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

EA/2010/0055

MRS D MURPHY

Appellant

And

THE INFORMATION COMMISSIONER

Respondent

And

THE MEDICINES AND HEALTHCARE REGULATORY AGENCY

Second Respondent

Hearing
Held on 17 December 2015 at Fox Court and 7 March 2016 at Field House.
Before Mr G Jones; Prof. D Stephenson and Judge C Taylor.

Decision
The appeal is unanimously dismissed for the reasons set out below. There are no steps to be taken.

Date of Decision: 18 April 2016

Date of Promulgation: 4 May 2016

Reasons

Background: Context

1. Pfizer Ltd manufactures Linezolid, marketed under the name Zyvox. Linezolid is a synthetic antibiotic used for the treatment of serious infections caused by Gram-positive bacteria that are resistant to several other antibiotics. The Medicines and Healthcare Products Regulatory Agency ('MHRA') is an executive agency with responsibility for ensuring the safety of medicines. It is the main regulator for Linezolid in the EU.

2. MHRA requested that Pfizer produce a mortality analysis after questions had been raised about the safety and efficacy of Linezolid. Pfizer conducted a clinical trial comparing the effects of Linezolid with those of similar drugs and produced a report dated January 2007. Patients participating in Pfizer's trial were from 25 countries.[1] None were from the UK.

3. MHRA then produced a report on the antibiotic, with parts of Pfizer's report in an annex.

The Request for Information

4. In response to the Appellant's request, MHRA provided her with a copy of the Pfizer's report redacting parts of it. On 16 September 2008, the Appellant then requested from MHRA the redacted pages, asking:

> *'Can you provide pages 9-31 –Annex 2 from FOI 8/524.'*

5. On 10 December 2008, MHRA provided part of the material requested and cited s.40 *(personal data exemption)* of the Freedom of Information Act 2000 ('FOIA'). After an internal review, it sought instead to rely on s.41 FOIA (*confidentiality exemption*) for all patients both living and deceased and section 40 for those patients that were living.

6. The Appellant proceeded to progress the matter seeking release of the withheld data, by complaining to the Commissioner.

7. MHRA made two attempts to settle the request. In the first attempt[2], all requested patient data was offered save for patient identification numbers, age and genders. On 10 December 2009, the Commissioner emailed the Appellant[3] explaining that MHRA had contacted Pfizer who had agreed that '*all information could be disclosed under [FOIA] apart from the patient reference numbers'*.[4] The Appellant declined the offers.

8. The Commissioner decided that s.41 FOIA applied to all the requested information because its disclosure would give rise to an actionable breach of confidence; and in terms of public interest, no compelling reason to breach that confidence had been shown.[5]

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[1] Argentina, Australia, Belgium, Brazil, Chile, Colombia, Czech Republic, Germany, Greece, Guatemala, Hungary, India, Italy, Mexico, Pakistan, Peru, Philippines, Russian Federation, Slovakia, South Africa, Spain, Thailand, Turkey, United States, Venezuela.

[2] Dated 30 April 2009, on pages 165 and 169.

[3] It is assumed from the context that this email was sent to the Appellant. However, we note that the Appellant's name seems to have been redacted from correspondence in the Open Bundle.

[4] See page 225. All page references in this decision are references to pages in the Open Bundle.

[5] See the decision notice dated 18 February 2010, Ref. FS50237119. ('Decision Notice').

9. On appeal, the First-tier Tribunal upheld the Commissioner's decision. The Appellant appealed to the Upper Tribunal[6], who set aside the First-tier Tribunal's decision and reverted it back down to this Tribunal to be considered afresh. This was because the First-tier Tribunal's decision had stated that the redacted information related to the patient's identification number, gender and age, where by upholding the Commissioner's decision it had endorsed a wider redaction as the withheld information also included other data. The Commissioner's Decision Notice had stated that:

> *'The information redacted from pages 9 to 31 [of the Pfizer Annex to the MHRA Report] ... contains information about the patients who took part in the study ... including their patient identification number, their age and gender as well as information about their symptoms, diagnosis, treatment and treatment outcome.' (See para. 9 of the Decision Notice).*

10. The Upper Tribunal raised additional points for this Tribunal to consider:

    a. **Details of two patients:** What the judge described as 'full details' of two patients that had already been revealed as was clear from a document supplied by the Appellant in the open bundle before the Upper Tribunal.

    b. **Trial outside UK:** The Pfizer trial was a worldwide trial concerning over 700 individuals, none of whom were in the UK.

    c. **Identification possible:** A question as to whether individuals could in fact be identified if identification numbers were redacted, given the worldwide nature of the trial.

    d. A question as to what extent, if any, the expert evidence submitted by MHRA on a closed basis should properly remain closed. This evidence was subsequently disclosed to the Appellant and is not considered further below.

    e. A question as to whether an action for breach of confidence could succeed if the breach occurred after the death of the confider.[7] The Appellant has helpfully accepted that an action would survive death, such that this matter is not considered further below.[8]

11. Hearings were held on 29 July 2014, 25 June 2015 (by telephone), 17 December 2015 and 7 March 2016. Various rulings and directions were issued which set out events leading up to the final hearing.[9]

The Task of the Tribunal

12. The Tribunal's remit is governed by section 58 FOIA. This requires the Tribunal to consider whether the decision made by the Commissioner is in accordance with the

[6] *GIA/3017/2010.*

[7] Lloyd-Davies, J. indicated as a non-binding observation that where the confidence arises in the context of a patient-healthcare professional relationship, he agreed with the observations of Mr Justice Foskett in *Lewis v. Secretary of State for Health [2008 1 EWHC 2196 (QB)* which lends support to the proposition that the obligation of confidence is capable of surviving the death.

[8] (See for instance, the Case Management Note of 22 January 2014; the Appellant's undated Reply and submissions.)

[9] At the hearing of 7 March, the Respondents requested time to make further submissions concerning an application an application under Rule14 of the Tribunal Procedure (First-Tier Tribunal) (General Regulatory Chamber) Rules 2009. A ruling has been issued concurrently with this decision concerning that application.

law or whether he should have exercised any discretion he had differently. The Tribunal is independent of the Commissioner, and considers afresh the Appellant's complaint. The Tribunal may receive evidence that was not before the Commissioner, and may make different findings of fact from the Commissioner. This is the extent of the Tribunal's remit in this case.

13. We have received bundles of documents and cases, and various submissions, all of which we have considered even if not specifically referred to below. We have also received the requested information in a closed bundle. We have not found it necessary to include details of the closed information in our decision, and accordingly there is no closed annex to this decision.

14. The Appellant's revised Grounds of Appeal [10] assert that the Commissioner misapplied the case of *Bluck*[11] and that the Decision Notice is not in accordance with the law. She does not explain in any detail what she meant by this. However, her Reply (undated) made in response to the Commissioner's response advanced various arguments. To the extent that we could find these pertinent in potentially advancing her case, they are as follows:

    a. Patients had consented to their medical data being disclosed and it is unlikely that publishing the data would be a cause of distress. (Presumably, the relevance here would be that this would mean that there could be no breach of confidence and that section 40 was also not applicable.)

    b. Clinical trial results were disclosed to a third party and are not considered personal information. (We presume the relevance is in supporting an argument that the information is neither confidential nor personal data because it was disclosed to Pfizer and MHRA.)

    c. The Respondents had offered to provide the information with redactions. *(See paragraph 7 above).* (In the absence of clarification, we presume the Appellant intended to argue that in view of this, sections 40 and 41 could not apply to the information the Respondents had offered to disclose.)

    d. The Respondents have not shown how one could identify patients if the unique identification numbers were removed. A very slight hypothetical possibility that someone might be able to reconstruct the data in such a way that the data subject is identified is not sufficient.

    e. There is a public interest in not withholding clinical trial findings necessary for the safety of the patient, next of kin and public. Removing the Patient Identification Numbers ('PID/PIDs') would be unethical because the Declaration of Helsinki requires research investigators to preserve the accuracy of results. (We presume the Appellant is also arguing here that there is an interest in patients receiving Linezolid treatment knowing whether there are safety concerns arising from its use, and in promoting MHRA transparency.)

    f. The Appellant explained the nature of the information she was seeking,

[10] Of 6 November 2014, at page 30, replacing that of 3 March 2010.
[11] *Bluck v Information Commissioner & Epsom St. Helier University Trust EA/2006/0090.*

alleging: '*MHRA approved updated prescribing advice for patients with skin infections, when the study was intended to look at study patients with blood infections, a different patient population. Neither MHRA nor Pfizer have provided detailed clinical trial results for the different type of patient populations in the study, for example those patients with no infections at baseline*.'

15. The Appellant has indicated that the submissions that she stands by are those dated 8 February 2015 and 19 March 2015, and 11 September 2015, which we have considered, along with later amendments.

The Law

16. Under s.1(1) FOIA, a person making an information request to a public authority is generally entitled to be informed in writing whether the public authority holds the requested information and to have it communicated to him. However, in certain circumstances, the authority is not required to provide the information and is exempt from doing so. In particular, for our purposes, the public authority may withhold the information if it is 'exempt information' because either of the exemptions set out in sections 41 or 40 apply.

S.41: Information Provided in Confidence

17. Section 41(1) provides:

> *'(1) Information is exempt information if—*
> *(a) it was obtained by the public authority from any other person (including another public authority), and*
> *(b) the disclosure of the information to the public (otherwise than under this Act) by the public authority holding it would constitute a breach of confidence actionable by that or any other person.'* *(Emphasis added.)*

18. For our purposes, the relevant factors for a disclosure to constitute an actionable breach of confidence[12] are:

    a. **Does the information have the necessary quality of confidence to justify the imposition of a contractual or equitable obligation of confidence?** If so,

    b. **Was the information communicated in circumstances that created such an obligation?** (There is no absolute test of what constitutes circumstances giving rise to an obligation of confidence. An obligation of confidentiality may be expressed explicitly, or implicitly. In *Coco*, the 'reasonable person' test was suggested: '*If the circumstances are such that any reasonable man standing in the shoes of the recipient of the information would have realised that upon reasonable grounds the information was being given to him in confidence, then this should suffice to impose upon him the equitable obligation of confidence*.') If so,

[12] As set out in *Coco v A N Clark (Engineers) Ltd* [1969] RPC 41 at 47 (*'Coco'*).

c. **Would disclosure cause detriment?** (It seems from the caselaw that it is an open question as to whether detriment to the confider is a necessary element of a cause of action for breach of confidence. Megarry, J. in *Coco* appears to indicate detriment to some other person may be sufficient. Lord Keith of Kinkel in Attorney General v Guardian Newspapers [1990] 1 AC 109 raised the question of whether there would be any need to establish a detriment in cases involving an invasion of personal privacy, indicating there to be sufficient detriment where the information is to be disclosed against one's wishes.) If so,

d. **Would MHRA nevertheless have had a defence to a claim for breach of confidence based on the public interest in disclosure of information?** There is a defence to an action for breach of confidence if the public interest favours disclosing the confidential information. The test the Tribunal adopts in considering the public interest is to assume that confidentiality should be preserved unless outweighed by countervailing factors.[13]

S.40(2): Personal Data

19. Section 40(2) FOIA provides in relevant part that:

> *'(2) Any information to which a request for information relates is also exempt information if—*
> *(a) it constitutes **personal data** which do not fall within subsection (1), and*
> *(b) either the first or the second condition below is satisfied.*
> *(3) The first condition is—*
> *(a) in a case where the information falls within any of paragraphs (a) to (d) of the definition of "data" in section 1(1) of the Data Protection Act 1998, that the disclosure of the information to a member of the public otherwise than under this Act **would contravene**—(i) any of the **data protection principles**...'*
>
> *(Emphasis Added.)*

20. Section 1(1) Data Protection Act 1998 ('DPA') defines 'personal data' as follows:

> *'"personal data" means data which relate to a living individual who can be identified (a) from those data, or (b) from those data and other information which is in the possession of, or is likely to come into the possession of, the data controller,*
> *and includes any expression of opinion about the individual and any indication of the intentions of the data controller or any other person in respect of the individual.'*

21. The first data protection principle has been identified in this appeal as of relevance by the Respondents and the seventh data protection principle has been identified by the Appellant.

Issues for the Tribunal

[13] This test has not been disputed by the parties and derives from the reasoning in *Derry City Council v Information Commissioner*, IT, 8 January 2006, para 35(m). In any event, the Tribunal in that case noted that the discrepancy between this public interest test and that applied under s.2(1)(b) FOIA will rarely affect the outcome of a case, as it would be unlikely that the relevant factors would be so finely balanced that the burden of proof will become the determinative factor.

22. The issues for the Tribunal to address are:

    a. **Are any persons identifiable?** (Unless persons - in this case, patients - are identifiable, then the information cannot constitute personal data, and could also not be actionable as a breach of confidence such that neither exemption could apply. The Respondents have argued that in assessing the possibility of identification taking place, the test to consider is whether there is a reasonable likelihood that disclosure of the withheld information to the public would result in the identification of any patients.[14] The Appellant has not disputed this.) If not,

    b. **Does s.41 FOIA apply in relation to all of the requested information?** If not,

    c. **Does s.40(2) FOIA apply for information related to those alive at the time of the request?**

Issue 1: Are Persons Identifiable

23. We are grateful to MHRA's two witnesses who attended the oral hearing, following requests from the Tribunal.

24. The first witness was Ms Kitcatt who is the Vice President and Assistant General Counsel for EU and International Regulatory Law at Pfizer Ltd. She explained that she advises on all aspects of pharmaceutical law and related regulatory issues. This includes the regulatory requirements and guidance for the conduct of clinical trials and for the disclosure of information relating to clinical trials in the EU. She also explained that the Pfizer study was designed as a randomized multinational study in seriously ill subjects with intravascular catheter-related gram-positive infections. The study was initiated in May 2002 and completed in August 2005. Ms Kitcatt then explained how Pfizer anonymises data by drawing together global guidance such that they do not just look at legislation restricted to one country. Her testimony (oral or written) included the following:

    Pseudonymisation

    a. Pseudonymisation consists of replacing one attribute in a record with another e.g. a person's name/initials and date of birth being replaced by a code. It reduces the ability to link the data to the person but does not result in an anonymous dataset. The person is still likely to be identifiable indirectly, by someone with access to the relevant elements of the code. In a clinical trial, all patients enrolled are assigned a unique PID. This is a form of pseudonymisation and patients remain identifiable, such that pseudonymised data is subject to data protection legislation and considerations of confidentiality. She explained that when the doctor entered a patient into the trial system, it would generate the PID number. It was unique for the purposes of the study, and would be on the trial documentation and known by the hospital. The witness did not expect that it would appear on normal medical records.

[14] The Commissioner supported the threshold for this test by reliance on Recital 26 of the European Council Directive 95/46/EC and *Department of Health v IC [QBD] 2011 2 Info LR* paragraphs 17, 47, 66 and 68 which concerned section 40, accepting that the same test would apply concerning section 41, and this was not contested.)

b. This PID is used throughout the study in lieu of specific identifying information, such as the name initials, in order to collect, access and analyse study data on an individual patient basis. PIDs are typically comprised of a combination of a specific site number and a series of numbers unique to an individual patient. It is still possible, with access to appropriate elements of information, to 'decode' the PID and identify the patient. For example, if the number of the trial centre is known, the patient may be identifiable through hospital medical records.

c. Availability of the PID, which can be linked to a particular study site, in combination with other patient level data, such as age, gender and medical history or disease details, may provide a means through which different sets of data from multiple sources may be combined to form a more complete record of an individual patient and thereby identify that individual. For example, age, gender and medical disease details that are provided in a narrative describing an adverse event may be cross-referenced to the age and gender details provided in a separate table elsewhere in the same or a separate document related to the trial. The various data points may collectively confirm or suggest the identity of an individual. In certain circumstances the witness expected that it would be possible to combine information, such as medical information, to link a person to it. Whilst medical records were confidential, death certificates were in the public domain, as well as details disclosed in inquests or clinical trials where increasing amounts of information was being released about trials. With the push towards greater transparency, there is a significant concern that it becomes easier to compare elements of data which is regarded as a real risk.

d. Pfizer's position is that the information in question was correctly redacted, as it has the potential to identify individual subjects who participated in the trial. The redactions made were entirely consistent with the appropriate standards for the protection of personal data at the time of the original request. Removal or redaction of the PID from a document is one important means of preventing linkage back to the patient and thereby anonymising a given dataset. This is consistent with the approach taken by regulatory authorities and other organisations in the EU and globally. In particular, the European Medicines Agency ('EMA') releases a great deal of information under its Access to Documents regime pursuant to Regulation (EC) No. 1049/2001. In recent years, the EMA has significantly increased the amount and degree of information that it discloses about authorised medicinal products, as part of a general trend towards greater transparency. However, this Regulation provides an important exception requiring EU institutions to refuse access to information where disclosure would undermine the protection of the privacy and integrity of the individual, particularly in accordance with EU data protection (privacy) legislation.[15] Protection of personal data and patient confidentiality remains a key principle and the EMA's practice is to redact any information, which may potentially identify trial subjects or patients in other contexts, before disclosing information or documents.

e. For example, in the context of requests for access to Periodic Safety Update Reports ('PSURs'), which are submitted by pharmaceutical companies to the regulatory authorities the applicable guidance, issued by the EMA and Heads

[15] Article 4(1)(b) Regulation (EC) No. 1049/2001.

of Medicines Agencies (HMA) of all the EU member countries, states that, in order to ensure anonymisation, the minimum personal data to be redacted before release are dates of birth, reporting country information and patient identification code, *(HMA/EMA Recommendations on Transparency - the handling of requests for access to Period Safety Update Reports EMEA/74133/2009*), as follows:

> *"...Information on the personal data of individual persons*
> *Right of access does not apply to information which reasonably could be traced back to individual persons… Therefore, before PSURs can be disclosed information on the health of natural persons, e.g. adverse drug reaction reports, which could be traced back to an individual person, have to be made anonymous… The minimum personal data to be deleted to ensure anonymisation of the information would require the deletion of information on 1) Date of birth; 2) (Reporting) country; 3) Patient identification code.*
> *In addition, case-by-case assessment should be made whether additional information should be deleted in any other part of the documentation of PSURs. This is particularly relevant concerning case narratives where much detailed personal information may appear.*
> *It should never be possible to identity a natural person from the information disclosed, so in case of reports related to patients suffering from a rare disease it may be needed to delete further information."*

f. Pfizer regards this guidance as binding and considers PSURs comparable with Pfizer's report in this appeal as both report information from clinical trials.)

g. In the USA, the federal Health Insurance Portability and Accountability Act ('HIPAA') privacy regulations consider any unique identifying number to be protected. This protected health information can only be disclosed under certain circumstances, including if the patient authorised the disclosure or if the disclosure is required by law.

h. In the EU, in its drive towards greater transparency of clinical data, the EMA will now proactively publish online clinical study reports that have been submitted in support of applications for marketing authorisation. Despite the unprecedented degree of transparency, protection of personal data remains fundamental:

> *'4.1…**Protecting personal data**: The protection of personal data is enshrined in EU legislation; it is a fundamental right of EU citizens... There are ways and means to anonymise data and protect patients from retroactive identification. Yet, the Agency is primarily concerned that emerging technologies for data mining and database linkage will increase the potential for unlawful retroactive patient identification. The Agency, therefore, takes a guarded approach to the sharing of patient-level data, which is done to enable legitimate learning from sharing patient-level data while preventing rare but potentially damaging instances of patient identification. Furthermore, patients' informed consent should be respected. The secondary analysis of personal data will have to be fully compatible with the individual privacy of clinical trial participants and data protection.'*

*'**4.2.3.** … Particular challenges in this respect are continuous developments in the field of technologies relating to data mining and database linkage, as well as specific scenarios to be considered in the area of medicine regulation, for instance the situation of rare diseases.'*

i. The protection of clinical trial subject identity remains a paramount concern, and modern technology may have increased the likelihood of subject identification from the different elements of information that may be released by regulatory authorities and other organisations. TransCelerate Biopharma Inc, as a group of more than 20 innovative pharmaceutical companies works with regulatory agencies to set standards in this area. They recommend patient level data listings, full patient narratives and corresponding forms are entirely removed, and that the following items are redacted from within the body of the clinical study reports or table footer: patient name, initials, email, phone number, signature, full address including country, all dates relating to an individual patient, randomization/treatment number, case ID, verbatim text, patient level demographic information (sex, age, race, ethnicity, height, weight) or socioeconomic information (such as occupation), patient ID numbers, subject ID numbers associated with any description of an individual patient's medical outcome or sensitive data. TransCelerate also recommend further assessment of the need to redact medical outcomes based on the risk of re-identification.

j. Pfizer's position is that it is inappropriate, and contrary to EU data protection law, to release age, sex and unique patient ID, medical history and disease details in relation to an FOI request. This information is confidential unless and until it has been wholly anonymised, so that it is not possible to link it back to the individual patients involved. It was provided by patients to healthcare professionals, regulators and Pfizer in confidence in the context of a clinical trial, and that confidence is potentially breached, and patients' privacy rights infringed, if the data may be traced back to identifiable persons. Based on EU privacy legislation, in Pfizer's view, all subject-specific information falls within this category (age, gender, disease details etc.) and not merely identification codes, as these details may be used to identify particular persons, particularly if the trial centre is known together with the condition for which the patient was treated, and especially taking into account the newer technologies now available that can facilitate retroactive patient identification using disparate data elements. Further, Pfizer regards PIDs as potentially identifiable and that there are those who had the means to be able to link patients to PIDs. The field of data mining involved intensive and extensive analysis of data in an automated fashion, using advanced techniques to spot trends and individual elements. It is conceivable that this could be used to identify patients although this would not be a normal use.

25. Dr Williams, PhD MSc, Head of Research at the Clinical Practice Research Datalink, part of MHRA, gave testimony in person as well as providing a report. His evidence was provided to analyse the likelihood of identification of an individual where the withheld health related information was disclosed. He stated:

"…5. The initial view by the CPRD team, was that this level of detailed information on a particular individual potentially permits a significant risk that an individual patient could be identified. This is especially so by individuals such as research scientists like myself who work in this area. I am one of at least 100 people in England with the skills and knowledge to do this

type of analysis rapidly. Others within my field would find it a similarly brief task, particularly those who work within the area from which the data has been collected. This expertise is available commercially, given that it is a specialist skill that those outside this field would find it impossible to complete without detailed guidance and assistance…

8. A number of investigations were carried out considering both the narrative parts of the Report and the tables of figures… as none of the trials took place in England, this exercise is simply a demonstration of how analysis could be carried out and the methodology employed to identify specific patients, using the data that I have to hand. Equivalent data sets in other countries will be available, although levels of sophistication in their presentation may vary.

9. I initially undertook an analysis based upon one patient description… This description allowed the identification of 10 clinical findings that could be potentially determined by examination of a patient's HES data. One of these factors was cause of death….

10. In order to attempt to model the parameters of this patient I undertook the following steps.

- *I included all patients with a hospital spell and who had a record that denoted that they had died in hospital...*
- *I then examined coded data fields in the HES or in the cause of death data. These fields are coded using the international classification of diseases version 10 (ICD-10) diagnoses code set...*
- *For the cause of death criteria we checked the primary cause of death information for all patients and set a flag for patients with a cause of death as sepsis.*

11. The results of this search are demonstrated in the following tables. Table 1 illustrates the number of patients that are thrown up by the database as having the relevant diagnosis listed in the first column. The second table, Table 2 shows the numbers of patients identified as each diagnostic criteria is looked at in combination with others.

Diagnosis Criteria	***Number of patients***
Sepsis …	*711*
Anaemia	*35995*
Congestive Heart Failure	*26784*
COPD	*27459*
Hypertension	*61561*
Hyponatraemia	*4068*
Malignant cancer	*67545*
Pneumonia	*39373*
Rectal carcinoma	*3385*
Septicaemia...	*14940*

Table 1: patient numbers associated with each Diagnosis criteria as flagged by the analysis of HES data

Number of identified criteria	***Number of patients***
0	*50480*
1	*72873*
2	*49495*
3	*22525*
4	*7557*
5	*1999*
6	*319*
7	*34*
8	*1*
9	*0*
10	*0*

Table 2: The number of patients with a record for the various diagnostic criteria and their combinations, simplified to show the number of patients against the number of criteria identified.

12. There were a total of 205,283 patients in the ONS Cause of Death - HES linked data that died... there is only 1 patient with 8 of the 10 factors - but this does not include a primary cause of death ... (The primary cause of death is Malignant neoplasm of Rectum)...

Conclusion for this example

13. I consider that there is a significant risk of patients being identified from cause of death and co-morbidity information alone. This is because as a greater number of co-morbidities is considered, there is vastly diminishing number of potential patients identified. Even if the patient identified from the database is not conclusive in identifying an individual, this material could lead to future searches, using public records and material like national statistics.

14. I have also considered what would happen if other criteria were revealed. The risk of identifying individuals would be doubled if gender were also supplied. If age were supplied the risk of patients being identified would be substantially increased, with a corresponding further increase if both age and gender information were supplied. The relative increase in the risk of identification can be seen in table 3 below

Criteria	No additional data		Including gender only		Including age only		Including age and gender	
	Patients	Proportion	Patients	Proportion	Patients	Proportion	Patients	Proportion
Sepsis…	711	1.0	356	2.0	10	72.0	6.0	119.0
Anaemia	35995	1.0	17998	2.0	330	109.0	170.6	211.0
Congestive Heart Failure	26784	1.0	13392	2.0	291	92.0	156.6	171.0
COPD	27459	1.0	13730	2.0	295	93.0	163.4	168.0
Hypertension	61561	1.0	30781	2.0	610	101.0	334.6	184.0
Hyponatraemia	4068	1.0	2034	2.0	44	92.0	25.3	161.0
Malignant cancer	67545	1.0	33773	2.0	625	108.0	321.6	210.0
Pneumonia	39373	1.0	19687	2.0	361	109.0	183.1	215.0
Rectal carcinoma	3385	1.0	1693	2.0	43	78.0	23.7	143.0
Septicaemia…	14940	1.0	7470	2.0	141	106.0	74.0	202.0

Table 3: shows the average number of patients per category and the proportionate reduction in mean patient numbers for data stratified by gender only, by age only and by age and gender. It also shows the proportionate reduction in mean patient numbers when using the various categories.

…The figures in table 3 show us that on average if we stratify by gender then for all criteria we halve the number of patients in each group, and consequently make it twice as likely that we would be able to identify them. In the case of age for example with anaemia, on average we increase the likelihood of identifying a patient 109 times, and if we know both age and gender this figure rises to 211.

16. The above analysis was undertaken with secondary care data only. Further data could be assessed and or clarified by integrating primary care data in a similar manner. This data relied upon access to appropriate data, in this case the HES data set. HES is a national data set that is available for research purposes to a wide array or researchers. Some demographic data would be available from public data sources. Most countries have an equivalent data collection forum, although these vary in the level of sophistication and the software that is built in to do searches. It may simply generate material that then has to be cross referenced for analysis and search purposes.

Provisional Conclusions

17. The analysis undertaken is simple and well within the scope of individuals with a decent level of training in data analysis. This analysis would be well within the capability of all of the research staff within the CPRD Research Team. It should be noted that this analysis does not consider a number of factors due to the data for them not being readily available in the records used, these include causative agent for the infection, and ethnicity - both of which may be available in a different context or setting.

18. From our results we could suggest that provision of age, gender, cause of death

and three or four additional comorbidities may be enough to identify a small pool of potential patients, which would be in danger of being identified in certain settings. Even without the provision of age and gender, given the level of clinical information provided in the example patient used, there would remain a significant risk of patient identification at the conceptual level. This risk would be highest for observers who would have access to the information referred to in the report.

19. It should be remembered however that due to the nature of observational data, such as CPRD primary care data and linked HES and death data, it is not true to say that if we match the conditions involved in the patient details with the data, we will have definitively matched the individual in the report to the data. This is because the data in the database can be relatively sparse and contains a degree of inaccuracy and misclassification which while less significant at the population level, will create difficulties at the individual patient level. Accordingly, there would still be some verification to do but statistically, the likelihood of identifying an individual are increased very significantly.

Final Conclusion
20. It is considered that there is a significant risk of patients being identified from cause of death and co-morbidity information alone. This risk would be doubled if gender were also supplied. If age were supplied the risk of patients being identified would be substantially increased, with a corresponding further increase if both age and gender information were supplied. The relative increase in the risk of identification can be seen in table 3 above.

21. Factors such as geography were considered less important because of the broad nature of the areas, e.g. Europe. However, as with any information search, pre-existing information about some individuals on the relevant trial will not simply mean that a loss of redaction allows them access to seemingly innocuous material but will allow them to obtain more of a picture that is greater than the sum of its parts in terms of refining further searches and eliminating irrelevant variables.

22. Accordingly, there is no loss of redaction, other than geography alone that would not increase the risk of individual patient identification. The more variables known, the greater the likelihood of individual patient identification occurring. This would mean that details that would not otherwise have been known being available publicly."

26. In response to questions from the Appellant or panel, he explained that:

a. Patients in clinical trials had the right to see their personal data and that as far as he knew, MHRA do receive such requests.

b. PIDs are important as potential identifiers.

c. There is an increased likelihood of identifying a patient where the patient identifiers were attached using sophisticated data mining techniques. For instance, insurance companies may have available information. However, it was likely that the people able to do this were highly skilled, being either those working in specialist units subject to ethical and legal standards or criminals with sophisticated use of the internet.

d. There was a diminished likelihood of identification with the increased number of identifiers withheld. The likelihood of identification without the PIDs is lower than a 'reasonable likelihood'. However, the typical approach of MHRA is to be very cautious because of the degree of sensitivity of medical information.

Submissions

27. MHRA's submissions included the following:

a. When the PID is broken down to reveal the 'study site' and 'unique patient identifier', it would result in a method by which the informed person could identify individual patients. The fact that the PID reveals the study site is highly important. The clinical trial was conducted in multiple jurisdictions with some of the study sites having a very limited number of participating patients. As illustrated by Dr Williams, once the informed person has worked out which numbers/figures correspond to which study site it would be possible to identify the participating patients using 'open source data' – see e.g. the expert witness statement of Dr Williams.

b. Disclosure of information under FOI is disclosure to the public at large. The internet provides a simple mechanism for that information to be widely disseminated to all areas in which the clinical trial was carried out and beyond.

c. The location and name of the many of the hospitals that treated patients who participated in the clinical trial is widely available, as is the approximate dates that treatment was provided. There were 101 study centres in 26 countries. However, when considering Asia, for example, there were only 16 patients who were treated with Linezolid and 18 comparators, and treatment took place at six study centres - three in India; two in Pakistan and one in Thailand.

d. A person who knew some information about a person treated in one of those centres (e.g. ethnicity, age, gender, date of death and country of treatment) would be able to identify an individual whose confidentiality this appeal concerns.

e. A person who knew more specific information concerning a participants' cause of death or his/her underlying medical condition would be able to identify information about his/her participation in the trial which they would not otherwise be entitled to know.

f. MHRA does not know the purpose of the Appellant's request for disclosure and in particular why the Appellant considers it necessary to obtain the PIDs. However, it is submitted that the Appellant is likely (and members of the public, certainly) to have additional information about the participants of this trial which is not contained in the requested information or publicly available and which would enable such a person to identify an individual whose confidentiality this appeal concerns.

g. It is not possible to provide the redacted information in a less radical form because it is the cumulative effect of disclosure of categories of information (age, gender, patient identification number) which would enable a person to identify an individual, particularly when considered together with information

that is already within the public domain and additional information which may be held by the Appellant and/or the public at large.

28. The Commissioner's submissions included:

a. He regarded the requested information as part of a mosaic where the risk of identification arose from the cumulative effect of pieces of the 'mosaic' being assembled. Since disclosure is to be treated as disclosure to the world at large, he considered that there would be some who knew a great deal of information about the relevant patients involved in the Pfizer trial such that the withheld information could identify them.

b. Parts of the mosaic already in the public arena were:

i. A 'hypothetical friend' known to a patient would know their age, gender, date of death, approximate area of residence. They would also likely be to have known that the patient had been ill, and the broad cause of illness.

ii. While the study was global, there was detailed information about that study in the public domain concerning the dates and venues of the drug trials. The method of 'pseudonymisation' (the replacement of overt identifiers with PIDs), which had been used in the compiling of this report, allowed for the withheld data to be linked to the relevant patients if necessary. Pfizer had explained that if, for example, the redacted information were to be combined with the patients' medical records at the hospitals or medical centres where they participated in the Pfizer trial, they could be identified.

iii. The Pfizer report and parts of Annex 2 that were in the public domain. This includes the medical problems from which the patients were suffering; discussions of the types of symptoms experienced; and detailed case studies of individual patients' circumstances.

c. The missing parts that a hypothetical friend could not be assumed to know in respect of which the claim to confidentiality arose were: that the patient participated in this study, details of their illness and the precise facts giving rise to the patient's death.

d. If the withheld information were to be disclosed, the hypothetical friend could review it and combined with the information already known or available, be able to identify that the person being referred to is the person known to them. They would then be able to discern other matters, resulting in the actionable breach of confidence.

e. It was not that the disclosure of some or all of the disputed information would result in patients becoming identifiable, but that this disclosure would add substantially to the risk of identification. In order for there to be a significant risk of identification, the 'hypothetical friend' would not need to populate that mosaic completely: he did not need every variable, just a sufficient number of variables.

f. In many 'mosaic' cases, disclosing all but one piece of that mosaic would result in unacceptable risks. Responsible disclosure often requires withholding a number of pieces in order to keep risks at a safe level. Each additional variable represented an incremental risk of identification.

29. The Appellant did not make specific submissions on the question of identifiability. However, these statements seem of relevance:

    a. '*The MHRA describe how Pfizer's description of the study number allows identification of patients in countries such as India (paragraph 17 (iii) of submissions submitted 10th February 2015), because of the very "limited number of participating patients" (paragraph 20 of submissions dated 27th August 2015). I submit this would be difficult considering India has a population of 1.25 billion*.'

    b. *'During his investigation the Commissioner (following approval by Pfizer) agreed to disclose all of the disputed information except for the patient's identification number.'*

    c. '*It is a mystery to me why MHRA /Commissioner redacted these patient numbers for years and then disclosed them without explanation*.'

    d. '*The patient numbers are in blocks of 8020, 8030 and 8040. It appears that patients with 8040 are from Spain -21 patients, and patients assigned 8030 are from Hungary -11 patients. 2 patients were assigned 8020. Patient [PID number redacted] (deceased patient) is referenced both in the Pfizer report (document I submitted) and the letter dated 23 October 2009 (filed many times by the Commissioner in the bundle). Patient [PID number redacted] (deceased patient from Spain) is not. I don't know the relevance or impact that is information has on respondent's arguments as I do not have access to the redacted information*.'

Our Findings on Issue 1

30. Taking the threshold test as being whether there was a reasonable likelihood of identification resulting from disclosure of the withheld information, we were not satisfied that the patients would have been identifiable without at least the PIDs. This was because:

    a. On Dr William's testimony, there was not a 'reasonable likelihood' of identifiability without the PIDs. We understood that where Ms Kitcatt's testimony indicated that Pfizer looked to redact more than this she was looking to 'wholly anonymise' data[16], which seems to be a more stringent test than that of 'reasonable likelihood'.

    b. As MHRA had previously been willing to disclose to the Appellant all withheld information save for the PIDs, it seemed unlikely to us that patients would be identifiable from that material. We did not find compelling the explanation that MHRA's offers were (in retrospect) made in error, notwithstanding that they were made prior to the present representatives were acting for them. This is

[16] See paragraph 24(j) above.

because the offer (in different terms) was made twice and apparently at least once was approved by Pfizer. *(See paragraph 7 above).*

c. From Ms Kitcatt's explanation of the guidance related to personal data confidentiality, it seems a common thread that at least the PIDs should be redacted to protect patient rights.

31. However, the facts revealed during the course of the appeal (and after the witnesses had been dismissed) were that the Appellant had been provided with the list of all PIDs under separate FOI requests made to the Commissioner and MHRA. It was explained that this was a result of mistakes made, and we accept this in the context of the complex nature of the broader case.[17] We note that (as was her prerogative), the Appellant did not take up the opportunity to voluntarily opt to agree to destroy the PIDs disclosed to her.

32. The question has then become, based on the table of PIDs (with cross-referenced page numbers) having been disclosed to the Appellant under FOIA, would there be a reasonable likelihood of patients being identifiable from this and/or the withheld information, and if so, was the material exempt from disclosure?

33. We (unanimously) find the PIDs to be the single most likely factor to cause identification of patients and that it is reasonably likely that identification could be made from these. This is supported by:

a. Our understanding of Ms Kitcatt's testimony (including her statement that redaction of the PID from a document was an important means of preventing linkage back to the patient and thereby anonymising a given dataset);

b. MHRA's offer to the Appellant set out in paragraph 7.

c. Our finding that it is reasonably likely that someone would be able identify a trial participant from the PIDs, together with information already in or likely to come into someone's possession. For instance, there may be some, say next of kin, that may know or being able to find the PIDs of a participating patient, for instance if the patient had been informed of his PID and kept the information or requested his/her personal data and been informed of the PID and kept it.

d. We consider it highly likely from the material before us that there will be those motivated to seek such identification.

34. We also believe it is conceivable and reasonably likely that the more information disclosed (where PIDs already have been disclosed), the more likely that a trial participant will be identified.[18] This is supported by Dr William's evidence above. For instance, there may be someone who knows the location of the hospital and trial centre where a patient participated in the trial, and will be able to find information sufficient to work out which PID numbers relate to that centre and together with some other parts of the withheld information would be able to identify an individual. We note that in considering this example we are using the scenario explained to us by the Commissioner of the person making the identification being a hypothetical friend

[17] See my previous rulings in this case.

[18] (We note from the statement set out in paragraph 14(d) that the Appellant seems to accept this, but in any event we have made this finding independently of this.)

rather than a motivated intruder acting criminally. We consider it less likely that a hypothetical friend would identify an individual through data mining where our understanding of the evidence is that those with such skills were bound by professional regulations or laws.

35. We have carefully considered whether any of withheld information could be disclosed without reasonable likelihood of identification. We do not think any can. This is because there is a reasonable likelihood that the PIDs alone (together with information already in or likely to come into someone's possession) may enable identification. We have already noted that the Respondents had been willing to disclose all of the information save for the PIDs. We consider this was because redacting the PIDs ensured that the other information could not be traced back to the patients.

36. We have taken into account that the trial was worldwide concerning over 700 individuals, none of whom were in the UK. Additionally, the Appellant raised the point that identification would be difficult given that in India alone there is a population of 1.25 billion. However, given that (a) the PIDs have been disclosed; (b) it is possible to do extensive and automatic searches using for instance, such readily available mechanisms as the internet; and (c) disclosure under FOIA, may constitute disclosure to world for these purposes, we consider there to be a reasonable likelihood of a patient being identified, notwithstanding the global nature of the trial.

37. We note that we accept MHRA's arguments that are set out in paragraph 27 above. We also accept the Commissioner's arguments that are set out in paragraph 28.

38. The Upper Tribunal had raised the point that the details of two patients had already been revealed in material disclosed to the Appellant. It seemed to us that there was an apparent inconsistency in the Respondents' arguments concerning the identification of patients and s. 40 and 41 FOIA where such material had already been disclosed. However, MHRA explained to us that this material had been disclosed to the Appellant by the EMA, and we accept this. (We note that the EMA is not a public authority subject to FOIA, and that in any event, from a review of the disputed information itself we are satisfied that identification would be reasonably likely.)

Issue 2: Does s.41 FOIA apply in relation to all of the requested information?

Evidence

39. MHRA's evidence from Ms Kitcatt included:

Confidentiality in clinical trials

a. The protection of confidentiality and personal data of participating patients is a legal and ethical obligation and a fundamental principle of good clinical practice, to which Pfizer adheres.

b. Examples are:

i. The World Medical Association's Declaration of Helsinki: '*Every precaution must be taken to protect the privacy of research subjects*

and the confidentiality of their personal information.'

ii. EU legislation *(Directive 2005/28/EC)*: '*All clinical trial information shall be recorded, handled, and stored in such a way that it can be accurately reported, interpreted and verified, while the confidentiality of records of the trial subjects remains protected.'*

c. She explained that doctors are responsible for the confidentiality of their medical records. Likewise, Pfizer are responsible for the confidentiality of medical information it holds about a person's history, disease state and outcome. Whilst this information would have been generated by the doctor, Pfizer remains responsible where it holds the information.

d. Across the globe, records provided to regulators are regarded as very confidential. However, they are sent to regulators because of their specific role that includes considering whether medicines are properly authorised; and any changes are needed in advertising medicines. Patients having provided informed consent, would be aware of their data being sent to regulators. Asked why the regulator would have PIDs disclosed to it, she explained that it had a special function to dig into data and analyse it, to thoroughly scrutinize, and to make sure to fully understand what has happened in a trial and any implications for the risk and benefit of the product. The regulator had such an important position that the pharmaceutical company would provide it with everything, and would always do so with an expectation that the regulator would keep confidence.

40. MHRA provided an example of an informed consent used for patients in Ireland (this being in English and thus easy for us to understand.) Whilst country Consent Forms may vary if local ethics committees had asked for amendments (e.g. for details on the medical affects of the medicine), Ms Kitcatt confirmed that in her experience the relevant clauses on confidentiality were uncontroversial and tended to remain the same. The relevant parts stated:

'16. Will my taking part in this trial be kept confidential?

Your family doctor (General Practitioner) will usually be told that you have decided to take part in this trial. Your records obtained while you are in this trial, as well as related health records will remain strictly confidential at all times. However, these will need to be made available to others working on Pfizer's behalf, the Independent Ethics Committee members and Medicines Regulatory Authorities.

Your rights under any applicable data protection laws are not affected as Pfizer will take all necessary measures and protections so that your data is only used for the purpose of the study and that all parties who will receive it shall keep it confidential.

By signing the consent form you agree to this access for the current trial and any further research that may be done. However, Pfizer will take steps to protect your personal information and will not include your name on any sponsor forms, reports, publications or in any future disclosures. If you withdraw from the study, we will no longer collect your personal information, but we may need to continue to use information already collected.'

17. What will happen to the results of the research trial?

The results of this trial will be reported in a Pfizer Medical Report. In consultation with the regulatory authorities this may be used to change the way linezolid is used in practice. The results may also be published at scientific or medical conferences and may be made available to regulatory authorities and other medical practitioners as appropriate. It will not be possible to identify the information that you have provided in any of these reports or publications.

19. Data Protection: What use will be made of the data collected from this trial?

Personal data, which may be sensitive, (e.g. date of birth) will be collected and processed, but only for research purposes in connection with this trial. The trial data may be sent around the world, but you will not be referred to by name or identified in any report or publication ***nor could the data be traced back to you.***

Your data may be transferred to a country that does not have the same level of personal data protection as within Ireland. However, you understand that Pfizer maintains high standards of data confidentiality and protection.

By taking part in this trial you agree not to restrict the use of any data even if you withdraw from the trial and agree to the transfer of your personal data to other Pfizer companies and to Medicines Regulatory Authorities both within and outside of Europe.

YOUR RIGHTS UNDER ANY APPLICABLE DATA PROTECTION LAWS ARE NOT AFFECTED.' (Paragraphs 16 to 19 of Consent Form at page 355.).

Submissions

41. MHRA's submissions included the following, relying to some extent on the reasoning of the Commissioner in his Decision Notice:

Was the information imparted in circumstances importing an obligation of confidence?

a. The redacted information was obtained by MHRA, the pubic authority, from Pfizer, a pharmaceutical company with conduct of the clinical trials for Linezolid.

b. The information was imparted by patients to a medical practitioner which implies an obligation of confidentiality. This carries a well-recognised and de-facto obligation of confidence, and is certainly tacit where a written understanding does not exist.

Does the information itself have the necessary quality of confidence?

c. The redacted information is personal information relating to the patients involved in the study and their medical symptoms, diagnosis, treatment and outcome. Bearing in mind the nature of the information concerned, the

information possesses the necessary quality of confidence, as it is not information that is already in the public domain, nor is it trivial.

d. The disclosure of information would cause distress to the patients (or their next of kin if deceased) and infringe their privacy contrary to Article 8 European Convention on Human Rights ('ECHR').

e. The Appellant argues that medical records kept at the study site were subject to the duty of confidence but that information ceased to retain the quality of confidence when it was provided to Pfizer. She argues that when a patient consents to participate in a clinical trial he consents to all his information being released to third parties. This is a misunderstanding of the nature of the information withheld. It is not the results of the clinical trial that is redacted but the information provided by the confider to his medical practitioner (and subsequently to Pfizer), which would enable his identification.

f. Patients participating in the clinical trial did so on the express understanding that data which could lead to their identification would not be released to parties other than Pfizer, their agents, and, in the case of Ireland, the Independent Ethics Committee Members and the Medicines Regulatory Authorities.

g. The Consent Form provided by Pfizer was the latest version of the form for patients situated in Ireland. However MHRA was advised that country specific Consent Forms were provided to and signed by all patients. In all versions of the Consent Form, MHRA understands that the parts relating to confidentiality are, so far as material, identical.

Would unauthorised use of the redacted information cause detriment to the patients?

h. Whilst difficult to quantify, where details of medical conditions are concerned, it was reasonable to assume that unauthorised disclosure of information, which was considered to have been imparted confidentially, is likely to cause distress to the patients who took part in the study (or next-of-kin where the patient has since deceased). It would be an infringement of the patients privacy and dignity as the disclosure would be to the public at large and not just to the patients, their families and/ or next of kin.

i. Medical information constitutes information of a personal nature. There is no need for there to be any detriment to the confider, in terms of any tangible loss, in order for it to be protected by the law of confidence and therefore it is not necessary to consider this further.

j. Article 8 of the Human Rights Act 1998 ('HRA') recognises the importance to individuals to have the privacy of the affairs respected and in line with this an invasion of privacy would be a sufficient detriment to the confider.

Would the public authority have a defence to a breach of confidence claim because the public interest in disclosure would outweigh the public interest in maintaining the duty of confidentiality

k. A defence to an action for breach of confidence is that the disclosure is in the public interest. A duty of confidence should not be overridden lightly,

particularly in the context of a duty owed to an individual. Disclosure of any confidential information undermines the principle of confidentiality itself, which depends on a relationship of trust between the confider and the confident.

l. It is in the interest of patients to have confidence that medical staff will not disclose sensitive medical data before they divulge full details of their medical history and lifestyle. Without that assurance patients may be deterred from seeking advice and without adequate information doctors cannot properly diagnose or treat patients. No compelling argument has been given as to a particular public interest in disclosure into the public domain in this case sufficient to outweigh the considerable public interest in maintaining the confidentiality of medical information.

m. The public interest in disclosing the results of clinical trials does not extend to disclosure of information which is capable of identifying patients.

n. Patients who participated in this clinical trial have a legitimate expectation that disclosure of information would be in accordance with the terms of the consent provided.

o. Clinical trials are a cornerstone of safe advances in medical technology. Disclosure of confidential information would have an adverse effect on the ability to attract sufficient numbers of human subjects to participate in future clinical trials, which would result in a loss of public confidence.

p. Disclosure of the information would represent a significant breach of the right to privacy protected by Articles 8 and 10 of HRA which is contrary to public interest and not justified in these circumstances.

q. The redacted information is part of Pfizer's report prepared to provide a respond to MHRA's request issued in furtherance of its regulatory function. The uninformed member of the public could easily be misled by drawing sweeping conclusions from the redacted information, which would not necessarily hold true under closer scrutiny. For example, by analysing the tables and case summaries detailing the causes of death the uninformed reader may conclude that there was a higher probability of death for a person within "X" age range and suffering from "Y" pathogen which may not necessarily be true once clinical input (e.g. pre-existing conditions) were factored into the analysis.

42. The Commissioner's submissions included:

a. It was well established that information about one's health and medical treatment provided to or created by professionals providing one with medical care is subject to a duty of confidence. Where patients participated in pharmaceutical trials, they are owed a duty of confidence by both (a) the medical professionals responsible for their treatment and care in relation to the study, and (b) others such as Pfizer, as illustrated by the confidentiality clauses set out in the Consent Form. This is because the individuals remained patients subject to medical treatment and supervision, notwithstanding the trial.

b. Whilst the patients did not undergo their medical treatment in the UK, this duty of confidence applied under the laws of the countries in which the trials were

conducted. This is illustrated by Pfizer's letter of 21 December 2009 at page 235, which explains that in the USA, where some of the trial patients were situated, the release of the data in response to the request may be contrary to HIPAA and its Freedom of Information Act.

c. Disclosure of the disputed information would give rise to a breach of confidence which could be actioned either by living patients or by representatives of the deceased. The test under s. 41(1)(b) FOIA is not whether the breach of confidence *would* be actioned, but whether it *could* be.

Public interest

d. He considered that in a case concerning s.41(1) FIOA, a public interest favouring disclosure must be established of sufficient strength to make it likely that it would, in the eyes of a Court, justify a breach of patient confidentiality. In the Commissioner's submission, this was lacking, and the Appellant had failed to advance anything capable of establishing a public interest defence in this case of sufficient weight to justify disclosure to the world of the particular information at issue in this appeal.

43. The Appellant's submissions included the following arguments, which we have organised so as to be able to consider them in their strongest light in relation to s.41 FOIA:

Was the information imparted in circumstances importing an obligation of confidence? Does the information itself have the necessary quality of confidence?

a. There was no duty of confidence related to the redacted information as it did not constitute medical records. It was clinical trial results, such that there was no duty of confidence between doctor and patient. The relevant confiding of information was from practitioner to Pfizer. The doctor who conducted the study already had to adhere to applicable local and national laws before disclosing clinical trial results of his patients to the pharmaceutical company. (We presume by this last sentence that the Appellant asserts that the doctors would have resolved confidence laws before passing on the data.)

b. Elsewhere, the Appellant stated: '*The Respondents are arguing that I do not believe the duty of confidentiality exists in a clinical trial setting. This is incorrect. The principle of the confidentiality between patient and doctor is well established and endorsed by Bluck*.' The Commissioner relied on a Tribunal ruling that confirmed the duty of confidentiality between doctor and patient and ruled against disclosure of medical records to the mother of the deceased. In his Decision Notice the Commissioner did not question the disclosure of the redacted information to Pfizer and MHRA; both have no relationship to the patients enrolled in the trial. In contrast to the ruling by the Tribunal in *Bluck*, clinical trial regulations - e.g. in the UK: The Medicines for Human Use Regulations - and guidelines legislate that trial related data, for example, safety data is made available to third parties. This allows for the safety of patients participating in trials to be monitored and when the drug is eventually marketed there is a transparent record of the drug's safety profile. Although the study was not conducted in the UK, this provides an example of the regulations for clinical trials and how they involve data.

c. The emails dated 10 February 2009 and 25th October 2011 at pages 360 and 361 show that there was no obligation of confidence between MHRA and Pfizer. The email from MHRA to Pfizer of 10 February indicates that MHRA wanted to disclose the information and Pfizer did not. It stated: "I would therefore like to know if you would "*1. Consent to release of this information in full; (MHRA preferred option) or 2. Consent to release of this information with the unique reference numbers redacted; or 3…"*

d. The clinical trial information is otherwise accessible since there were two patient case summaries disclosed by the EU regulatory agency at page 250. (We presume the Appellant seeks to argue that the requested information does not have the necessary quality of confidence because it is otherwise accessible, being already in the public domain.)

e. The reliance of the Commissioner on *Coco* and *Bluck* is flawed because it relates to medical records held by a UK public authority, the NHS. The redacted information is clinical trial related data collected from patients around the world and provided to MHRA, a public authority, by Pfizer a pharmaceutical company. The Commissioner applies UK common law to patients who were not enrolled in the UK. The Commissioner does not explain how he can extend UK common law to patients for example who reside in the US.

f. Regarding patient consent,

    i. The information would not have been provided in confidence, since patients would have consented to it being communicated to third parties for the purposes of the trial.

    ii. The Commissioner should have taken into account that clinical trial regulations such as the Declaration of Helsinki dealt with issues of consent and ethical considerations.

    iii. The solicitor for MHRA was not certain if the consent form had been approved by the Ethics Committee. If it is not this version would not have been reviewed and signed by patients and is irrelevant to the appeal.

    iv. The MHRA do not describe the legal basis for this select sharing of data between certain parties. The MHRA argues that employees of pharma companies would not seek to re-identify research participants as distinct from the general public who they believe would want to re-identify these patients.

    v. Patients participate in clinical trials for altruistic reasons, they wish to help other patients by sharing their clinical trial related data.

Would unauthorised use of the redacted information cause detriment to the patients?

g. Disclosure would involve no detriment to the patient.

Would the public authority have a defence to a breach of confidence claim because the public interest in disclosure would outweigh the public interest in maintaining the duty of confidentiality

h. There is a public interest in the disclosure of information bearing on the safety of Linezolid including for the sake of patients and their relatives. The requested information would shed more light on the decisions that relate to patient safety, where MHRA are responsible for monitoring the safety of linezolid in the entire EU. There is a public interest in not withholding clinical trial findings and in transparency.

i. The disputed information relates to patients who were enrolled in a Pfizer clinical trial and were inadequately treated for their serious infections. Safety issues related to the clinical trial were not initially reported to MHRA by Pfizer.

j. The Commissioner relied on *Bluck* to support his public interest argument. This is without merit because MHRA regulates clinical trials and has a different function from that of the NHS.

k. The Decision Notice issued contained many factual inaccuracies and omissions. For instance, the patients were not enrolled in the UK. This allowed him to argue that the information under dispute was similar to medical records held by the NHS.

l. The case of *Rabi Abdullahi v. Pfizer Inc.*[19] is relevant to a public interest test in favour of disclosure of clinical trial results.

m. The Declaration of Helsinki specifies disclosure of clinical trial results as an ethical principle in the conduct of experimentation in humans. The physicians involved in the medical research are responsible for protecting the privacy and confidentiality of the research subjects.

n. It is in the public interest to disclose information that drug regulators such as MHRA rely on to make decisions in relation to the activities of pharmaceutical companies. For example, the disputed information was part of regulatory documents reviewed by MHRA because of potential safety issues related to the promotion of linezolid by Pfizer to the medical profession in the UK and the EU in 2006. MHRA did not investigate the advertising complaint against Pfizer.[20]

o. By contrast in 2009, Pfizer agreed to pay $2.3 billion in the US, to resolve liability arising from the illegal promotion of drugs including linezolid. In 2012 Pfizer Inc. agreed to pay Oregon (one of 33 US states who successfully sued Pfizer) more than $3.3 million to settle claims that the company used misleading statements and studies to market drugs including linezolid.[21]

p. Patients participate in clinical trials for altruistic reasons, they wish to help other patients by sharing their clinical trial related data. This has to be taken into account when analyzing the risk of disclosure.

q. The clinical trial showed that there were public health issues with the use of linezolid in seriously ill patients. For example, a significant number of patients who had no infections were treated with linezolid and other patients were

[19] Page 314 to 315.
[20] See last paragraph of letter from MHRA to the Appellant on page 150.
[21] See pages 291 and 294.

inadequately treated for their infections. A significant number of these patient's died - 20 out of 76 who were treated with linezolid treated passed away, and 12 out of 92 who were treated with a comparator medicine.

r. Pfizer changed the research plan for the clinical trial two years into the study to analyse complicated skin infections primarily and serious blood infections as a subset. The informed consent was not changed so patients thought they were signing up for a different study. Case summaries such as those included in the disputed information provide an insight into the type of patient enrolled in clinical trials[22] which cannot be accurately described in statistical analysis. Pharmaceuticals can take advantage of statistical analysis to spin favorable results. It is more difficult to do this with patient case summaries.

s. Patients participate in clinical trials to help other patients and at considerable risk to themselves as is demonstrated in this clinical trial. The MHRA, Pfizer and the Commissioner are more concerned with the withholding of information that would hinder independent verification of safety data. By removing the patient id, age gender, the data cannot be independently verified, for example, it would be impossible to link information for patient *[PID number redacted]* submitted by Pfizer in their report to the EU at page 250 of the bundle to the patient information at page 187 of the bundle which is part of a MHRA/Pfizer analysis.

t. Pfizer allegedly published flawed linezolid studies and used them for advertising purposes. In other words Pfizer allegedly hid safety information - *See Pfizer settlement with US Department of Justice - see pages 294 and 431* - such as the disputed information and selectively promoted more favorable parts of the clinical trial results to increase sales of linezolid - *see page 291*.

u. The MHRA believe that Pfizer should decide if clinical trial results are disclosed to the public because they invest in biomedical research. There is a public interest to know that regulators, such as MHRA, put the interests of patients first and are not influenced by money or by powerful interests. In the case of clinical trial information, MHRA have decided on a two-tier system where Pfizer decides what information is disclosed. It is a policy decision by MHRA and subsequently the Commissioner, which is contrary to European law.[23]

v. The Commissioner relied on Article 8, to support withholding the disputed information, and did not apply much focus to the competing rights of Articles 8 and 10.

Our Findings on Issue 2

44. We accept and adopt the reasoning set out above as advanced by MHRA and the Commissioner with the exception of paragraph 41(q).

45. As regards the Appellant's arguments above:

a. Regarding sub-paragraphs 43(a) and (b): as explained by Ms Kitcatt and the

[22] See page 250.
[23] The Commission directive *2005/28/EC 8 April 2005. Good Clinical Practice, Article 2: 'The rights, safety and well being of the trial subjects shall prevail over the interests of society' - at page 385* was referred to.

Respondents, the duty of confidence is not limited to doctors, and covers medical information held by Pfizer and MHRA. It is clear from the text of the Consent Form set out above that both bodies would need to continue to comply with relevant laws and obligations related to such information. Ms Kitcatt also explained why the redacted information would have been disclosed to MHRA, and it seems self-evident to us as to why it would have been disclosed to Pfizer. We find Ms Kitcatt's explanations compelling. If the Appellant assumes that obligations of confidence were extinguished when the doctor passed on the material to Pfizer, this is incorrect and contrary to the terms of the Consent Form.

b. Regarding sub-paragraph 43(c): We do not accept that the emails refute an obligation of confidence. The email of 26 October 2011 from MHRA to Pfizer also on page 360 indicates that MHRA considered they had a '*strong case for the existing redactions'*, and that they were keen to '*demonstrate a willingness to be as helpful as possible*' and that the different categories of redacted information had differing degrees of sensitivity. In any event, it is clear that these are emails between MHRA and Pfizer and do not represent the final considered position of MHRA in presenting its case formally to the Court. It seems appropriate to respect their space to communicate between themselves to reach a considered position, and to consider these emails within that context.

c. Regarding sub-paragraph 43(d): So far as we are aware, the requested information is not already in the public domain.

d. Regarding sub-paragraph 43(e): Where the Appellant has objected to the application of UK common law, she did not provide any suggestion of another forum or jurisdiction that was more appropriate to this case. The request for information has been made under FOIA, to a UK public authority holding the information here, such that we have considered the law applicable here. In considering actions for breach of confidence, any potential action being brought by a patient or next of kin against the MHRA (were they to disclose confidential information) would likely have to be brought here applying our law, unless the Courts could be persuaded of a more appropriate jurisdiction.

e. Regarding sub-paragraph 43(f):

    i. The details of the patient Consent Form confidentiality clauses, demonstrate that patients were told trial and medical records would remain strictly confidential and patients were consenting to disclosure to Pfizer and regulators and not to the data being made public in a way that would make them identifiable or able to be traced back to them.

    ii. It was not clear to the panel what the Appellant meant by her sentence in sub-paragraph 43(f)ii, and she was not present at the relevant hearing to explain it.

    iii. Ms Kitcatt made clear that the Consent Form provided was that used in Ireland and that the confidentiality clauses were either very similar if not identical across the trial. We accept this and find the form highly relevant to the appeal.

iv. Both the Consent Form and Ms Kitcatt made clear the legal basis for sharing of data between Pfizer and MHRA.

v. We consider that patients will have participated in the clinical trial for various and individual reasons not all of which will be altruistic. For instance, the Consent Form at paragraph 12 sets out possible benefits to the patient of taking part. These include that the treatment may help and that the tests, examinations and medical care are provided free of charge.

f. Regarding sub-paragraph 43(g), we accept the Respondents arguments. Additionally we note that given the sensitive, medical or personal nature of the withheld information and the Consent Form confidentiality clauses, disclosure contrary to the forms will be against at least some of the patients'/relatives' wishes, and that this is sufficient detriment.

g. Regarding sub-paragraph 43(h), we accept that there is a public interest in the disclosure of information bearing on the safety of Linezolid; in patients receiving Linezolid treatment knowing whether there are safety concerns arising from its use; and in promoting MHRA transparency. However, we consider this to have been adequately satisfied by disclosures already made, and that the redacted information will add little of genuine value to the picture.

h. Regarding sub-paragraph 43(i), this is an unsubstantiated allegation, compellingly refuted by Ms Kitcatt.

i. Regarding sub-paragraph 43(j), we were unable to find relevance in this argument based on the text of the Appellant's submission.

j. Regarding sub-paragraph 43(k), the Appellant has not shown any factual inaccuracies or omissions that would have any bearing on our decision.

k. Regarding sub-paragraph 43(l), we were unable to find relevance in this argument. The Appellant appears to be alleging that Pfizer had failed to secure consent of the patients and disclose the risks associated with the Pfizer trial, but this along with similar allegations were refuted by Ms Kitcatt. The Appellant does not give a proper basis or evidence to support her assertion or a nexus between the allegation and precise relevance as to the matters in this appeal.

l. Regarding sub-paragraphs 43(m) and (u), the argument does not support the disclosure of the requested information, where the trial results have been disclosed such that the utility of disclosing further information is not apparent and there is a need to balance privacy and confidentiality against further transparency.

m. Regarding sub-paragraph 43(n), the panel were unable to find relevance in this argument based on the text of the Appellant's submission and page 150. Even if there were some complaint related to advertising which had been substantiated, it would not have sufficient relevance to affect our decision. The Appellant made other allegations of misleading advertising, and our assessment of these is the same.

n. Regarding sub-paragraph 43(o), again, the panel were unable to find sufficient relevance or accuracy in this argument based on the text of the Appellant's submission. Pages 291 and 294 indicate a settlement between Oregon Department of Justice and Pfizer Inc. over 'alleged' deceptive marketing claims rather than 'liability'. Ms Kitcatt explained that the requirements in advertising in the USA exist in an environment where it is permitted to advertise medicines directly to the public, such that it is important to ensure the language in advertising medicines will be understood by a different audience, i.e. the lay-person. Even if Pfizer Inc. had been found liable for deceptive marketing, this would not have had sufficient relevance to affect our decision where the usefulness of disclosing further information is not apparent and there is a need to balance privacy and confidentiality against further transparency.

o. Regarding sub-paragraph 43(p), as stated above, we would expect patients to have participated in the trial for their own different reasons.

p. Regarding sub-paragraph 43(q), we could not find the accuracy of this statement from the references provided, but in any event we fully recognise that there is a public interest in the disclosure of information bearing on the safety of Linezolid. However, as stated above, that interest is adequately satisfied by disclosures made.

q. Regarding sub-paragraph 43(r), Ms Kitcatt refuted these allegations, and we found her testimony as to how a trial may evolve compelling. The Appellant provided no compelling evidence to support the allegations she made.

r. Regarding sub-paragraphs 43(s) and (t), we find these arguments uncompelling, unsubstantiated and insufficient to justify disclosure of confidential medical information in the context of what has already been disclosed.

s. Regarding sub-paragraph 43(v), the Appellant does not elaborate in any detail as to why consideration of Article 10 would require disclosure of the requested material. Article 10, which establishes a right to a freedom of expression, does provide that the exercise of the freedom may be subject preventing disclosure of information received in confidence. In this case, where the requested material was imparted in circumstances importing an obligation of confidence, and certainly has the necessary quality of confidence, and where we have found no strong public interest justifying the disclosure of the requested information, we see no reason why the relevant individual rights to privacy set out in Article 8 should yield to the right to freedom of expression under Article 10.[24]

46. We note that details of two patients have been disclosed, and it was explained that the EMA had disclosed these. Regardless of this, we make our findings based on our assessment of the disputed information that has not been disclosed.

47. It is clear to us that the disputed information constituted personal data. However, since we have found that none of the withheld information needs to be disclosed by virtue of the exemption set out in s.41 FOIA, there is no need for us to consider the

[24] See *Ash v McKennitt [2006] EWCA Civ 1714.*

exemption set out in s.40 FOIA.

48. Our decision is unanimous.

Judge Taylor

18 April 2016