Freedom of Information Act 2000 (FOIA)

Decision notice

Date: **11 July 2018**

Public Authority: **Medicine and Healthcare Products Regulatory Agency**

Address: **151 Buckingham Palace Road**
London
SW1W 9SZ

Decision (including any steps ordered)

1. The complainant has requested information relating to reports of adverse incidents submitted to the Medicine and Healthcare Products Regulatory Agency (MHRA) from 1 April 2003 to 30 March 2017.

2. The Commissioner's decision is that MHRA has incorrectly applied section 14(1) to the request.

3. The Commissioner requires MHRA to take the following steps to ensure compliance with the legislation.

   - Issue a fresh response without reliance on section 14(1).

4. The public authority must take these steps within 35 calendar days of the date of this decision notice. Failure to comply may result in the Commissioner making written certification of this fact to the High Court pursuant to section 54 of the Act and may be dealt with as a contempt of court.

Request and response

5. The complainant initially requested assistance under section 16 of the FOIA in order to make a request under section 1 of the FOIA. The proposed request was in relation to a similar request made 2015 in

which the Commissioner issued a decision notice (FS50616856[1]) and was subject to an appeal to the First-Tier Tribunal (FTT).

6. The MHRA explained that it was waiting for the outcome of the Tribunal and stated that on the basis that the judgment was expected imminently, it considered that it would be premature to provide advice and assistance under section 16 at this stage. It further stated that it would re-address the request for advice and assistance on receipt of the judgment.

7. The complainant disputed that the awaited judgement would affect his request and went on to request information relating to voluntary reports of adverse incidents.

8. On 25 May 2017, the complainant wrote to MHRA and requested information relating to information from voluntary reports of adverse incidents submitted to the MHRA from 1 April 2003 to 30 March 2017. Full details of the request are contained in an annex at the end of this decision notice.

9. MHRA responded on 12 July 2017 and confirmed that it held the information requested and provided some in an Excel file. It refused to provide the remaining information citing sections 21, 40, 44(1)(a) of the FOIA as its basis for doing so.

10. Following an internal review MHRA wrote to the complainant on 1 September 2017, although the review itself was dated 16 August 2017. It revised its position and stated that it should have withheld all the requested information and relied on section 14(1) of the FOIA when responding to the request.

Scope of the case

11. The complainant contacted the Commissioner on 1 December 2017 to complain about the way his request for information had been handled.

12. The Commissioner considers the scope of this investigation to be to determine if MHRA has correctly applied section 14(1) to the request.

[1] https://ico.org.uk/media/action-weve-taken/decision-notices/2016/1625338/fs50616856.pdf

Reasons for decision

13. Section 14(1) of the FOIA states that a public authority is not obliged to comply with a request for information if the request is vexatious. There is no public interest test.

14. The term "vexatious" is not defined in the FOIA. The Upper Tribunal (Information Rights) considered in some detail the issue of vexatious requests in the case of the Information Commissioner v Devon CC & Dransfield (GIA/3037/2011). The Tribunal commented that vexatious could be defined as the "manifestly unjustified, inappropriate or improper use of a formal procedure". The Tribunal's definition clearly establishes that the concepts of proportionality and justification are relevant to any consideration of whether a request is vexatious.

15. In the Dransfield case, the Upper Tribunal also found it instructive to assess the question of whether a request is truly vexatious by considering four broad issues: (1) the burden imposed by the request (on the public authority and its staff); (2) the motive of the requester; (3) the value or serious purpose of the request and (4) harassment or distress of and to staff.

16. The Upper Tribunal did however also caution that these considerations were not meant to be exhaustive. Rather, it stressed the: *"importance of adopting a holistic and broad approach to the determination of whether a request is vexatious or not, emphasising the attributes of manifest unreasonableness, irresponsibility and, especially where there is a previous course of dealings, the lack of proportionality that typically characterise vexatious requests"* (paragraph 45).

17. The Commissioner has identified a number of "indicators" which may be useful in identifying vexatious requests. These are set out in her published guidance on vexatious requests[2]. In brief these consist of, in no particular order: abusive or aggressive language; burden on the authority; personal grudges; unreasonable persistence; unfounded accusations; intransigence; frequent or overlapping requests; deliberate intention to cause annoyance; scattergun approach; disproportionate effort; no obvious intent to obtain information; futile requests; frivolous requests.

[2] https://ico.org.uk/media/for-organisations/documents/1198/dealingwith-vexatious-requests.pdf

18. The fact that a request contains one or more of these indicators will not necessarily mean that it must be vexatious. All the circumstances of a case will need to be considered in reaching a judgement as to whether a request is vexatious. Where relevant, public authorities may also need to take into account wider factors such as the background and history of the request.

19. The Commissioner's guidance suggests that if a request is not patently vexatious the key question the public authority must ask itself is whether the request is likely to cause a disproportionate or unjustified level of disruption, irritation or distress. In doing this the Commissioner considers that a public authority should weigh the impact of the request on it and balance this against the purpose and value of the request.

The complainant's position

20. In correspondence to the Commissioner, the complainant asked the Information Commissioner to determine that:

    - the request of 25 May 2017 under s.1 of the Act was not vexatious; and

    - the MHRA's purported notice under s.17 of the Act of 1 September 2017 is ineffectual.

21. The complainant has presented lengthy arguments in support of his complaint which, for brevity have not been repeated here but are summarised below. He stated that:

    - On 25 May 2017 the only information requested that was currently subject of the First-tier Tribunal decision was: Model; Manufacturer name; Catalogue number; Serial number; Lot or batch number; Date of incident.

    - The overwhelming majority of information outlined in points 1-133 fall into the same categories as the information previously provided by the MHRA.

    - This request under s.1 of the Act was for only a small proportion of the information that had already been requested (10%) – and subsequently disclosed by the MHRA. He commented that a mere 10% is hardly an earthshattering amount, and not enough to engage s.14 of the Act. Had the MHRA provided assistance under s.16 of the Act, the request for information under s.1 of the Act simply would not have been made until the decision of the First-tier Tribunal had been promulgated.

22. *With regards to this statement:*

- "The request was made in the knowledge that the ICO (on multiple occasions) and existing FTT case law has confirmed that the Agency is entitled to maintain the confidentiality of the information which was requested."

- He stated that the MHRA had been proved wrong "on multiple occasions", and the MHRA will be proved wrong again. The Information Commissioner has been proved wrong "on multiple occasions". He stated that he was of the opinion that the First-tier Tribunal's decision case EA/2016/0283 is simply wrong.

- The First-tier Tribunal has been proved wrong "on multiple occasions", and the First-tier Tribunal will be proved wrong again. The complainant stated that such a position is not vexatious, it is to merely acknowledge fact.

- His request for assistance under s.16 of the Act of 16 May 2017 stated: "I appreciate that some of the information requested is subject to the judgment in Leonard Spencer v Information Commissioner & Medicines and Healthcare products Regulatory Agency, and understand, therefore, that you may need to await judgement to be able to provide guidance in relation to any information marked with an asterisk (*). I do not, however, think that this should delay any guidance in relation to information not affected by that case [emphasis added]."

  This approach is hardly vexatious.

23. *With regards to the statement:*

- "The request was made despite the Agency's reasonable advice that this request should follow after the FTT judgment, to provide some legal certainty over the position (which was rejected)."

- He said that there was no "legal certainty" that was required in relation to that information which was not subject of the decision in the First-tier Tribunal. The MHRA acknowledged as much by providing a spreadsheet consisting of 160,010 rows and 70 columns in response to the request under s.1 of the Act.

MHRA's position

24. In relation to this particular request, some information was again disclosed to the complainant. This did not satisfy the complainant, who sought an Internal Review (IR). The IR concluded that MHRA should have instead relied on section 14(1) of the FOIA to withhold the

information sought by the request, which includes the information which was voluntarily released. The IR deemed that the request was vexatious in nature and all information should have been withheld by MHRA. The IR sets out in detail at points 1-5 the reasons for deeming the request to be vexatious. MHRA considers that the request:

- was designed to cause disruption or annoyance, and;
- can be characterised as obsessive or manifestly unreasonable.

25. The IR concluded that the request was vexatious on the grounds that it exhibited the following indicators:

- unreasonable persistence
- intransigence
- a futile request
- a frequent or overlapping request

26. The IR identified the following features of the request, which exhibited some or all of these indicators:

- At the time the request was made, it sought the same (or substantially similar) information and repeated identical arguments that were already before the FTT for a decision.
- The request was made in the knowledge that the ICO (on multiple occasions) and existing FTT case law has confirmed that MHRA is entitled to maintain the confidentiality of the information which was requested.
- The request was made with an unwillingness to recognise the established legal position which has since been repeated by the FTT in its most recent judgment. The request itself included the statement, *"I do not accept that that the judgement in the First-tier Tribunal (FTT) case is necessary to "provide useful guidance on the correct approach to a number of aspects of [my] proposed request". It is my contention that the law in this area is already clear, and I am not, without being provided with evidence to the contrary, going to change my position."* It is MHRA's position that this statement is telling, and supports its assertion that this request exhibits unreasonable persistence and intransigence, and can be characterised as obsessive. To put it simply, the complainant refuses to accept the clear and established legal position.

- MHRA's position on this issue is well-established and especially in a case where a FTT judgment is pending, it would have been clear that a refusal of the request was inevitable and the request was, therefore, futile.

  The Commissioner's view is that although the complainant may have expected another refusal notice, he may equally expect MHRA to take the same approach as it had done before and provided the updated information for the parts of the request previously.

- The request was made despite MHRA's reasonable advice that this request should follow after the FTT judgment, which would provide some legal certainty over the position (which was rejected by the complainant).

  The Commissioner notes that MHRA advised the complainant it would reconsider his request following the decision by the FTT, however a requestor was entitled to reject this advice and make a new request.

- MHRA stated that it could have continued to rely on the same exemptions it relied on at the FTT to withhold the information sought by the complainant, namely section 44(1)(a) of FOIA. However, at the internal review stage it considered that that approach had the potential to result in an identical complaint to the ICO, and subsequent appeal to the FTT, on identical issues which had just been determined by the FTT in the appeal raised by the complainant in relation to his previous request for very similar information. MHRA considered that this would be an extraordinary position to arrive at, and in its view, would rightly raise the question of why this request was not refused on the basis of vexatiousness.

- MHRA considers it highly improper, and a waste of scarce and valuable public resources, for a complainant to continue raise the same arguments which have already been determined by the ICO and the Courts. This is especially the case where the complainant states that he will dismiss the FTT judgement before it has been made.

  The Commissioner would accept this argument if, *after* the FTT decision had been made, the complainant *continued* to make requests for the same information.

27. MHRA therefore consider that it is left in a position where it is impossible to satisfy the repeated request for the same information. Attempts at a compromise by releasing some information to the complainant voluntarily have also failed to see a halt to this repeated request, or any change in his position.

28. At this point MHRA also stated it would not respond to any further FOIA requests from the complainant for information contained in the AITS database, in accordance with section 17(6) of the FOIA.

The Commissioner's decision

29. It is clear to the Commissioner that the complainant holds the very firm belief that the information he requested should be disclosed to him.

30. The Commissioner notes this request was made in May 2017. MHRA had previously disclosed some information in response to a similar request made in 2015 and the FTT decision had not yet been made with regard to the remaining withheld information. The latest request, although also asking for information since 2003, additionally sought up-to-date information.

31. MHRA's response of 12 July 2017 again disclosed some information as it had done previously, and again withheld information relying on the exemptions at sections 21, 40 and 44(1)(a). At this time, both parties appeared to be of the view that at least some of the information could be provided.

32. The Commissioner further notes that the FTT decision was promulgated on 2 August 2017, and following this MHRA changed its position, stating in its IR response that it was now relying on section 14(1).

33. The Commissioner acknowledges MHRA's argument that it could have continued to rely on section 44(1)(a) and that this would have resulted in a similar complaint to the ICO and a subsequent appeal to the FTT. However, the Commissioner also acknowledges that this request, although substantially similar is not, in fact, identical. It asked for up to date information and at the time the request was made it is reasonable to say that MHRA's approach was to withheld some information under section 44(1)(a) but disclosed other information.

34. The Commissioner further acknowledges MHRA's position that the FTT commented that *"Indeed, we are somewhat surprised that MHRA did not seek to withhold the remainder of the information on the same basis, although we have not delved into that issue"*. This is not indicative that section 14(1) was applicable at the time of the request in May 2017. The FTT judgement post-dates the request and at the time of the request the complainant had already received *some* information from MHRA in relation to his request from 2015. Indeed, MHRA continued to take a similar approach to this request as it did in 2015. It issued a refusal notice addressing the request that is the subject of this notice in July 2017, again disclosing some information and withholding other elements.

35. In all the circumstances of this particular case the Commissioner finds that section 14(1) is not engaged. Although it is quite acceptable for a public authority to change its position at IR and reconsider any exemptions applied, the timing of that IR is crucial in this case. At the time of the request, MHRA considered that some of the information could be provided. It was only *after* the FTT decision which was issued in August 2017 that MHRA cited section 14(1).

36. It should further be noted that that case is under appeal to the Upper Tribunal, which has not yet been decided.

37. The Commissioner therefore finds that section 14(1) is not engaged.

38. With regards to the complainant's concerns in respect of section 17 of the FOIA, the Commissioner considers such a response must constitute an updated refusal notice for the purposes of and the ability to apply section 17(6) should future requests of the same nature be made.

39. However, she considers MHRA has breached section 10 of the FOIA in this case. The refusal notice was issued in July 2017 after the 20 working days permitted by section 10 of the FOIA had expired.

40. Additionally, it has breached section 17(5) of the FOIA. This states that if a public authority wishes to claim that section 12 or 14 applies it must, within the time for complying with section 1, give the applicant a notice stating that fact. As section 14 of the FOIA was claimed late at the internal review stage, MHRA failed to inform the complainant within the time for complying with section 1 (20 working days from the receipt of the request) that it wished to rely on section 14.

Right of appeal

41. 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,
    LEICESTER,
    LE1 8DJ

    Tel: 0300 1234504
    Fax: 0870 739 5836
    Email: GRC@hmcts.gsi.gov.uk
    Website: www.justice.gov.uk/tribunals/general-regulatory-chamber

42. 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.

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

Signed .....

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

Annex – Request

Request 16 May 2017

Dear Sir,

I refer you to the Freedom of Information Act 2000 (FOIA) request of 17 September 2015 (15/469), the Decision Notice of 3 November 2016 (FS50616856), the information disclosed by the Medicines and Healthcare products Regulatory Agency (MHRA) on 8 December 2016, and the First-tier Information Tribunal case of *Leonard Spencer v Information Commissioner & Medicines and Healthcare products Regulatory Agency* (EA/2016/0283).

The FOIA request of 17 September 2015 sought disclosure of information from 1 April 2003 to the date the request was received by the MHRA – i.e. 1 April 2003 to 17 September 2015. In the letter to the Information Commissioner of 20 June 2016, the MHRA advised that it preferred – for no stated reason – to provide information in complete years. Following discussion with the Information Commissioner, the period of the FOIA request was duly extended to 31 March 2016 – solely to accommodate the MHRA's preference.

The MHRA has now received and generated over one year's worth of information since the last disclosure. I therefore write to you under the provisions of s.16 of the FOIA to seek your guidance in relation to a further FOIA request. It is my intention to seek disclosure of the information outlined in the numbered points below from voluntary reports of adverse incidents submitted to the MHRA from 1 April 2003 to 30 March 2017 in, as far as is possible, one single Microsoft Excel file.

I would be grateful if you would confirm, for each numbered point, whether you would be able to provide the information, or advise as to the FOIA exemption(s) you consider prevent disclosure. I appreciate that some of the information requested is subject to the judgment in *Leonard Spencer v Information Commissioner & Medicines and Healthcare products Regulatory Agency*, and understand, therefore, that you may need to await judgement to be able to provide guidance in relation to any information marked with an asterisk (*). I do not, however, think that this should delay any guidance in relation to information not affected by that case.

The following information was disclosed pursuant to the 17 September FOIA request for the period 1 April 2003 to 30 March 2017. The descriptions at points 1 to 14 are based upon the headings used in the Excel file provided on 8 December 2016.

PROTECT

1. Incident number

2. Number of devices involved

3. Number of incidents in summary

4. Device description

5. Item description

6. Reported event type 1

7. Reported event type (broad level)

8. Reported event type (detailed level)

9. Reported injury

10. Clinical effect

11. Concluded responsibility

12. Conclusion (Broad)

13. Conclusion (Detailed)

14. Outcome

The following information was part of the 17 September 2015 FOIA request and is now subject of the judgment in the case of *Leonard Spencer v Information Commissioner & Medicines and Healthcare products Regulatory Agency*:

15. Model*

16. Manufacturer name*

17. Catalogue number*

18. Serial number*

19. Lot and/or batch number*

20. Date of incident*

The following information was part of the 17 September FOIA request but, after being advised by the MHRA that it was "*not present in routine extract*", the requests were withdrawn:

21. Date of manufacturer

22. Expiry date

A comprehensive review of the MHRA's online Yellow Card forms for medical devices – outlined below – has revealed that the MHRA is (now) routinely collecting this information.

The following information was subject of the 17 September FOIA request but, following discussion with the Information Commissioner, the request was withdrawn on the basis that the MHRA was only content to supply information by quarter years:

23. Date report submitted

I do not consider the date a report was submitted to be exempt under any provision of the FOIA; it was internally generated, the same as the MHRA's incident numbers. The Information Commissioner ordered disclosure of the MHRA's incident numbers, and would likely order disclosure of the date reports were submitted for the same reason(s).

The MHRA has likely internally generated the following information:

24. Type of MHRA investigation – i.e. In-depth, Standard, Information, non-MHRA (Devices), Others, knowns, echo, Specialist, Monitored, Trending & Surveillance

25. Device code – i.e. GMDN, UMDNS, or EDMS

26. Class – i.e. I, Is, Im, IIa, IIb, III, AIMD, or IVD: other/generic, self-test, List A, or List B

27. Reference number(s) of relevant Recall(s), and/or Field Safety Notice(s), and/or Medical Device Alert(s)

In addition, the MHRA's online Yellow Card form for "General Report Form/All other devices" collects the following information:

28. Was the device CE marked – i.e. Yes, No, or Don't know

29. Was the manufacturer/supplier contacted – i.e. Yes or No

In addition, the MHRA's online Yellow Card form for "Artificial Limbs/External limb prostheses" collects the following information:

30. Weight (user)

31. Height (user)

32. Amputation side (upper) – i.e. None, Both, Don't know, Left, Right

33. Amputation side (lower) – i.e. None, Both, Don't know, Left, Right

34. Activity level – i.e. Very low, Low, Medium High, Very High

35. Was the device CE marked – i.e. Yes, No, or Don't know

36. Date parts fitted

37. Date of failure

In addition, the MHRA's online Yellow Card form for "Cochlear implants" collects the following information:

38. Gender – i.e. Male or Female

39. Date of implantation

40. Implantation side – i.e. Left or Right

41. Date of follow-up prior to incident

42. Component involved – i.e. Implant, Speech processor, or Accessory

43. Device explanted – i.e. Yes or No

44. Date of explant

45. Device failure details – i.e. Loss of output, Loss of telemetry, or loss in electrical function

46. Patient factors – i.e. Patient suffered from infection, or Patient suffered impact to head or device area

47. Has the device been re-implanted – i.e. Yes or No

48. Re-implanted device Model

49. Re-implanted device catalogue number

50. Re-implanted device serial number

In addition, the MHRA's online Yellow Card form for "Orthotic devices" collects the following information:

51. Wight (user)

52. Height (user)

53. Orthotic side

54. Activity level – i.e. Very low, Low, Medium High, Very High

55. Was the device CE marked – i.e. Yes, No, or Don't know

56. Date parts fitted

57. Date of failure

In addition, the MHRA's online Yellow Card form for "Implantable pacemakers/defibrillators" collects the following information:

58. Clinical Trial Device – i.e. Yes or No

59. Device – i.e. IPG, ICD, ART, VENT, CRT-P, CRT-D, or Other

60. Programmed as – i.e. DDD or VVIR

61. Manufacturer for device*

62. Model Name for device*

63. Model Number for device*

64. Serial Number for device*

65. Lead 1 – i.e. ART, DEFIB, VENT, Other: specify

66. Lead 1 Polarity/Material – i.e. Bipolar, Unipolar, Silicone or PolyU

67. Manufacturer for lead 1*

68. Model Name for lead 1*

69. Serial number for lead 1*

70. Lead 2 – i.e. ART, DEFIB, VENT, or Other: specify

71. Lead 1 Polarity/Material – i.e. Bipolar, Unipolar, Silicone or PolyU

72. Manufacturer for lead 2*

73. Model Name for lead 2*

74. Serial number for lead 2*

75. Lead 3 – C3, SVC, LV, Other: specify

76. Lead 3 Polarity/Material – i.e. Bipolar, Unipolar, Silicone or PolyU

77. Manufacturer for lead 3*

78. Model Name for lead 3*

79. Serial number for lead 3*

80. Failed/suspected components – i.e. Lead 1, Lead 2, Lead 3/Other

81. Date of implantation

82. Date of failure

83. Explanted – i.e. Yes or No

84. Mode of failure or reason for explant/termination – i.e. Premature end of life, Power on reset, or Backup mode pacing

85. Date of last follow-up

86. Date of 2nd last follow-up

87. Reported to Coroner – i.e. Yes, No, or Unknown

88. Performance information – i.e. Loss of telemetry, Partial loss of telemetry, Loss of capture, Under sensing, or Oversensing

89. Telemetered status indicator

90. Gas gauge indicator

91. Impedance (k Ohms)

92. Voltage (Volts)

93. Measured magnet rate (bpm)

94. Measured pacing rate (bpm)

95. Expected magnet rate (bpm)

96. Programmed pacing rate (bpm)

97. Measured lead impedance (Lead 1) – i.e. Bipolar, Unipolar: Ohms

98. Measured lead impedance (Lead 2) – i.e. Bipolar, Unipolar: Ohms

99. Measured lead impedance (Lead 3) – i.e. Bipolar, Unipolar: Ohms

100. Device already on advisory – i.e. Yes or No

In addition, the MHRA's online Yellow Card form for "In Vitro Diagnostic Medical Devices" collects the following information:

101. Device description – i.e. Clinical Chemistry, Cytopathology/Histopathology, Extra-Lab Testing, Genetic Testing, Haematology, Immunology, Microbiology, Self/Home Testing, or Specimen Receptacle

102. Product – i.e. Calibrators, Instrumentation/Software, QC Materials, Reagents, Reagent strip, Test-kit Colorimetric, Test-kit Immunoassay, or Test-kit Other

103. (Instrumentation) Product name*

104. (Instrumentation) Model*

105. (Instrumentation) Manufacturer*

106. (Instrumentation) Supplier*

107. (Instrumentation) Date supplied

108. (Instrumentation) Was the device CE marked – i.e. Yes, No, or Don't know

109. (Kits, reagents and specimen receptacles) Brand name*

110. (Kits, reagents and specimen receptacles) Analyte/marker

111. (Kits, reagents and specimen receptacles) Manufacturer*

112. (Kits, reagents and specimen receptacles) Supplier*

113. (Kits, reagents and specimen receptacles) Serial number*

114. (Kits, reagents and specimen receptacles) Expiry date

115. (Kits, reagents and specimen receptacles) Was the device CE marked – i.e. Yes, No, or Don't know

In addition, the MHRA's online Yellow Card form for "Wheeled Mobility and Associated Equipment" collects the following information:

116. Wight (user)

117. Usage – i.e. Domestic/Similar, Frequent steps/Kerbs, New/Not used, Outdoor, Rough terrain, or Sport

118. Severity of use – i.e. Hard, Fairly hard, Moderate, Light

119. Type of device – i.e. Manual wheelchair, Tricycle/Bicycle, Supportive seating system, Transportation related equipment, Powered

wheelchair, Buggy, Spare parts, Powered scooter, Ancillary equipment, or Cushion

120. Component – i.e. Brakes, Frame, Supportive seating, Upholstery, Castors, Protective finish, Wheels, Footrest, Electrical, Cushions, Accessories, None/Not applicable, or other

121. Was the device CE marked – i.e. Yes, No, or Don't know

122. Was the manufacturer/supplier contacted – i.e. Yes or No

123. Is litigation likely – i.e. Yes or No

In addition, the MHRA's online Yellow Card form for "Breast implants" collects the following information:

124. Date of original operation

125. Placement of implants – i.e. submuscular or subglandular

126. Incision cites(s)

127. Indication for implantation – ie Cosmetic augmentation, Development asymmetry, Postmastectomy, Replacement, Other: specify

128. Left Breast Implant – i.e. Manufacturer*, Model Name* (or filler material and/or volume), Serial Number*, and Batch/Lot Number*

129. Right Breast Implant – i.e. Manufacturer*, Model Name* (or filler material and/or volume), Serial Number*, and Batch/Lot Number*

130. Reason(s) for revision/removal (Left Implant) – i.e. Rupture/leak, Capsular contracture, Breast swelling, Shape change, Inflammation, Infection, Possible systemic adverse reactions, or Other: specify

131. Reason(s) for revision/removal (Right Implant) – i.e. Rupture/leak, Capsular contracture, Breast swelling, Shape change, Inflammation, Infection, Possible systemic adverse reactions, or Other: specify

132. Date of revision

133. Has patient consented to analysis of the implant by the manufacturer – i.e. Yes or No