



IN THE FIRST-TIER TRIBUNAL
GENERAL REGULATORY CHAMBER
(INFORMATION RIGHTS)

Appeal No: EA/2016/0283

ON APPEAL FROM:

**The Information Commissioner's Decision Notice No: FS50616856
Dated: 3 November 2016**

Appellant: Leonard Spencer

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

Determined without a hearing

**Before
HH Judge Shanks
and
Pieter de Waal and Henry Fitzhugh**

Date of decision: 1 August 2017

Subject matter:

Freedom of Information Act 2000 (FOIA)
Section 44 (Prohibitions on disclosure)

DECISION OF THE FIRST-TIER TRIBUNAL

For the reasons set out below the Tribunal dismisses the appeal.

REASONS FOR DECISION

Introduction

1. The MHRA, the Second Respondent to this appeal, is an executive agency of the Ministry of Health 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.

2. By a FOIA request dated 17 September 2015 the Appellant, Mr Spencer, sought from MHRA information about “all voluntary reports of adverse incidents [involving medical devices] received since 1 April 2003”; in particular he sought in relation to each report:
 - (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.

3. In response the MHRA disclosed the information requested at (1), (7), (8), (9), (11), (12), (13), (14) and (15) and, in a decision notice dated 3 November 2016, the Information Commissioner also required them to disclose (16). But the Commissioner decided that they had correctly withheld the information requested at (2), (3), (4), (5), (6) and (10) on the basis of section 44(1)(b) of FOIA, which exempts information from disclosure under FOIA if such disclosure (otherwise than under FOIA) “ ... is incompatible with any EU obligation”.
4. Mr Spencer has appealed against the Commissioner’s decision notice contending that he is entitled to the withheld information under FOIA. His case, set out at some considerable length, is that the relevant EU Directives have been transposed into domestic law and therefore any obligations contained in them have ceased to exist and that, since there is nothing in the relevant domestic law (that is the 2002 Regulations) which requires the MHRA to receive voluntary reports of adverse incidents, section 44(1)(a) of FOIA (which exempts information whose disclosure is prohibited by any domestic enactment) does not apply either. The parties agreed to the appeal being decided without a hearing and we consider that we can properly determine the issues in that way.

Legal framework

5. The Tribunal (differently constituted though with the same Tribunal Judge) has considered the relevant law in an earlier case, *Oxford Phoenix Innovations Ltd v the Information Commissioner* EA/2015/0055-7, which was decided on 3 November

2015. The following summary of the legal framework is taken largely verbatim from the decision in that case.

6. MHRA is, as we have said, an executive agency of the Ministry of Health which acts on behalf of the Secretary of State in relation to the enforcement of the Medical Devices Regulations 2002. Those Regulations were made by the Secretary of State in the exercise of his powers under the European Communities Act 1972 in order to implement the European Directives referred to above. The Regulations were also made under other powers, including section 11 of the Consumer Protection Act 1987.

7. Regulation 61 which is headed “Enforcement etc” provides as follows:

(1) Notwithstanding that they were made partly in the 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) ... as safety regulations as defined in that Act ...

(2) ... [the] duty imposed by section 27(1) of the 1987 Act [ie the duty to enforce safety regulations] in so far as it is exercisable in relation to relevant devices ... is transferred to the Secretary of State.

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.

9. Section 238 of the Enterprise Act 2002 provides that information is “specified” 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 ...

The list of enactments in schedule 14 to the Enterprise Act 2002 includes the Consumer Protection Act 1987. Thus it is clear that information which comes to the

MHRA as agent for the Secretary of State in connection with the enforcement of the 2002 Regulations is “specified” for the purposes of the Enterprise Act 2002. Section 237 of the Enterprise Act 2002 provides:

- (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 by this Part [of the Act].**
- (3) But subsection (2) does not prevent the disclosure of any information if the information has on an earlier occasion been disclosed to the public in circumstances which do not contravene [that subsection or any other enactment]**

Section 239 of the Act provides:

- (1) This Part [of the Act] does not prohibit the disclosure by a public authority of information held by it to any other person if it obtains each required consent.**
- (2) If the information was obtained by the authority from a person who had the information lawfully and the authority knows the identity of that person the consent of that person is required.**
- (3) If the information relates to the affairs of an individual the consent of the individual is required.**
- (4) If the information relates to the business of an undertaking the consent of the person for the time being carrying on the business is required.**

10. Section 44 of FOIA provides:

- (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 ...**

Given the statutory framework set out above there can be no doubt that the MHRA is entitled (indeed obliged) by virtue of section 44(1)(a) FOIA to withhold information which relates to the affairs of an individual or the business of an undertaking which comes to it in connection with its function of enforcing the Medical Devices Regulations 2002, unless one of the exceptions in the Enterprise Act 2002 (e.g. section 239) applies.

Our conclusions

11. Notwithstanding Mr Spencer's strongly expressed assertions to the contrary we are quite clear that voluntary reports of adverse incidents relating to medical devices comprise information which comes to the MHRA in connection with that function. The only reason people supply the information to the MHRA and the only reason it receives and records the information is because it is responsible for enforcing the Regulations which are designed to ensure the safety of medical devices. The fact that the Regulations may not refer to voluntary reports of adverse incidents (or indeed the fact that not every report will lead to enforcement action) is irrelevant: the information is still supplied and received in connection with the function of enforcing the Regulations.

12. Since there is no suggestion that any of the exceptions in the Enterprise Act 2002 applies, 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. 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.

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, and in particular to consider the interesting question of how it applies to the provisions of Directives which have been transposed into domestic law.

Outcome

14. For somewhat different reasons to those of the Commissioner we therefore unanimously dismiss the appeal.

HH Judge Shanks

1 August 2017

Promulgated

2 August 2017