inquiry, Ms Marion Kelly of the CTPA said that

Throughout this period the DTI Consumer Safety Unit (responsible for cosmetic legislation) kept the Association informed of any issue impacting on cosmetic safety and liaised with other relevant DTI divisions and other Government departments. 548

**Regulatory framework**

**The Cosmetics Directive**

The regulation of cosmetics was based on the EU Cosmetics Directive (1976), 549 which was implemented in the UK by Regulations made under the Consumer Protection Act 1987. Cosmetic products were required to meet various safety requirements but, unlike medicinal products, they did not require a licence.

The Directive sought to ensure the safety of cosmetics and their unhindered trade throughout the EU. In relation to safety, Article 2 provided that:

> Cosmetic products put on the market within the Community must not be liable to cause damage to human health when they are applied under normal conditions of use. 550

Dr Robin Fielder of DH told the Inquiry that the Cosmetics Directive placed the onus on manufacturers and suppliers to ensure that the product was safe for the use intended. 551

Article 2 was amended on 14 June 1993 by Directive 93/35/EEC to read:

> A cosmetic product put on the market within the Community must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of the product’s presentation, its labelling, any instructions for its use and disposal as well as any other indication or information provided by the manufacturer or his authorised agent or by any other person responsible for placing the product on the Community market.

The provision of such warnings shall not, in any event, exempt any person from compliance with the other requirements laid down in this Directive.

Member States had a duty to

> . . . take all necessary measures to ensure that only cosmetic products which conform to [the Directive] may be put on the market. 552
7.116 Article 4 of the Cosmetics Directive prohibited the marketing of cosmetic products containing:

i. substances listed in Annex II of the Directive;

ii. substances listed in Annex III Part 1, beyond specified limits and conditions (e.g., concentration limits, labelling requirements);

iii. colouring agents other than those listed in Annex III part 2, if these products were intended for application to specified areas of the body; and

iv. colouring agents listed in Annex III part 2, beyond specified limits and conditions, if these products were intended for application to the same specified areas of the body.

7.117 These ‘prescribed lists’ could be amended following consideration by the European Commission’s Working Party on Cosmetic Products. Chaired by the Commission, this consisted of representatives from the Member States and from industry. DTI led for the UK on this with a DH professional attending to advise on chemical toxicology. \(^{553}\) Decisions to amend were taken by the Committee on the Adaptation to Technical Progress, which was chaired by the Commission and consisted of representatives from Member States. Both the Working Party and the Committee had access to the opinions of the Scientific Committee on Cosmetology (SCC), an independent multidisciplinary body of scientists appointed by the Commission to assess the safety of cosmetics ingredients, as well as the advice from their own national scientific advisers. \(^{554}\)

7.118 The Cosmetics Directive limited the action individual Member States could take to regulate cosmetics. \(^{555}\) If a product complied with the relevant Annex, the UK Government could not prohibit its use unless, on the basis of a ‘substantiated justification’, it represented a hazard to health. Even then, the prohibition was provisional, pending consideration by the European Commission in consultation with Member States. \(^{556}\)

**Implementation into UK law**

7.119 Regulations made, in part, under section 11 of the Consumer Protection Act 1987 gave effect to the Cosmetics Directive in UK law. The Cosmetic Products (Safety) Regulations 1984 (made under a predecessor of the Act) \(^{557}\) were replaced on 1 January 1990 by the Cosmetic Products (Safety) Regulations 1989 (‘the 1989 Regulations’).

7.120 The main provisions of the 1989 Regulations were as follows:

i. A cosmetic product should not be liable to cause damage to human health when it is applied under normal conditions of use (reg. 3(1)).

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\(^{553}\) S436 Fielder p. 6 para. 18  
\(^{554}\) DO01 tab 6 para. 6  
\(^{555}\) L16 tab 3 article 7  
\(^{556}\) L16 tab 3 article 12  
\(^{557}\) L9 tab 12
ii. No cosmetic product might contain any substance listed in column 2 of schedule 1, unless it was only a trace that could not reasonably have been removed during or after manufacture (reg. 4(2)).

iii. A cosmetic product must not contain any substance listed in column 2 of schedule 2 unless specified requirements in that schedule were satisfied (reg. 4(3)).

iv. The Secretary of State might authorise the use in a cosmetic product of any substance not listed in either schedule 1 or 2 (reg. 5(1)). In giving authorisation the Secretary of State might impose conditions relating to the use of the substance (reg. 5(2)).

v. Various conditions and standards in respect of labelling and packaging (reg. 6). 558

7.121 The Consumer Protection Act imposed a general safety requirement in respect of all consumer goods. Section 10 of the Act made it an offence to supply consumer goods that failed to comply with this requirement – i.e., if consumer goods were not reasonably safe having regard to all the circumstances. ‘Safe’ meant that there was no risk (apart from one reduced to a minimum) that the goods would (whether immediately or later) cause death or personal injury to any person. 559

7.122 The Cosmetics Directive and the 1989 Regulations left only limited scope for the application of section 10 of the Consumer Protection Act to cosmetics. Since the introduction of the General Product Safety Regulations 1994 560 there has been virtually no scope for its application.

7.123 In practice the regulation of the cosmetics industry operated almost entirely on an informal and voluntary basis, relying on the industry to cooperate.

Enforcement

7.124 DTI had policy responsibility for the safety of cosmetics in the UK. Day-to-day enforcement of safety regulations such as the 1989 Regulations fell to the Trading Standards Departments of local authorities. 561

7.125 Supplying consumer goods that failed to comply with the general safety requirement or with certain requirements of safety Regulations was an offence and punishable in the courts. 562 In addition, enforcement authorities (which for these purposes meant DTI and the Trading Standards Departments of local authorities) had power to:

i. serve a suspension notice prohibiting the person on whom it was served from supplying goods for up to six months; and

ii. apply to the court for a forfeiture order. 563

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558 L9 tab 11. These re-enacted provisions in the 1984 Regulations
559 L9 tab 6 pp. 17–18 section 19
560 S.I. 1994/2328
561 L9 tab 6 p. 24 section 27(1)(a)
562 L9 tab 6 pp. 10–11 section 12
563 L9 tab 6 pp. 12–15 sections 14, 16
An authorised officer of the enforcement authority could enter any premises, inspect any goods, or examine any procedure, or in appropriate circumstances seize and detain goods.564

7.126 The Secretary of State also had the power to serve a notice on a person prohibiting that person from selling consumer goods if the Secretary of State considered them to be unsafe (a prohibition notice), or requiring the person to publish a warning about such goods (a notice to warn).565 However, these powers applied only to the person on whom the notice was served or against whom the order was sought, rather than to a general category of goods, and no power existed to recall products under these provisions.566

7.127 DTI told the Inquiry that it was unaware of any instance in which these powers had been used in respect of a BSE risk in cosmetics.567 The Department considered that in practice, public statements (eg, press notices) offered a quicker and more effective way of protecting the public than notices to warn.568