IN THE FIRST-TIER TRIBUNAL **Case No.** EA/2010/ 0055

GENERAL REGULATORY CHAMBER

INFORMATION RIGHTS

ON APPEAL FROM:

The Information Commissioner's

Decision Notice No: FS50237119

Dated:19th.February, 2010

Appellant:	**Deirdre Murphy**
Respondent :	**The Information Commissioner**
Additional Party :	**Medicines and Healthcare Products Regulatory Agency**

Decision on paper

Date of Decision: 04th. October, 2010:

Before

David Farrer Q.C.(Judge)

and

Henry Fitzhugh

and

Paul Taylor

Subject matter: FOIA S.41(1) Confidential Information

Cases: ***Bluck v ICO & Epsom and St Helier University NHS Trust (EA/2006/90)*,**
Coco v A.N.Clark (Engineers) Limited (1968) FSR 415.

Attorney General v Guardian Newspapers [1990] 1 AC 109

DECISION OF THE FIRST-TIER TRIBUNAL

The Tribunal upholds the decision notice dated 19th.February, 2010 and dismisses the appeal.

Dated: 04th. October, 2010

Signed

D.J.Farrer Q.C.

Tribunal Judge

REASONS FOR DECISION

Introduction

1 The Appellant was given permission to identify herself as "EY", when she appealed to the Tribunal.

2 The Additional Party, the Medicines and Healthcare Products Regulatory Agency (MHRA) is an executive agency with responsibility for ensuring the safety of medicines and medical devices. It is empowered, where appropriate, to withdraw medicines from the market.

3 Pfizer Ltd. (Pfizer) is a pharmaceutical company which manufactures an antibiotic called Linezolid, marketed under the name Zyvox. It is used in the treatment of gram-positive bacteria that are resistant to other antibiotics.

Pfizer conducted a clinical trial comparing the effects of Linezolid with those of other similar drugs in the treatment of catheter – related gram positive bloodstream infections. A review of the data raised questions, about the safety and efficacy of Linezolid and the MHRA requested a mortality analysis from Pfizer. Pfizer had difficulty in explaining the number of deaths that occurred during the course of its trial.

The MHRA commissioned a number of reports and prepared a report for the Commission on Human Medicines and the Pharmacovigilance Expert Advisory Group (" the MHRA Report"). To the MHRA Report was attached an Annex 2 which consisted of a report to the MHRA from Pfizer, dated January, 2007 containing answers to questions from the MHRA relating to the mortality statistics. It was based on information provided by patients to their practitioners for the purposes of the trial.

Pages 9 – 31 of the Pfizer report were omitted from Annex 2 to the MHRA report, as the MHRA informed the Appellant in September, 2008

The Request

4 The Appellant requested the missing pages on 16th. September, 2008. The MHRA supplied them in redacted form on 10th.December, 2008. It justified the redactions by reference to the fact that they related to personal data to which applied the absolute exemption conferred by s.40 of FOIA. The data referred both to living and deceased patients and provided data relating to them in tabular form. The redacted information related to the age, gender and the identification number of the patients.

5 The Appellant sought a review on 18th. January, 2009. The MHRA acknowledged that s.40 provided no valid exemption for information relating to patients who had died. It maintained its refusal as to the redacted information, now invoking FOIA s.41 on the grounds that :

(a) It had been communicated to the MHRA in confidence;

(b) The information concerned patients who could be linked to a particular study site which would enable the requester directly or indirectly to identify particular patients, even if the unique identification number were removed;

Following the decision of the Information Tribunal in *Bluck v ICO & Epsom and St Helier University NHS Trust (EA/2006/90)*, for the purposes of FOIA section 41, an action for breach of confidence in respect of a disclosure of such information survives a patient`s death.

6 EY complained to the IC on 2nd. March, 2009. She advanced arguments similar to those in her Notice of Appeal to which we refer below.

7 Pending the decision of the IC, attempts were made to settle this request informally. The MHRA, after consultation with Pfizer, offered to disclose to EY all patient data, that is, including sex and age, save the identification number. The offer was rejected so we treat this appeal as relating to all three classes of information.

8 By his Decision Notice dated 19th. February, 2010, the IC upheld the refusal of the MHRA to disclose the redacted information. He ruled that FOIA s.41, an absolute exemption , applied to all the information requested, whether the patient was alive or dead. Disclosure of such information would give rise to an actionable breach of confidence and, in so far as the public interest was engaged in any such cause of action, no compelling reason to breach that confidence had been shown.

9 EY appealed. Taking the grounds of appeal and the Appellant`s Reply together, the arguable grounds advanced were :

(i) This was not information provided in confidence, since patients had consented to such information being communicated to third parties for the purposes of the trial.

(ii) The relevant confiding of information was from practitioner to Pfizer.

(iii) There is a public interest in the disclosure of information bearing on the safety of Linezolid.

(iv) Any right of action for breach of confidence ceases on the death of the person supplying the confidential information.

(v) Disclosure involves no detriment to the patient, such as is required to found an action for breach of confidence.

We referred to arguable grounds. EY`s citation of a proposal to compromise does not affect in any way the strength of the argument against disclosure. Whether the IC made factual errors unrelated to the issues (which he denies) is immaterial to our decision.

The IC submitted a Reply and a full skeleton argument. EY provided a detailed

Reply and a further written submission. She exhibited a wealth of material relating principally to Linezolid which we have considered, though doubtful that it touched on the limited issues raised by this appeal. The Additional Party also provided a written Response.

10 We have no doubt that the information in question was provided by patients to medical practitioners in circumstances giving rise to a duty of confidence, in accordance with the principles set out in *Coco v A.N.Clark (Engineers) Limited (1968) FSR 415.*

- The information must have the necessary quality of confidence about it;
- It must have been imparted in circumstances importing an obligation of confidence
- There must be an unauthorised use of it to the detriment of the confiding party.

11 It clearly had the quality of confidence, since it involved symptoms and other personal data known only to patient and practitioner.

12 It was communicated in the knowledge that it would be passed to Pfizer for the purposes of its study. It may be that this was expressly stipulated in any form of consent employed. To that extent only, the patient consented to widen the range of recipients and did so, as EY acknowledges, on condition that his identity was protected.

13 A communication to the general public was plainly unauthorised. It would cause no positive harm to the confider but we have no doubt that knowledge of its disclosure would distress many patients or surviving relatives. Like the Tribunal in *Bluck*, we respectfully adopt the view of Lord Keith in *Attorney General v Guardian Newspapers [1990] 1 AC 109* that knowledge that confidential information has been passed to those to whom the confider would not willingly convey it may be sufficient detriment.

14 We do not accept EY`s analysis of the material communication as being that

between the practitioner and Pfizer. Whether or not later redacted, the critical communication is from patient to practitioner. The practitioner may be regarded as simply the patient`s agent in its further communication to Pfizer.

15 Further, we agree with the Tribunal in *Bluck* for the reasons that it gives at paragraph 20, that the duty of confidence is not ended by death. Were that so, the patient`s most intimate secrets could be published by his doctor as soon as he had issued a death certificate.

16 No doubt, the information would lose the quality of confidence, if communicated in a form that wholly dissociated it from the patient. We do not accept that the mere removal of the identification number would necessarily achieve that result. The MHRA, in its internal review, concluded that :

"if the study site is known, as well as the patient s age, gender, and medical condition, it may be possible to identify them. The use of a pseudonym identification number, or even the redaction of that number, may not be sufficient to protect the patients` identities;"

That appears to the Tribunal to be an authoritative statement of the position and one, moreover, that appeals to commonsense.

17 There remains the question of the public interest inherent in the determination of actions for breach of confidence.

18 There is clearly a public interest in disclosure of information which may alert the public to a risk linked to a particular drug. It is not clear, however, how the disclosure of the redacted information would enlighten even informed recipients to a significantly greater degree than the disclosure already conceded.

19 Be that as it may, the public interest in preserving the integrity of drug trials of the kind involved here is fundamental to medical research. As the MHRA submits, a loss of public confidence in respect for confidentiality as to such information would be gravely damaging. Future trials could be endangered by refusals to take part, if personal information was not to be adequately protected. Furthermore, a significant breach of the rights of patients to privacy provided for by Article 8 of the ECHR

would be plainly contrary to the public interest.

20 We have, therefore, no doubt that the public interest, so far from compelling disclosure, plainly favours the preservation of confidentiality.

21 For these reasons, this appeal is dismissed.

22 Our decision is unanimous.

Signed

David Farrer Q.C.

Tribunal Judge Date: 04th. October, 2010

.

Tribunals Service
Information Rights

IN THE FIRST-TIER TRIBUNAL **Case No.** EA/2010/0055

GENERAL REGULATORY CHAMBER

INFORMATION RIGHTS

Between

Deirdre Murphy

Appellant

and

The Information Commissioner

Respondent

and

Medical and Healthcare Products Regulatory Agency

Additional Party

Refusal of Permission to appeal to the Upper Chamber against a Decision dated 22nd. September, 2010

1 The essential facts as to the history of and background to this request are set out at paragraphs 2 to 9 of the Decision.

2 The reasons for our decision to uphold the Decision Notice are set out at paragraphs 12 – 22.

3 In the "Attachment to section D" ("AD"), the Appellant continues to refer to FOIA S.40. For the avoidance of doubt, that was not an exemption relied on by the ICO in his Decision Notice nor by the Tribunal in its Decision. The sole material exemption is FOIA s.41.

4 The information as to age, gender, medical history etc., was indisputably information having the quality of confidence.

5 A critical issue, as acknowledged by the Appellant at paragraph 3 of AD, was which provision of that information is said to have been made in circumstances giving rise to a duty of confidence.

6 The Tribunal's view, endorsing that of the ICO, was that the relevant communication was by the patient, initially to his/her general practitioner and thence to Pfizer and to the MHRA. We were not concerned, as the Appellant suggested at AD paragraph 24, with the relationship between Pfizer and the MHRA and whether or not other factors affected any duty of confidentiality as to communications between them.

7 We had no doubt that the doctor – patient relationship imparted the quality of confidence to that communication and that the *Bluck* [1] principle applied to such cases.

8 The Appellant appears to treat the patient's "consent" as unqualified (see paragraph 8 of the Appeal submission). The Tribunal's view was that, whether expressly (we saw no consent forms) or by necessary implication, the consent to provide information and to allow that information to be used in a clinical trial was plainly conditional on the restriction of its use to that purpose and the preservation of anonymity.

9 Anonymisation was relevant, not to data protection issues under FOIA, s.40 but to the questions of consent and confidentiality. Wholly anonymous information would not retain the quality of confidentiality.

10 We concluded, on the basis of the evidence from the MHRA, that the information *"concerned patients who can be linked to a particular study site* - - which *"would make it possible for the requester to directly or indirectly identify specific patients even if the unique identification number were removed".*

[1] *Bluck v ICO & Epsom and St. Hellier University NHS Trust (EA/2006/90)*

11 That being so, the Tribunal concluded that the redactions to the information provided were justified as maintaining that duty of confidence.

12 As to deceased participants in the trial, the Appellant's contention that the duty of confidentiality dies with them seems to the Tribunal to involve a quite unacceptable undermining of the doctor/patient relationship. We agreed with the Tribunal in *Bluck.*

13 As to the element of detriment, the Tribunal can add nothing to paragraph 15 of the Decision.

14 It was not obvious what public interest beyond that catered for by publication of the redacted survey would be served by provision of the information withheld. Even in AD, the Appellant seems to assert rather than demonstrate an overriding public interest (see e.g., paragraph 31).

15 On the other hand, the public interest in withholding the redacted information seems perfectly clear, namely the protection of the Article 8 right to privacy and the reassurance to future participants that participation in trials will not expose them to identification.

16 I do not consider that AD, though it cites further material, raises any argument that should cause the Upper Tribunal to revisit this appeal.

Signed

David Farrer Q.C.
Tribunal Judge

7th. December, 2010