Freedom of Information Act 2000 (Section 50)

Decision Notice

Date: 22 August 2011

Public Authority: **Medicines and Healthcare Products Regulation Agency (MHRA)**

Address: **10-2 Market Towers**
1 Nine Elms Lane
London
SW8 5NQ

Summary

The complainant requested under the Freedom of Information Act 2000 (the 'Act') some information about a compliance investigation that the MHRA had undertaken.

The MHRA replied that it believed that section 44 applied and it withheld the information. It also withheld the name of one of its member's of staff by virtue of section 40(2).

The complainant referred this case to the Commissioner. In particular, he argued that the wrong statutory bar had been applied by the MHRA.

The Commissioner finds that section 44(1)(b) has been applied appropriately to all of the information withheld under section 44. He also finds that the MHRA have applied the appropriate statutory bar. He has also found that section 40(2) has been applied appropriately to the one name.

He finds procedural breaches of sections 17(1) and 17(1)(b), but requires no remedial steps to be taken in this case.

The Commissioner's Role

1. The Commissioner's duty is to decide whether a request for information made to a public authority has been dealt with in accordance with the requirements of Part 1 of the Freedom of Information Act 2000 (the "Act"). This Notice sets out his decision.

The Request

2. On 24 December 2010 the complainant made a number of requests for information about a complaint about a named product and referred the following five requests to the Commissioner for consideration (the Commissioner has renumbered them for ease of reference):

> *'(i) Kindly advise the outcome of the complaint*
>
> *(ii) including which officer was delegated to deal with it;*
>
> *(iii) when a decision was reached ie if no action*
>
> *(iv) what the decision was and the grounds thereto if closed*
>
> *(v) the evidence taken into consideration for that decision.'*

3. On 19 January 2011 the MHRA issued its response. It confirmed it held relevant information but would not provide it because the section 44[1] exemption applied to parts (i), (iii), (iv) and (v). It said that the relevant legislation that prohibited disclosure was Article 20 of the Medical Devices Directive 93/42/EC. It explained that it would not disclose the information for part (ii) because it would not accord with its policy. It did not specify an exemption.

4. On the same day the complainant requested that an internal review was conducted. He disputed that the bar to disclosure had been applied correctly.

5. On 4 February 2011 the MHRA communicated the results of its internal review. It upheld its original position in relation to section 44 and explained why. It did not reconsider its position in relation to part (ii).

The Investigation

Scope of the case

6. On 9 February 2011 the complainant contacted the Commissioner to complain about the way his request for information had been handled. The complainant specifically asked the Commissioner to consider the following points:

[1] Copies of all of the statutory provisions that are cited in this Notice can be found in its Legal Annex.

- He argued that the wrong statutory bar had been applied - Article 20 of the Medical Devices Directive 93/42/EC rather than Article 19 of the In Vitro Devices (IVD) Directive 98/79 EU;

- That the meaning of both statutory bars would not cover the information that has been requested – they should be restricted to the protection of commercial information;

- That the failure to use the right statutory provision is part of a 'vexatious' attempt of the MHRA not to provide information;

- That he is being discriminated against and harassed; and

- That section 77 may have been breached by the MHRA.

7. On 28 April 2011 the complainant agreed that the scope of this investigation will be for the Commissioner to consider:

   1. Whether the MHRA has appropriately applied exemptions to the requests outlined above dated 24 December 2010;

   2. If not, whether the relevant recorded information can be provided to the public;

   3. To consider whether the public authority has complied with its obligations in relation to timeliness; and

   4. To consider whether there is sufficient evidence to make out the criminal offence in this case.

8. The complainant also raised other issues that are not addressed in this Notice because they are not requirements of Part 1 of the Act. In particular, the Commissioner is not the forum to decide whether the MHRA has classified a medical device in the correct way. The MHRA have been given this role by Parliament and it is not for the Commissioner to challenge the operation of the legislation that it regulates.

9. In addition, it is noted above that the complainant asked the Commissioner to consider section 77 of the Act. This is Part VIII of the Act and cannot be considered in this Notice. The Commissioner's analysis of the complainant's allegations will be contained in a separate letter.

Chronology

10. On 27 April 2011 the Commissioner wrote to the complainant to establish the scope of this investigation and to gather his arguments.

11. The Commissioner received a number of emails containing the complainant's arguments and they have been considered in this case. These continued for the duration of this investigation.

12. On 19 May 2011 the Commissioner wrote to the MHRA in order to understand its position in this case and gather its detailed arguments.

13. The Commissioner received a number of emails containing the MHRA's arguments and responses to his requests for clarification.

14. On 10 June 2011 the Commissioner wrote to the complainant to explain his preliminary verdict on the operation of section 44 and asked whether the complainant wanted this investigation to continue. He was told the same day that he did.

15. On 13 June 2011 the Commissioner wrote to the MHRA to gather further arguments about the operation of section 40(2). He received those arguments on 24 June 2011.

Findings of fact

16. The MHRA has classified the named product as a Medical Device. The definition of what constitutes a Medical Device is found in the Medical Devices Directive 93/42/EC.

17. The Medical Devices Directive 93/42/EC does not apply to In Vitro Devices (IVDs). Instead the IVD Directive 98/79 EU applies to them.

18. The complainant argues that the named product has been misclassified and is indeed an IVD.

19. Both Directives contain similarly worded confidentiality provisions:

    - Article 20 of the Medical Devices Directive 93/42/EC; and
    - Article 19 of the IVD Directive 98/79 EU.

20. The complainant received some of the requested information privately through the court disclosure process on 1 March 2011.

Analysis

Substantive Procedural Matters

Exemptions

21. The MHRA clarified its position to the Commissioner that it was applying:

- Section 44(1)(b) – to the information withheld for requests (i), (iii), (iv) and (v) – because it disclosure to the public would be a contravention of a community obligation; and

- Section 40(2) – to the information withheld for request (ii), because its disclosure would be a breach of the data protection principles as it would be unfair to the data subject.

22. The Commissioner will consider the exemptions in the order outlined above:

Section 44(1)(b)

23. Section 44(1)(b) explains:

> *'Information is exemption information if its disclosure (otherwise than under this Act) by the public authority holding it –*
>
> *…*
>
> *(b) is incompatible with any Community obligation.'*

24. Section 44(1)(b) provides an exemption from disclosure under the Act for information where disclosure is incompatible with any Community obligation. It is an absolute exemption, so if the statutory bar applies then the information is exempt and no public interest test is necessary.

25. In its refusal notice dated 19 January 2011 and its internal review dated 4 February 2011, the MHRA identified Article 20 of the Medical Devices Directive 93/42/EC as the community obligation that would be contravened by the disclosure of this information.

26. The Commissioner will first detail the relevant parts of the legislation before moving on to consider its operation in this case.

Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices

27. Article 1 of the Directive (found in the legal annex) provides the definition of what constitutes a Medical Device.

28. Article 20 places the following obligation on the MHRA in relation to its duties when considering Medical Devices:

> *'Without prejudice to the existing national provisions and practices on medical secrets, Member States shall ensure that all the parties involved in the application of this Directive are bound to observe*

confidentiality with regard to all information obtained in carrying out their tasks. This does not affect the obligation of Member States and notified bodies with regard to mutual information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.'

Its application on the facts of this case

29. As noted above, the MHRA are the body who decides whether a device is a Medical Device, or is something else. The Commissioner considers it is appropriate to defer to the expertise of the MHRA in relation to the classification of such devices. It follows that the Commissioner is satisfied that the legislation that he should consider is Council Directive 93/42/EEC and Article 20 of that Directive.

30. The Commissioner is satisfied that Article 20 places an obligation on the MHRA to keep 'all information' confidential when it is 'obtained in carrying out their tasks'.

31. The Commissioner is satisfied that 'obtained' should be given its natural meaning and refer both to information which the MHRA proactively obtains as part of its investigations and information supplied by those wishing the MHRA to carry out an investigation.

32. The Commissioner is also satisfied that any investigation that was undertaken was part of the MHRA's tasks as Regulator of Medical Devices.

33. He is satisfied that the four categories of information that have been withheld under section 44(1)(b) – the decision, the date of decision, its grounds and the evidence considered – all constitute information that was obtained by the MHRA in carrying out its tasks.

34. It follows that an obligation of confidentiality is placed upon the MHRA in relation to this information.

35. The Commissioner has noted that the obligation is qualified in that it does not apply in limited circumstances specified in the last sentence of Article 20. This sentence is limited to when the MHRA needs to disclose the information for their purposes. It does not allow disclosure to the public outside those limited circumstances. He notes that the wording of section 44(1) explicitly requires the disclosure to be considered without consideration of the Act (for it states 'otherwise than under this Act').

36. In conclusion, the Commissioner has found that the MHRA was entitled to rely on section 44(1)(b) in respect of the all the information that fell within requests (i), (iii), (iv) and (v) as outlined above.

37. By virtue of section 2(3) of FOIA, the exemption in section 44(1)(b) is absolute. The only issue the Commissioner can consider is whether disclosure of the withheld information was prohibited by or under the statutory bar. There is no public interest component.

38. As he is satisfied that the statutory bar applies, the MHRA was entitled to withhold the information from the public and the Commissioner upholds its position.

39. The Commissioner has noted the complainant's argument that the MHRA have misclassified the device and that it should be an IVD. As stated above, it is inappropriate for the Commissioner to make a judgment on this matter.

40. However, the Commissioner does recognise that the information would not be covered by this community obligation if the device was declared to be an IVD by a court. The Commissioner therefore feels it is appropriate in this case to come to a view about the situation in these hypothetical circumstances.

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

41. Article 1 defines what constitutes an IVD device. Article 19 places the following obligation on the MHRA in relation to its duties when considering IVD Devices:

> *'Without prejudice to national law and practice on medical secrecy, Member States shall ensure that all the parties involved in the application of this Directive are bound to observe confidentiality with regard to information obtained in carrying out their tasks. This does not affect the obligations of Member States and notified bodies with regard to mutual information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.'*

42. The Commissioner notes that the wording of this Article is exactly the same as Article 20 of the Medical Devices Directive that was considered above.

43. Thus, if the product was declared to be an IVD by a court then it would not alter the position.

44. This is because section 44(1)(b) would apply for the same reasons as are noted in paragraphs 30 to 35 above (the only difference being that the obligation would be found in a different piece of legislation). It would continue to be an absolute exemption and the information could not be disclosed to the public.

Section 40(2)

45. The remaining information is the name of the officer who undertook the investigation into the product. The MHRA explained that section 40(2) had been applied to this name because the disclosure of this name to the public would be unfair to the officer.

46. Section 40(2) of the Act provides an exemption for information that constitutes the personal data of third parties where its disclosure would contravene one or more of the data protection principles found in the Data Protection Act 1998 ('DPA').

47. In analysing the application of section 40(2), the Commissioner has considered:

> *(a) whether the information in question was personal data; and*
>
> *(b) whether disclosure of the personal data under the Act would contravene the first data protection principle.*

48. Section 40(2) operates as an absolute exemption and has no public interest component. Therefore no public interest test is required.

Is the information personal data?

49. Personal data is defined in section 1 of DPA as data 'which relate to a living individual who can be identified—

> *(a) from those data, or*
>
> *(b) from those data and other information which is in the possession of, or is likely to come into the possession of, the data controller,*

and includes any expression of opinion about the individual and any indication of the intentions of the data controller or any other person in respect of the individual.'

50. The Commissioner is satisfied that an individual can be identified from their name. He agrees with the MHRA that the disclosure of the name will indicate where an individual is likely to be during standard working hours. It proves that the individual worked for the MHRA and took a decision. It follows that he is satisfied that this name constitutes a living individual's personal data.

Would disclosure contravene the first data protection principle?

51. The first data protection principle has three main components. These are as follows:

- The requirement to process all personal data fairly;
- The requirement to process all personal data lawfully; and
- The requirement to satisfy at least one DPA Schedule 2 condition for processing of all personal data.

52. All three requirements must be satisfied to ensure compliance with the first data protection principle. If even one requirement cannot be satisfied, processing will not be in accordance with the first principle.

Would disclosure be fair?

53. The complainant contends that it is appropriate and fair for the information to be disclosed to the public. He has explained that in his view there is a real public interest in understanding how the MHRA has conducted itself in relation to the potential investigation.

54. The MHRA has explained that it has adopted the DoH policy which acknowledged that names should be disclosed of individuals who are of Senior Civil Service (SCS) grade and above; or where the names of individuals are already in the public domain (or are required as part of a public duty – for example the FOI officer's name is available so that people can direct requests for information correctly).

55. It must be noted that the DoH policy cannot be regarded as being determinative. For example, in **FS50091230** the Commissioner ordered the disclosure of less senior names when circumstances demanded it: http://www.ico.gov.uk/~/media/documents/decisionnotices/2009/FS_50091230.ashx

56. The MHRA accepted that there may be a legitimate interest in knowing the names of officials at senior levels, but it explained that civil servants below SCS grade are not normally responsible for projects and policies of sufficiently high profile as to merit a public interest in knowing their identities. Accountability for such projects and policies is at SCS grade, and there are mechanisms in place for holding such individuals to account. Releasing the name of this more junior staff member would not add any value to the legitimate interest in knowing that there is named accountability for the actions of civil servants.

57. The Commissioner does accept that it is appropriate to make some distinction in relation to seniority. This is because the more senior a member of staff is the more likely it is that they will be responsible for making influential policy decisions and/or decisions related to the expenditure of significant amounts of public funds.

58. The Commissioner asked the MHRA for the name, position and salary band of this individual along with a description of the contact the individual has with the public. He also asked for further details about how their expectations were influenced by the policy. He is satisfied that the individual fell below SCS grade, has no line management responsibilities and that the policy and its application would indicate that they would have the expectation that their name would not be disclosed to the public in these circumstances. He notes that the individual in question would not expect to come into contact with members of the public outside speaking to people who are necessary to contact during the course of an investigation and that the individual has not provided consent.

59. The Commissioner has also noted for the reasons outlined above (in his section 44 analysis) that individuals have the obligation to keep their investigations confidential and would expect their employer to do the same. Should public allegations be made against an individual's conduct, they would not be able to defend their handling of the case without being in contravention of the confidentiality obligation. The MHRA explained that it has checks and balances in place to ensure the behaviour and probity of its staff, including performance reviews and external audits. In this case, the Commissioner considers that the expectation of the individual that the information would not be disclosed is reasonable.

60. In favour of disclosure being fair, the Commissioner considers that an important factor is that the name has been requested in relation to a professional engagement rather a personal one. Where information relates solely to an individual's professional life the Commissioner considers that disclosure is less likely to be unfair. This approach is also supported by the Information Tribunal decision *(House of Commons v Information Commissioner and Norman Baker MP EA/2006/0015 and 0016)*. In its decision the Tribunal noted that:

> *"where data subjects carry out public functions, hold elective office or spend public funds they must have an expectation that their public actions will be subject to greater scrutiny than would be the case in respect of their private lives." (Tribunal at paragraph 78)*

61. The Commissioner has also considered whether the disclosure of this information to the public would be likely in its context to cause unjustified damage or distress to the data subject. Having considered the nature of the investigation that was done and the presence of some individuals within the public who are determined to discredit the MHRA and would use the name to support this campaign, he is satisfied that

the disclosure of the name in this context could cause the data subject some distress.

62. In conclusion, the Commissioner considers that the disclosure of this name to the public would be unfair to the data subject. He is satisfied that it would be unfair because it would be against their reasonable expectations, that it could cause unjustified distress to them and the individual is insufficiently senior to be held individually accountable for any decision.

63. As he has found that disclosure would be unfair, he has not gone on to consider the lawfulness of the disclosure or it compliance with the conditions found in schedule 2 of the DPA. He also has not gone on to consider any of the other Data Protection Principles.

64. He finds that section 40(2) has been applied appropriately to the part (ii) request and therefore this information should not be disclosed to the public.

Procedural Requirements

Section 17(1)(b)

65. Section 17(1)(b) explains that a public authority must explain what exemption it is relying on. In the Commissioner's view this means that it must state the exemption down to it subsection.

66. In this case, the MHRA did not state what exemption it was applying to the part (ii) request in either its refusal notice or internal review. In the Commissioner's view this was a breach of section 17(1)(b).

67. It also failed to explain which subsection of section 44 it was applying to requests (i), (iii), (iv) and (v) and this was also in breach of section 17(1)(b).

68. The Commissioner notes that the MHRA has recognised these procedural breaches occurred.

Section 17(1)

69. Section 17(1) requires a complete refusal notice to be issued in 20 working days. As the refusal notice failed to comply with section 17(1)(b), the Commissioner also finds a breach of section 17(1) in this case.

The Decision

70. The Commissioner's decision is that the MHRA dealt with the following elements of the request in accordance with the requirements of the Act:

- It applied section 44(1)(b) appropriately to the information requested in parts (i), (iii), (iv) and (v); and
- It applied section 40(2) appropriately to the information requested in part (ii).

71. However, the Commissioner has also decided that the following elements of the request were not dealt with in accordance with the Act:

- It breached section 17(1)(b) because it failed to specify the exemptions that it relied upon; and
- It breached section 17(1) because it failed to issue a complete refusal notice in 20 working days.

Steps Required

72. The Commissioner requires no steps to be taken.

Right of Appeal

73. Either party has the right to appeal against this Decision Notice to the First-tier Tribunal (Information Rights). Information about the appeals process may be obtained from:

First-tier Tribunal (Information Rights)
GRC & GRP Tribunals,
PO Box 9300,
Arnhem House,
31, Waterloo Way,
LEICESTER,
LE1 8DJ

Tel: 0300 1234504
Fax: 0116 249 4253
Email: informationtribunal@hmcts.gsi.gov.uk
Website: www.justice.gov.uk/guidance/courts-and-tribunals/tribunals/information-rights/index.htm

74. If you wish to appeal against a decision notice, you can obtain information on how to appeal along with the relevant forms from the Information Tribunal website.

75. Any Notice of Appeal should be served on the Tribunal within 28 (calendar) days of the date on which this Decision Notice is sent.

Dated the 22nd day of August 2011

Signed ……

Pamela Clements
Group Manager, Complaints Resolution
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Legal Annex

General Right of Access

Freedom of Information Act 2000

Section 1(1) – General right of access to information held by public authorities

(1) "Any person making a request for information to a public authority is entitled –

(a) to be informed in writing by the public authority whether it holds information of the description specified in the request, and

(b) if that is the case, to have that information communicated to him."

Section 2(3) – Effect if the exemptions in Part II

(3) For the purposes of this section, the following provisions of Part II (and no others) are to be regarded as conferring absolute exemption –

(a) section 21

(b) section 23

(c) section 32

(d) section 34

(e) section 36 so far as relating to information held by the House of Commons or the House of Lords

(f) in section 40 –

(i) subsection (1), and

(ii) subsection (2) so far as relating to cases where the first condition referred to in that subsection is satisfied by virtue of subsection (3)(a)(i) or (b) of that section,

(iii) section 41, and

(iv) section 44"

Section 10(1) – Time for compliance with the request

(1) Subject to subsections (2) and (3), a public authority must comply with section 1(1) promptly and in any event not later than the twentieth working day following the date of receipt."

Section 17(1) – Refusal of request

(1) A public authority which, in relation to any request for information, is to any extent relying on a claim that any provision of Part II relating to the duty to confirm or deny is relevant to the request or on a claim that information is exempt information must, within the time for complying with section 1(1), give the applicant a notice which -

(a) states that fact,

(b) specifies the exemption in question, and

(c) states (if that would not otherwise be apparent) why the exemption applies."

Section 40 – Personal information

(1) Any information to which a request for information relates is exempt information if it constitutes personal data of which the applicant is the data subject.

(2) Any information to which a request for information relates is also exempt information if—

(a) it constitutes personal data which do not fall within subsection (1), and

(b) either the first or the second condition below is satisfied.

(3) The first condition is—

(a) in a case where the information falls within any of paragraphs (a) to (d) of the definition of "data" in section 1(1) of the [1998 c. 29.] Data Protection Act 1998, that the disclosure of the information to a member of the public otherwise than under this Act would contravene—

(i) any of the data protection principles, or

(ii) section 10 of that Act (right to prevent processing likely to cause damage or distress), and

(b) in any other case, that the disclosure of the information to a member of the public otherwise than under this Act would contravene any of the data protection principles if the exemptions in section 33A(1) of the [1998 c. 29.] Data Protection Act 1998 (which relate to manual data held by public authorities) were disregarded.

(4) The second condition is that by virtue of any provision of Part IV of the [1998 c. 29.] Data Protection Act 1998 the information is exempt from section 7(1)(c) of that Act (data subject's right of access to personal data).

(5) The duty to confirm or deny—

(a) does not arise in relation to information which is (or if it were held by the public authority would be) exempt information by virtue of subsection (1), and

(b) does not arise in relation to other information if or to the extent that either—

(i) the giving to a member of the public of the confirmation or denial that would have to be given to comply with section 1(1)(a) would (apart from this Act) contravene any of the data protection principles or section 10 of the [1998 c. 29.] Data Protection Act 1998 or would do so if the exemptions in section 33A(1) of that Act were disregarded, or

(ii) by virtue of any provision of Part IV of the [1998 c. 29.] Data Protection Act 1998 the information is exempt from section 7(1)(a) of that Act (data subject's right to be informed whether personal data being processed).

(6) In determining for the purposes of this section whether anything done before 24th October 2007 would contravene any of the data protection principles, the exemptions in Part III of Schedule 8 to the [1998 c. 29.] Data Protection Act 1998 shall be disregarded.

(7) In this section—

- "the data protection principles" means the principles set out in Part I of Schedule 1 to the [1998 c. 29.] Data Protection Act 1998, as read subject to Part II of that Schedule and section 27(1) of that Act;
- "data subject" has the same meaning as in section 1(1) of that Act;
- "personal data" has the same meaning as in section 1(1) of that Act.

Section 44 – Prohibitions on disclosure

(1) Information is exempt information if its disclosure (otherwise than under this Act) by the public authority holding it-

(a) is prohibited by or under any enactment,

(b) is incompatible with any Community obligation, or

(c) would constitute or be punishable as a contempt of court."

Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices

Article 1 - Definitions, scope

1. This Directive shall apply to medical devices and their accessories. For the purposes of this Directive, accessories shall be treated as medical devices in their own right. Both medical devices and accessories shall hereinafter be termed devices.

2. For the purposes of this Directive, the following definitions shall apply:

(a) 'medical device' means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

(b) 'accessory' means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device;

(c) 'device used for in vitro diagnosis' means any device which is a reagent, reagent product, kit, instrument, equipment or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of samples derived from the human body with a view to providing information on the physiological state, state of health or disease, or congenital abnormality thereof;

(d) 'custom-made device' means any device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient.

The abovementioned prescription may also be made out by any other person authorized by virtue of his professional qualifications to do so.

Mass-produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user are not considered to be custom-made devices;

(e) 'device intended for clinical investigation' means any device intended for use by a duly qualified medical practitioner when conducting investigations as referred to in Section 2.1 of Annex X in an adequate human clinical environment.

For the purpose of conducting clinical investigation, any other person who, by virtue of his professional qualifications, is authorized to carry out such investigation shall be accepted as equivalent to a duly qualified medical practitioner;

(f) 'manufacturer' means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name. This subparagraph does not apply to the person who, while not a manufacturer within the meaning of the first subparagraph, assembles or adapts devices already on the market to their intended purpose for an individual patient;

(g) 'intended purpose' means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials;

(h) 'placing on the market' means the first making available in return for payment or free of charge of a device other than a device intended for clinical investigation, with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished;

(i) 'putting into service' means the stage at which a device is ready for use on the Community market for the first time for its intended purpose.

3. Where a device is intended to administer a medicinal product within the meaning of Article 1 of Directive 65/65/EEC, that device shall be governed by the present Directive, without prejudice to the provisions of Directive 65/65/EEC with regard to the medicinal product.

If, however, such a device is placed on the market in such a way that the device and the medicinal product form a single integral product which is intended exclusively for use in the given combination and which is not reusable, that single product shall be governed by Directive 65/65/EEC. The relevant essential requirements of Annex I to the present Directive shall apply as far as safety and performance related device features are concerned.

4. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of Article 1 of Directive 65/65/EEC and which is liable to act upon the body with action ancillary to that of the device, that device must be assessed and authorized in accordance with this Directive.

5. This Directive does not apply to:

(a) in vitro diagnostic devices;

(b) active implantable devices covered by Directive 90/385/EEC;

(c) medicinal products covered by Directive 65/65/EEC;

(d) cosmetic products covered by Directive 76/768/EEC (18);

(e) human blood, human blood products, human plasma or blood cells of human origin or to devices which incorporate at the time of placing on the market such blood products, plasma or cells;

(f) transplants or tissues or cells of human origin nor to products incorporating or derived from tissues or cells of human origin;

(g) transplants or tissues or cells of animal origin, unless a device is manufactured utilizing animal tissue which is rendered non-viable or non-viable products derived from animal tissue.

6. This Directive does not apply to personal protective equipment covered by Directive 89/686/EEC. In deciding whether a product falls under that Directive or the present Directive, particular account shall be taken of the principal intended purpose of the product.

7. This Directive is a specific Directive within the meaning of Article 2 (2) of Directive 89/336/EEC.

8. This Directive does not affect the application of Directive 80/836/Euratom, nor of Directive 84/466/Euratom.

Article 20 - Confidentiality

Without prejudice to the existing national provisions and practices on medical secrets, Member States shall ensure that all the parties involved in the application of this Directive are bound to observe confidentiality with regard to all information obtained in carrying out their tasks. This does not affect the obligation of Member States and notified bodies with regard to mutual information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic (IVD) medical devices

Article 1 - Scope, definitions

1. This Directive shall apply to in vitro diagnostic medical devices and their accessories. For the purposes of this Directive, accessories shall be treated as in vitro diagnostic medical devices in their own right. Both in vitro diagnostic medical devices and accessories shall hereinafter be termed devices.

2. For the purposes of this Directive, the following definitions shall apply:

(a) 'medical device` means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,

- diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap,

- investigation, replacement or modification of the anatomy or of a physiological process,

- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

(b) 'in vitro diagnostic medical device` means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination,

intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- concerning a physiological or pathological state, or

- concerning a congenital abnormality, or

- to determine the safety and compatibility with potential recipients, or

- to monitor therapeutic measures.

Specimen receptacles are considered to be in vitro diagnostic medical devices.

'Specimen receptacles` are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination.

Products for general laboratory use are not in vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination;

(c) 'accessory` means an article which, whilst not being an in vitro diagnostic medical device, is intended specifically by its manufacturer to be used together with a device to enable that device to be used in accordance with its intended purpose.

For the purposes of this definition, invasive sampling devices or those which are directly applied to the human body for the purpose of obtaining a specimen within the meaning of Directive 93/42/EEC shall not be considered to be accessories to in vitro diagnostic medical devices;

(d) 'device for self-testing` means any device intended by the manufacturer to be able to be used by lay persons in a home environment;

(e) 'device for performance evaluation` means any device intended by the manufacturer to be subject to one or more performance evaluation studies in laboratories for medical analyses or in other appropriate environments outside his own premises;

(f) 'manufacturer` means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these

operations are carried out by that person himself or on his behalf by a third party.

The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as devices with a view to their being placed on the market under his own name. This subparagraph does not apply to the person who, while not a manufacturer within the meaning of the first subparagraph, assembles or adapts devices already on the market to their intended purpose for an individual patient;

….

6. This Directive shall not affect national laws which provide for the supply of devices by a medical prescription.

7. This Directive is a specific directive within the meaning of Article 2(2) of Directive 89/336/EEC, which shall cease to apply to devices which have complied with this Directive.

Article 19 Confidentiality

Without prejudice to national law and practice on medical secrecy, Member States shall ensure that all the parties involved in the application of this Directive are bound to observe confidentiality with regard to information obtained in carrying out their tasks. This does not affect the obligations of Member States and notified bodies with regard to mutual information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.

Data Protection Act 1998

Section 1 - Basic interpretative provisions

(1) In this Act, unless the context otherwise requires—

- “data” means information which—

  (a)

  is being processed by means of equipment operating automatically in response to instructions given for that purpose,

  (b)

  is recorded with the intention that it should be processed by means of such equipment,

(c)

is recorded as part of a relevant filing system or with the intention that it should form part of a relevant filing system, or

(d)

does not fall within paragraph (a), (b) or (c) but forms part of an accessible record as defined by section 68;

- "data controller" means, subject to subsection (4), a person who (either alone or jointly or in common with other persons) determines the purposes for which and the manner in which any personal data are, or are to be, processed;
- "data processor", in relation to personal data, means any person (other than an employee of the data controller) who processes the data on behalf of the data controller;
- "data subject" means an individual who is the subject of personal data;
- "personal data" means data which relate to a living individual who can be identified—

(a)

from those data, or

(b)

from those data and other information which is in the possession of, or is likely to come into the possession of, the data controller,

and includes any expression of opinion about the individual and any indication of the intentions of the data controller or any other person in respect of the individual;

- "processing", in relation to information or data, means obtaining, recording or holding the information or data or carrying out any operation or set of operations on the information or data, including—

(a)

organisation, adaptation or alteration of the information or data,

(b)

retrieval, consultation or use of the information or data,

(c)

disclosure of the information or data by transmission, dissemination or otherwise making available, or

(d)

alignment, combination, blocking, erasure or destruction of the information or data;

- "relevant filing system" means any set of information relating to individuals to the extent that, although the information is not processed by means of equipment operating automatically in response to instructions given for that purpose, the set is structured, either by reference to individuals or by reference to criteria relating to individuals, in such a way that specific information relating to a particular individual is readily accessible.

(2) In this Act, unless the context otherwise requires—

(a) "obtaining" or "recording", in relation to personal data, includes obtaining or recording the information to be contained in the data, and

(b) "using" or "disclosing", in relation to personal data, includes using or disclosing the information contained in the data.

(3) In determining for the purposes of this Act whether any information is recorded with the intention—

(a) that it should be processed by means of equipment operating automatically in response to instructions given for that purpose, or

(b) that it should form part of a relevant filing system,

it is immaterial that it is intended to be so processed or to form part of such a system only after being transferred to a country or territory outside the European Economic Area.

(4) Where personal data are processed only for purposes for which they are required by or under any enactment to be processed, the person on whom the obligation to process the data is imposed by or under that enactment is for the purposes of this Act the data controller.