First-tier Tribunal
(General Regulatory Chamber)
Information Rights

Appeal Reference: EA/2016/0283

Before
Judge Stephen Cragg Q.C.

Tribunal Members

Mr Roger Creedon
Ms Jean Nelson

Heard at Field House on 14 May 2019

Between

Leonard Spencer

Appellant

-and-

(1) The Information Commissioner
(2) Medicines and Healthcare Products Regulatory Agency

Respondents

Attendances:

For the Appellant: No appearance

For the 1st Respondent: Elizabeth Kelsey

For the 2nd Respondent: Ivan Hare QC

DECISION AND REASONS

INTRODUCTION

1. This is an appeal against the Commissioner's decision notice dated as long ago as 3 November 2016. It is a case with a history: a differently constituted First- Tier Tribunal (FTT) panel convened to consider this case on the papers and issued its decision on 1 August 2017, dismissing the Appellant's appeal.

2. However, that decision was subject to an appeal to the Upper Tribunal (UT) by the Appellant. Upper Tribunal Judge Jacobs concluded on 22 October 2018, in *Leonard Spencer v Information Commissioner and the Medicine and Healthcare Products Regulatory Agency* [2018] UKUT 349 (AAC) that:-

> As the decision of the First-tier Tribunal (made on 1 August 2017 under reference EA/2016/0283) involved the making of an error in point of law, it is SET ASIDE under section 12(2)(a) and (b)(i) of the Tribunals, Courts and Enforcement Act 2007 and the case is REMITTED to the tribunal for rehearing by a differently constituted panel.

3. We are that differently constituted panel and so heard the remitted appeal, this time at an oral hearing, where the Medicine and Healthcare Products Regulatory Agency (referred to as the MHRA) was represented by Mr Ivan Hare QC, and the Information Commissioner by Ms Elizabeth Kelsey. The Appellant was not represented and had informed the Tribunal that he did not wish to attend, although he submitted written arguments which we have read and fully taken into account.

BACKGROUND AND HISTORY OF PROCEEDINGS

4. The UT gave this short history of proceedings, which is a useful starting point:-

2. Mr Spencer made a request under the Freedom of Information Act 2000 (FOIA) asking the MHRA for information about voluntary reports of adverse incidents involving medical devices. It supplied some of the information and the Information Commissioner ordered it to disclose more. Mr Spencer's appeal to the First-tier Tribunal concerned the remaining information, which related to the date of the incident and to the model, manufacturer name, catalogue number, serial number, and lot or batch number of the devices involved. The tribunal dismissed the appeal, deciding that there was an absolute exemption prohibiting disclosure under section 44(1)(a) of FOIA.

5. More fully, by a FOIA request dated 17 September 2015 the Appellant sought from the MHRA information about "all voluntary reports of adverse incidents received since 1 April 2003". The MHRA, is an executive agency of the Department of Health and Social Care which acts on behalf of the Secretary of State in relation to the enforcement of the Medical Devices Regulations 2002. The Medical Devices Regulations transpose into domestic law three EU Directives (90/385/EEC, 93/42/EEC and 98/79/EC) which are designed to ensure the safety of various types of medical device.

6. In particular the Appellant sought in relation to each of the voluntary reports, the following information:

(1) Type of device
(2) Model
(3) Manufacturer name
(4) Catalogue number
(5) Serial number
(6) Lot or batch number
(7) Expiry date
(8) Date of manufacture
(9) Quantity defective
(10) Date of incident
(11) Type of injury
(12) Details of incident/nature of device defect
(13) Details of injury (to patient, carer or healthcare professional

(14) Action taken (includes any action by patient or healthcare professional or by the manufacturer or supplier
(15) Date report submitted
(16) MHRA reference number.

7. Following the MHRA's response (disclosing some of the information requested) and the Commissioner's decision notice, the information requested at (2), (3), (4), (5), (6) and (10) in the above list remained withheld on the basis of section 44(1)(b) of FOIA. This exempts information from disclosure under FOIA if such disclosure (otherwise than under FOIA) " … is incompatible with any EU obligation".

8. The Appellant appealed against the Commissioner's decision notice on the basis that he was entitled to the rest of the information under FOIA, as there were no domestic or EU provisions which exempted the material from disclosure, and therefore neither s44(1)(a) or (b) applied.

9. In effect, section 44(1) of FOIA ensures that a request under FOIA cannot bypass prohibitions in other legislation or under EU obligations:-

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 EU obligation, or
(c)…..

10. By section 2(3)(f)(i) FOIA these exemptions are 'absolute' exemptions where they are applicable.

11. Relevant to the application of s44(1)(a) FOIA is section 237 Enterprise Act 2002 (EA 2002), which provides a prohibition on disclosure in certain situations:

237 *General restriction*
(1) This section applies to specified information which relates to—
(a) the affairs of an individual;
(b) any business of an undertaking.
(2) Such information must not be disclosed—
(a) during the lifetime of the individual, or
(b) while the undertaking continues in existence, unless the disclosure is permitted under this Part.
(3) …

12. Section 238(1) EA 2002 defines 'specified information':

238 *Information*
(1) Information is specified information if it comes to a public authority in connection with the exercise of any function it has under or by virtue of— …

(b) an enactment specified in Schedule 14; …

13. The Consumer Protection Act 1987 is one of the enactments specified in Schedule 14.

14. Thus, (subject to s237(2) EA 2002) information cannot be disclosed under FOIA if it is held by a public authority to which it came in connection with the exercise of any function under the Consumer Protection Act 1987.

15. Section 11 Consumer Protection Act 1987 (CPA 1987) authorises the making of what are described as 'safety regulations':

11 Safety regulations.

(1) The Secretary of State may by regulations under this section ('safety regulations') make such provision as he considers appropriate … for the purpose of securing—
(a) that goods to which this section applies are safe;
(b) that goods to which this section applies which are unsafe, or would be unsafe in the hands of persons of a particular description, are not made available to persons generally or, as the case may be, to persons of that description; and

(c) that appropriate information is, and inappropriate information is not, provided in relation to goods to which this section applies.

16. The Medical Devices Regulations 2002 (SI No 618) (the 2002 Regulations) were made in part under section 11 CPA 1987. The MHRA is, as mentioned already, an executive agency of the Department of Health and Social Care and acts on behalf of the Secretary of State in relation to the enforcement of the Regulations. Regulation 61 provides that for the purposes of enforcement the Regulations are 'safety regulations' and 'safety provision':

> 61 Enforcement etc
>
> (1) Notwithstanding that they are made partly in exercise of powers other than those conferred by section 11 of the 1987 Act, these Regulations shall be regarded for all purposes relating to enforcement (whether by criminal proceedings, notices or otherwise) and for the purposes of section 38 of that Act (disclosure of information) as safety regulations as defined in that Act, and any provision of these Regulations made under those other powers shall be regarded for those purposes as a safety provision as defined in that Act.
>
> (2) Except as provided by paragraph (3), each weights and measures authority in Great Britain and each district council in Northern Ireland is relieved of its duty imposed by section 27(1) of the 1987 Act in so far as it is exercisable in relation to relevant devices or devices for performance evaluation, and that duty is transferred to the Secretary of State.
>
> (3) Paragraph (2) does not relieve an authority or council of its duty in relation to devices which are consumer goods for the purposes of Part II of the 1987 Act, and accordingly but subject to paragraph (4), each weights and measures authority in Great Britain and each district council in Northern Ireland shall, concurrently with the Secretary of State, enforce these Regulations in relation to such devices.

17. Thus, any function under the Regulations is within the scope of the 1987 Act and thereby the prohibition against disclosure, as described above, applies.

18. The original FTT decision commented that (para 8):-

> Thus, the position in English law is that the rules in the European directives relating to medical devices have been implemented by the 2002 Regulations, the Secretary of State is responsible for their enforcement and they are to be regarded for the purposes of enforcement as regulations made under the Consumer Protection Act 1987.

19. On this basis, the FTT concluded that (para 12 and 13):-

> "…..we are quite satisfied that section 44(1)(a) applied to the withheld information and that MHRA were entitled (and indeed obliged) to withhold it….
>
> 13. Since we are clear that the domestic statutory provisions prohibit disclosure of the information in question we do not think there was any need to consider section 44(1)(b) of FOIA…..'

20. UT Judge Jacobs largely agreed with the FTT's analysis in relation to domestic statutory provisions prohibiting the disclosure of information in question. However, Judge Jacobs found that the FTT had overlooked the fact that not *all* the requested information held by the MHRA was necessarily covered by the statutory provisions set out.

21. To this effect, the UT noted as follows at paragraphs 30 -31, in relation to section 237(2)(a) and (b) EA 2002 (as set out above):-

> 30. …..Section 237 does not contain an absolute prohibition. It is qualified to apply only to individuals who are still alive and undertakings that are still in existence. The MHRA and the Information Commissioner now accept that this is so. The First-tier Tribunal went wrong in law by overlooking this point.
>
> 31. The MHRA had relied on the prohibition. It was only entitled to do so to the extent that it applied. It does not apply to individuals who have died or to undertakings that no longer exist.

22. Thus, the UT found that although section 237 EA 2002 contained a relevant statutory prohibition, it did not necessarily apply to all the information held by the MHRA, and that the FTT had erred in concluding that this was a complete answer to the Appellant's appeal.

23. It appears that the MHRA raised with the UT the practical problems of identifying which information was or was not covered by the prohibition. These problems were developed more fully before us and we return to them below. The UT addressed the issue as follows:-

> 31…..If the MHRA wants to rely on section 237, it has to show that it applies. I accept that there are practical problems for MHRA in identifying whether an undertaking is still in existence, but that that cannot relieve it of its responsibility if it wants to rely on the prohibition. Again, if it wants to rely on section 237, it has to show that it applies.
>
> 32. I suggested that the MHRA might be able to rely on section 12 of FOIA:
>
> > **12 Exemption where cost of compliance exceeds appropriate limit**
> > (1) Section 1(1) does not oblige a public authority to comply with a request for information if the authority estimates that the cost of complying with the request would exceed the appropriate limit.
> > (2) Subsection (1) does not exempt the public authority from its obligation to comply with paragraph (a) of section 1(1) unless the estimated cost of complying with that paragraph alone would exceed the appropriate limit.
> > (3) In subsections (1) and (2) 'the appropriate limit' means such amount as may be prescribed, and different amounts may be prescribed in relation to different cases.
>
> As the MHRA could only comply with a request by identifying those cases that were outside the scope of the prohibition, the cost of identifying the information that it could disclose would come within section 12. The practical difficulties that I have mentioned would fall to be taken into account in that way. It would be for the MHRA to show that the cost would exceed the limit.

24. The UT also mentioned other reasons for not disclosing the information raised by the MHRA, which have become of importance in this remitted hearing. Thus:-

> 33. At the hearing, Mr Hare relied principally on section 14, arguing that the request was vexatious. He also told me that if there were a rehearing, he would rely on section 12 and section 44(1)(b) of FOIA. His argument on the latter was that there were obligations under EU legislation that existed independently of any incorporation of directives I have

mentioned into domestic law. For good measure, he suggested that the MHRA might not 'hold' the information requested, because it contained information necessary to identify whether an organisation still existed. I make no comment on any of those arguments, as they will require a rehearing before the First-tier Tribunal.

25. The directions given by the UT were that 'The tribunal must undertake a complete reconsideration of the issues that are raised by the appeal in accordance with my analysis of the issues I have decided in this appeal'.

26. It was also directed that the MHRA provide 'the other parties and the First-tier Tribunal with a statement of the arguments that it will rely on at the hearing so that Mr Spencer in particular has time to prepare his arguments'.

THE REMITTED HEARING

27. As a result of these directions, the MHRA made written submissions to the effect that it would be relying on the following sections of FOIA at the renewed hearing:-

    (a) S3 FOIA: the information is not held by the MHRA
    (b) S12 FOIA: the cost of complying with the request exceeds the appropriate limit set out.
    (c) S14 FOIA(1): the request is vexatious.
    (d) S44(1)(b): the information is exempt under that sub-section.

28. If any of the points in (a) – (c) are established by the MHRA then it will be the case that it will not be able to disclose the information, or it will not have to consider doing so. In such circumstances, it would be strictly be unnecessary to consider whether any exemptions (such as s44(1)(b) FOIA) apply.

29. The position of the Commissioner is that the MHRA does hold the information, and that s12 FOIA does not assist MHRA. The Commissioner said that she was minded to agree that s14 FOIA applies (but reserved her position pending examination of any witnesses), and agreed that s44(1)(b) FOIA would be applicable (which was, of course, her position in the 2016 decision notice).

30. The Appellant sets out in his skeleton argument his response to the s44(1)(b) FOIA point, and we will return to that below. He argues that his request cannot be vexatious and the MHRA cannot rely on s12 FOIA as directive 2007/47/EC does not allow for any bar to disclosure. Again, we will return to this argument below.

31. In its skeleton argument, the MHRA argue that there is now only one narrow issue in the case, namely:-

> Is…the MHRA required to disclose that part of the requested information which relates to undertakings which have ceased to exist or individuals who are no longer living.

32. That might be true, but the Tribunal will need to examine a number of bases upon which the MHRA say that it is not required to disclose the information, and we deal with these in turn.

EVIDENCE

33. At the remitted hearing we heard evidence from Ms Janine Jolly who is employed by the MHRA as Devices Patient Safety Unit Manager. Her job includes encouraging adverse incident reporting from the healthcare system and also managing FOIA requests and processes. Ms Jolly provided a witness statement. The open version of that is in the bundle, with some redactions. We can say that the content of the redactions have no particular

effect on our decision and reasons, although we have seen and read the unredacted version. Ms Jolly was asked questions by the Commissioner's representative and by members of the Tribunal.

34. Ms Jolly also provided a further bundle with sample information in it to help explain the MHRA's position. Having looked at this information it is our view that s14(6) of the Tribunal rules should be applied to prevent disclosure, to anyone other than the Commissioner and the MHRA. To do otherwise would defeat the purpose of the proceedings. However, there was nothing in particular in the information that we need to refer to in this judgment.

35. Ms Jolly's evidence was that, in relation to voluntary medical device reports, the MHRA does not record or keep track of whether an undertaking is still in existence or a person is still alive for the purposes of s237 EA 2002, and therefore, when considering whether information should be disclosed, it would need to investigate each case to establish the status of the undertaking or person involved. She told us that it was not feasible for the MHRA to keep the information on these issues up-to-date, and it did not have the resources to attempt it.

36. Ms Jolly explained that in the period in question in this case – 1 April 2003 to 17 September 2015 there were 60,358 voluntary reports made referring to 6,700 manufacturers and approximately 40,000 different models of device. Ms Jolly explained that to establish whether a request for information in relation to these reports related to an undertaking in existence or a person still alive, would take hundreds if not thousands of hours and would require the employment of a dedicated member of staff, which would, conservatively, cost in excess of £150,000. We accept this evidence, and also accept that it would be a massive task for the MHRA to undertake, which would be a considerable burden on its resources.

DISCUSSION AND DECISIONS

Not held

37. MHRA's case is that it does not hold the information as to whether undertakings have ceased to exist or individuals are no longer living (and therefore cannot disclose it under FOIA). It receives reports on medical devices which relate to undertakings and individuals, but does not seek to update its database to record what has happened to an undertaking (eg whether it still exists) or whether an individual is still living at any particular time.

38. The Commissioner disagrees with this analysis. She points out that under s1(1) FOIA if there is information 'of the description specified in the request' then, subject to other provisions (set out in s1(2)), the requester is entitled to have the information 'communicated to him'. We agree with the Commissioner that the request was about specific details of voluntary reports of adverse incidents involving medical devices, and did not distinguish between whether an undertaking still existed or not or whether a person was still alive. That distinction applies only because of the wording of s237 EA 2002. The MHRA must apply the wording of s237 EA 2002 to find out whether the exemption in s44(1)(a) FOIA applies in relation to all or some of the requested information, but this does not mean that it does not hold the information requested.

39. We reject the reliance on this ground by MHRA.

Section 12 FOIA

40. MHRA explained to the UT that it would be expensive to extract the information requested that was not covered by s237 EA 2002. We have no

doubt that this is true and we consider evidence to this effect when we consider vexatiousness and s14(1) FOIA below. The UT suggested that the MHRA should rely on s12 FOIA in a passage which we have set out above.

41. However, the parties accepted at the hearing that this was simply a suggestion by the UT, and not a finding that s12 FOIA would necessarily apply. Significantly, and as the Commissioner points out, the UT did not refer (and we are told was not referred to) the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004 ('the 2004 Regulations'). Regulation 4 (3) reads as follows:-

> (3) In a case in which this regulation has effect, a public authority may, for the purpose of its estimate, take account only of the costs it reasonably expects to incur in relation to the request in–
>
> (a) determining whether it holds the information,
>
> (b) locating the information, or a document which may contain the information,
>
> (c) retrieving the information, or a document which may contain the information, and
>
> (d) extracting the information from a document containing it.

42. The MHRA state that they would incur 'very substantial costs' in 'locating the information' concerning the relevant individuals and undertakings and that this would come within regulation 4(3)(b) of the 2004 Regulations. The Commissioner disagrees and argues that the 2004 Regulations do not allow a public authority to take into account the cost of determining whether any exemptions to disclosure apply, and therefore s12 FOIA is not applicable in the current case. In our view this is the correct analysis: MHRA can locate all the information it holds in relation to the request (and has not argued otherwise). Its (expensive) problem is identifying which parts of the information requested are exempt because of s44(1)(a) FOIA, and which are not. This is not covered by s4(3) of the 2004 Regulations and therefore cannot be taken into account.

43. Having rejected the MHRA's argument we do not need to address the Appellant's argument, in this context at least, that Directive 2007/47/EC does not allow for any bar to disclosure, and therefore a costs limit cannot be placed on disclosure requests.

Section 14 FOIA

44. Section 14(1) FOIA states that "Section 1(1) [FOIA] does not oblige a public authority to comply with a request for information if the request is vexatious". Vexatiousness is not defined in section 14 FOIA, but it is immediately noticeable that it is the request that must be vexatious and not the person making the request.

45. The approach to vexatiousness is set out in the case of *Information Commissioner vs Devon County Council & Dransfield* [2012] UKUT 440 (AAC). There is an emphasis on protecting public authorities' resources from unreasonable requests which is described by the Upper Tribunal in *Dransfield* when it defined the purpose of section 14 as follows at paragraph 10:

> 'Section 14…is concerned with the nature of the request and has the effect of disapplying the citizen's right under Section 1(1)…The purpose of Section 14…must be to protect the resources (in the broadest sense of that word) of the public authority from being squandered on disproportionate use of FOIA…'.

46. Also in *Dransfield,* the Upper Tribunal took the view that the ordinary dictionary definition of the word vexatious is only of limited use, because the question as to whether a request is vexatious ultimately depends upon the circumstances surrounding that request. As the Upper Tribunal observed:

> 'There is…no magic formula – all the circumstances need to be considered in reaching what is ultimately a value judgement as to whether the request in issue is vexatious in the sense of being a

> disproportionate, manifestly unjustified, inappropriate or improper use of FOIA'.

47. *Dransfield* was also considered in the Court of Appeal *(Dransfield v Information Commissioner and Devon County Council* [2015] EWCA Civ 454) where Arden LJ observed at paragraph 68 that:-

> "…the emphasis should be on an objective standard and that the starting point is that vexatiousness primarily involves making a request which has no reasonable foundation, that is, no reasonable foundation for thinking that the information sought would be of value to the requester or to the public or any section of the public… The decision maker should consider all the relevant circumstances in order to reach a balanced conclusion as to whether a request is vexatious.'

48. Specific reference should also be made to paragraph 72 of *Dransfield* in the Court of Appeal where Arden LJ addressed paragraph 10 of the UT decision and said:-

> 72 Before I leave this appeal I note that the UT held [2012] UKUT 440 AAC at [10] that the purpose of section 14 was "to protect the resources (in the broadest sense of that word) of the public authority from being squandered on disproportionate use of FOIA". For my own part, I would wish to qualify that aim as one only to be realised if the high standard set by vexatiousness is satisfied. This is one of the respects in which the public interest and the individual rights conferred by FOIA have, as Lord Sumption JSC indicated in *Kennedy v Charity Commission (Secretary of State for Justice and others intervening [2015] AC 455* para 2 above), been carefully calibrated.

49. The recent Upper Tribunal case of *Cabinet Office v Information Commissioner v Ashton* [2018] UKUT 208 (AAC) made clear that s14(1) FOIA can apply on the basis of the burden placed on the public authority, even where there was a public interest in the request being addressed and where there was a 'reasonable foundation' for the request:-

> 27. The law is thus absolutely clear. The application of section 14 of FOIA requires a holistic assessment of all the circumstances. Section 14 may be invoked on the grounds of resources alone to show that a request is vexatious. A substantial public interest underlying the request for information does not necessarily trump a resources argument. As Mr Armitage put it in the Commissioner's written response to the appeal (at §18):
>
> a. In deciding whether a request is vexatious within the meaning of section 14(1), the public authority must consider all the relevant circumstances in order to reach a balanced conclusion as to whether a request is vexatious.
>
> b. The burden which compliance with the request will impose on the resources of a public authority is a relevant consideration in such an assessment.
>
> c. In some cases, the burden of complying with the request will be sufficient, in itself, to justify characterising that request as vexatious, and such a conclusion is not precluded if there is a clear public interest in the information requested. Rather, the public interest in the subject matter of a request is a consideration that itself needs to be balanced against the resource implications of the request, and any other relevant factors, in a holistic determination of whether a request is vexatious.

50. In this case it is not really possible to establish why the Appellant has requested the information, and we do not know whether he would advance any particular public interest reason for making the request. However, it would seem obvious to us that there is a general public interest in greater awareness and transparency about reports made on medical devices where something has gone wrong and we will proceed on that basis.

51. However, the evidence we have heard about the inevitable cost in extracting the information that can, in fact, be disclosed is something that we must also consider when taking an 'holistic' approach to the case. It is also our view that we should consider the fact that s237 EA 2002 clearly restricts the information that can be disclosed to those undertakings that no longer exist and to persons no longer alive. This is as a direct result of the UT judgment

which accepted the general applicability of s237 EA 2002, whilst emphasising that it did not apply to all information.

52. On that basis it seems to us appropriate to ask whether there is any particular public interest in the limited disclosure to which the Appellant would ultimately be entitled, again from the point of view of taking the required 'holisitic' approach. On the face of it, there would not seem to be any particular public interest in reports on medical devices where an undertaking now ceases to exist or an individual is no longer alive, and none has been put forward by the Appellant.

53. We accept that the cost of extracting the information that can be disclosed to the Appellant would lead to a disproportionate burden upon the MHRA's resources. We set against this the limited public interest in disclosure of the information permitted once s237 EA 2002 is applied. The case law allows us to find that a request is vexatious on the basis of a disproportionate burden on a public authority, even where, applying the usual meaning of vexatiousness, a request would not be deemed as such. In this case, the public interest in disclosure cannot outweigh the huge costs to which the MHRA would be exposed if the request were complied with.

54. As noted above, the Appellant argues that Directive 2007/47/EC does not allow for any bar to disclosure, and therefore any request cannot be vexatious. For the reasons set out below, when we address the EU legislation in the context of the exemption in s44(1)(b) FOIA, we do not accept that the Directive has the effect argued for by the Appellant and therefore this cannot impact on our decision on vexatiousness.

55. On that basis we find that the request is indeed vexatious and FOIA does not require the MHRA to comply with the request.

S44(1)(b) FOIA

56. Having reached that conclusion, it is not strictly necessary for us to go on to consider whether any of the exemptions in FOIA apply. However, in the original decision notice the Commissioner made it clear that s44(1)(b) FOIA applied, in her view, to the withheld information. The Appellant addressed this reliance in his original appeal document, and all parties have now made further submissions to us on this issue. On that basis it seems appropriate to us to express our view as to whether s44(1)(b) FOIA applies to the withheld information in any event.

57. The Commissioner originally expressed her reliance on this exemption in the decision notice as follows (footnotes excluded):-

> 19. The MHRA is the regulator for medical devices and works under the Medical Devices Regulation 2002 ("MDR2002") which implement several European Directives – Directive 90/385, Directive 93/42 and Directive 98/79.
>
> 20. Article 20 of Directive 93/42 places the following obligation on the MHRA in relation to its duties when considering medical devices:
>
> "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."
>
> 21. This is also echoed in Article 15 of Directive 90/385 and Article 19 of Directive 98/79.
>
> 22. 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'.
>
> 23. She is also satisfied the information that is subject to this exemption is information that would have been obtained by the MHRA as part of the discharge of its functions under the MDR2002.
>
> 24. The complainant has argued though that this confidentiality requirement set out in Article 20 is not applicable to information

obtained voluntarily by the MHRA. The Commissioner recognises that the information in this case is information which was obtained by the voluntary reporting of adverse incidents involving medical devices so has gone on to consider this point further.

25. The complainant points to Article 8 of Directive 90/385, Article 10 of Directive 93/42 and Article 11 of Directive 90/79 which all state:

"Where a Member State **requires medical practitioners or the medical institutions to inform the competent authorities of any incidents** referred to in paragraph 1, it shall take the necessary steps to ensure that the manufacturer of the device concerned, or his authorised representative, is also informed of the incident."

26. The complainant argues that there is no requirement in the UK for medical practitioners or medical institutions to report incidents to the MHRA. Therefore, he argues that reports of incidents to the MHRA made by anyone other than the manufacturer of the device, their authorised representative or a notified body do not fall under the provisions of the Directives as they have been made voluntarily and not through requirement, and the confidentiality requirements do not apply.

27.The MHRA have countered these arguments by highlighting that all of the Articles in the Directives refer to "**all** parties" and "with regard to **all** information obtained" and there is therefore no differentiation made between information obtained voluntarily or by requirement. The MHRA argues further that if the intention was to make a distinction between voluntarily provided and provided by requirement then this would have been stated.

28. The Commissioner understands that the MHRA operates a compulsory reporting system for use by medical device manufacturers to report faults. This works in parallel with the voluntary reporting system for adverse incidents where faults can be reported by patients, members of the public, medical practitioners and medical institutions. The voluntary reports are logged and sent to the medical device manufacturers for them to investigate and the MHRA will monitor the progress of this investigation.

29. In making a decision on this point, the Commissioner has referred back to earlier decisions made[5]. In these cases, the Commissioner considered this issue in relation to different requests to the MHRA. She noted that:

> "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'.
>
> 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."
>
> 30. Taking this into account; the Commissioner sees no reason to alter her view on this matter and would accept that information obtained by the MHRA, both voluntarily and proactively, is subject to the obligation of confidence set out in Article 20 of Directive.

58. Before us, the MHRA now takes a similar approach. It is pointed out that Article 20 of Directive 93/42/EEC has been amended by Directive 2007/47/EU. The MHRA set out other aspects of Article 20 as follows. Thus paragraph 2 of Article 20 lists information which is not to be treated as confidential. This includes 'information to users sent out by the manufacturer, authorised representative or distributor in relation to a measure according to Article 10 (3)'. There is also, in paragraph 3 of Article 20 a procedure for amending 'non-essential elements of this Directive' which includes 'conditions under which other information may be made publicly available'.

59. The MHRA argues that the Directive sought to establish a complete regime for conditions under which information obtained pursuant to legislation implementing the Directive might be released. That this is the case is said to be supported by the recitals and drafting history and in particular recital 16 of Directive 2007/47/EC and COM (2005) 681 final, p7 which explains that paragraphs 2 and 3 to Article 20 have been added to 'relax' Article 20, which otherwise maintained all information under the Directive as being confidential. It is pointed out that, other than the exceptions in paragraph 2 of Article 20 there are, at present, no other exceptions. Thus, the MHRA agrees

with the position set out in the decision notice. The Commissioner repeats her position in the skeleton argument for this hearing.

60. The Appellant argues that we should read the amended Directive as providing for general availability of information, but that appears to go against the current clear wording of Article 20, and we do not accept his argument. The information he seeks does not come within Article 20 paragraph 2 and in particular is not 'information to users sent out by the manufacturer' etc. The MHRA told us that this information is available on its website in any event.

61. The Appellant refers to the actual wording of recital 16 of Directive 2007/47/EC which states that 'certain information related to medical devices….in particular information on registration, on vigilance reports and on certificates, should be available to any interested party and the general public' and argues that this means that any information on these issues should, in fact, be made available. However, the actual provisions of this directive only amend Article 20 to the extent indicated above and, as we have found, the information sought by the Appellant does not come within the amendments to Article 20. We therefore do not agree that recital 16 has the effect advocated for by the Appellant.

62. The Appellant also argued that the Directives do not apply to voluntary reports made to the MHRA. However, this argument was rejected by the UT at paragraphs 28-29.

63. The Appellant further argued that the information sought does not fall within the confidentiality requirements of the Directives because of EU Regulation 765/2008 for Accreditation and Market Surveilance (RAMS). However, we accept the argument of the MHRA that RAMS sets out a general framework for market surveillance and post-dates the regime set out in the Directives cited above. We note that recital (5) of RAMS specifically states that it only

applies where there 'are no specific provisions with the same objective' etc. As there are, RAMS cannot apply.

64. Therefore, on the particular facts of this case, and as the point was fully argued and forms the basis of the Commissioner's decision notice we find that, if the Appellant's request was not vexatious, the exemption in s44(1)(b) FOIA applies for the reasons set out in the decision notice and amplified in further written submissions from the Commissioner and the MHRA.

A narrower request

65. Finally, we should note that the Appellant has proposed that a request in relation to one undertaking that ceases to exist should be considered. However, that is not the request under appeal, and any further request will have to be considered according to FOIA by the MHRA and the Commissioner before it becomes something upon which the Tribunal can comment.

CONCLUSION

66. For those reasons, we dismiss this appeal.

Stephen Cragg QC

Judge of the First-tier Tribunal

Date: 31 May 2019

Promulgation date: 4 June 2019