Cochrane Nordic

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22 February 2017

To the Broadcasting Authority of Ireland (BAI)

This is my reply to the letter from 14 February from David McKenna, the RTÉ, to the Broadcasting Authority of Ireland.

Firstly, I summarise the most important parts of our complaint, as these are still valid, also considering McKenna's letter. We explained in our letter to RTÉ from 1 December (item 3 in my submission to the BAI from 4 January):

"1. It is outright false that I and my four colleagues who wrote the complaints have accused Enerica Alteri, an EMA employee, of having worked for the HPV vaccine manufacturer, Merck, until 2012. We did not say this, neither in our complaint to the EMA, nor in our complaint to the ombudsman (see http://nordic.cochrane.org/research-highlights) where we said: "we found out that Enrica Alteri from the EMA, who had no restrictions on her participation, nonetheless had conflicts of interest declared on the EMA's website. She was employed by Merck-Serono till June 2012 and her husband has a consulting contract with Merck-Serono for 2016." This is entirely correct, according to Alteri's public declarations on the EMA's website, most recently updated 24 July 2016: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/07/WC500129303.pdf."

"2. It is outright false when O'Reilly says in the documentary: "Last month Nordic Cochrane was forced to apologize when it admitted it got it wrong on allegations that the review was compromised by conflicts of interest." We did not get it "wrong on allegations that the review was compromised by conflicts of interest." The review WAS compromised by conflicts of interest and we mentioned several such conflicts of interest, also in our complaint to the ombudsman. During the interview with O'Reilly, I discussed such conflicts at length in relation to Andrew Pollard, the chair of the EMA's scientific committee, and in relation to Guido Rasi, the EMA's executive director, who had not declared that he is inventor of patents. It is therefore wrong of O'Reilly to say otherwise, and since she knew that her statement was false, I believe it is a falsehood. The ombudsman wrote to us on 8 November that she would address our complaint about "the alleged conflict of interest involving a senior EMA staff member." Research has shown that conflicts of interest in relation to the drug industry are important, whether or not they are directly related to the product that is being evaluated."

"O'Reilly was very well prepared and asked me a lot of questions about our complaints to the EMA and to the European ombudsman, and about the science, but by the end of the interview she became very aggressive, and it dawned on me that it didn't matter what I said, as she had a personal agenda she pursued."

In my letter to the BAI from 4 January, I furthermore explained:

"Furthermore, we mentioned several other conflicts of interest in our complaint to the ombudsman and even documented that some of these conflicts of interest had compromised the EMA's review."

"3. Diamond writes: "The rules are clear. Neither Nordic Cochrane nor any other organisation can, after the fact, devise its own set of rules and then claim that they have been broken." We have not devised our own rules. According to the rules, it is a conflict of interest to work for a drug company, whether or not that company sells the product that is under investigation. And there is a good reason for this, which we explained

in our letter from 1 December: “Research has shown that conflicts of interest in relation to the drug industry are important, whether or not they are directly related to the product that is being evaluated.””

“4. Whether the EMA’s Executive Director, Guido Rasi, should have declared - in the public interest - that he is the inventor for several patents is not up to the RTÉ to decide upon, although Diamond seems to believe that this omission is not a problem. We believe it is a problem and have asked the European ombudsman to look into this. We also believe it is a conflict of interest that Rasi should have declared and have given our reasons why in our complaint to the ombudsman.”

Below, I shall comment on the letter from 14 February from David McKenna, the RTÉ to the BAI. The letter may look convincing on the surface of it, but it is misleading and glosses over crucial issues and arguments.

McKenna: “there is a perception that Nordic Cochrane speaks for Cochrane on the HPV vaccine.” This is not correct. We complained to the EMA on the letterhead of the Nordic Cochrane Centre. If the governor of Texas writes a letter using that state’s letterhead, no one would think the letter came from the White House. When we complained to the Ombudsman, we made this crystal clear, as we wrote on the first page:

“Please note: This complaint to the ombudsman is not about whether the HPV vaccines do more good than harm. It is about the EMA’s conduct, which we believe is an instance of maladministration. It is possible that many of the serious harms that occur after vaccination are autoimmune diseases. However, as we don’t know whether these diseases are caused by the HPV vaccines, it must be a research priority to find out. The views we express here and our conclusions are based on the facts we present; they are ours and not those of any organisation.”

McKenna: “Cochrane has previously expressed concern that statements Professor Gøtzsche made about an unrelated matter (psychiatric drugs) could have been misconstrued as representing the views of Cochrane itself.”

McKenna’s comments have nothing to do with my complaint over the RTÉ. They are totally irrelevant. They are the sort of comments lawyers make in court in an attempt to smear and discredit the other side. I have explained to the Cochrane leadership that it was not possible for any sound person to think that what I wrote in my own name in a scientific article or in my book about psychiatric drugs expresses some official Cochrane policy.

McKenna: “on the issue of conflicts of interest, having researched the matter, Prime Time established that there was no evidence to show that the EMA had not followed the law and its rules relating to the interests of people working on the HPV Vaccine review and that, in the absence of evidence, it would be unfair and partial to suggest otherwise.”

Firstly, there WAS evidence that the EMA had broken its own rules, and we described this evidence in our complaint to the Ombudsman who wrote back that she would look into the matter. Secondly, we pointed out that the EMA was its own judge when it stated that it had followed its own rules. In public administration, we do not allow people to be their own judges and the EMA is not accountable to itself but to the European citizens.

McKenna: “In addition, Prime Time had to be mindful that whilst Nordic Cochrane took issue with the EMA's review, it was not coming to it as a neutral, independent and impartial voice - both its complaint to the EMA alleging 'maladministration' and its subsequent complaint to the European Ombudsman repeating this was co-signed by Dr Louise Brinth, who had a direct interest in the matter.”

This comment is irrelevant for our complaint over the RTÉ, and misleading, too. The Nordic Cochrane Centre IS a “a neutral, independent and impartial voice” and we are internationally highly respected for this, also among journalists. The fact that I asked Brinth to co-sign does not change our status. We felt that her research had been treated in a highly partial manner and unfair manner by the EMA, which is why I wanted her to co-sign.

McKenna: “It is hard to see how the Nordic Cochrane Centre can claim not have got it wrong in relation to conflicts of interest when it has apologised for doing so."

This statement violates rules of logic. To apologize in some cases and to maintain that there are conflicts of interest in other cases cannot possibly lead to the conclusion that there were no conflicts of interest. If a criminal is suspected of having murdered four people, and it turns out that he murdered only two, this does not and cannot be taken to mean that he murdered no one!

McKenna: “There is no basis or evidence for the allegation that what Prime Time said in relation to Nordic Cochrane's claims about conflicts of interest was "outright false". The reporting was accurate, fair, impartial and objective.”

Evidently, this statement is false. McKenna continues to deny that we reported on conflicts of interest to the Ombudsman. I told O’Reilly about the conflicts of interest that the chair of the EMA’s Scientific Advisory Group had, and McKenna mentions this part of the interview with me. In our complaint to the Ombudsman (http://nordic.cochrane.org/sites/nordic.cochrane.org/files/public/uploads/ResearchHighlights/Complaint-to-ombudsman-over-EMA.pdf), we wrote:

“12. Contrary to the EMA’s statements, the EMA’s policy about restricting members of its Scientific Advisory Group meeting to participate fully in the meeting was not correctly applied. For example, there were no restrictions for the chair of the meeting, Andrew Pollard, although he had declared several conflicts of interest in relation to the HPV vaccine manufacturers, while some of the restricted people had no such conflicts of interest.”

This illustrates that the EMA, contrary to McKenna’s assertions, DID NOT adhere to its own rules. McKenna’s statements are so intensely misleading that I need to quote a good deal of our complaint to the Ombudsman:

“There were no restrictions for the chair of the meeting, Andrew Pollard, although he had declared several conflicts of interest in relation to the HPV vaccine manufacturers GlaxoSmithKline and Sanofi Pasteur MSD until 2014 and 2013, respectively. In an article dated 24 September 2015 (while the process at the EMA was ongoing and one month before the SAG meeting), which described a 12-year old girl that had been diagnosed with chronic fatigue syndrome after having been vaccinated, Pollard, the “chairman of the government’s Joint Committee on Vaccination and Immunisation (JCVI),” was quoted as saying (45): “We have no evidence of a safety signal with the vaccine. But what we do have is very clear evidence that this year 900 women, who have not received the vaccine, will die of cervical cancer, and the vaccine has the potential to prevent such deaths in future generations. So the place of this vaccine in defending women’s health is probably the most important thing we have ever done.””

“We noted that Pollard, who was a member of the expert group of the British government responsible for the decision to include HPV vaccination in the childhood vaccination program in the UK, seemed to have participated in the meeting with a predetermined opinion on the issue of POTS/CRPS prior to the formal review of the data, and that, in a court of law, such evidence of partiality prior to a trial would be grounds for exclusion from the jury. We asked the EMA to inform us of its justification for offering the chair of the SAG, Andrew Pollard, privileges that were denied others with similar or fewer conflicts of interest than the chair.”

“The EMA did not respond to our pertinent questions related to Pollard other than providing a nonsense reply, considering the substance of our observations: “Finally, with regard to your claim of a potential conflict of interest of the SAG's chair, please note that the European Medicines Agency takes due care to ensure that its scientific committee members and experts, including SAG members and experts, do not have any financial or other interests that could affect their impartiality.” After this came some general statements about the EMA’s procedures and “We would like to assure you that the policy was correctly applied to the participants of the SAG meeting on HPV vaccines which took place on 21 October 2015.” This demonstrates that the EMA’s policy was NOT correctly applied. It is pointless to exclude a person from parts of the meeting who is investigator on a study by Novartis in infants with type 1 spinal muscular atrophy, which has nothing to do with the HPV vaccine, while allowing the chair of the meeting to attend the whole meeting although he had recent conflicts of interest in relation to the HPV vaccine manufacturers, and who in the press had praised highly the vaccines one month before the crucial SAG meeting. Pollard spoke about the many lives it saved and said there was no evidence of safety problems. The statement about the lack of harms was clearly inappropriate to make for a chairman of an EMA committee in the middle of an ongoing process to assess whether or not there is a safety signal. Furthermore, we found out that Enrica Alteri from the EMA, who had no restrictions on her participation, nonetheless had conflicts of interest declared on the EMA’s website. She was employed by Merck-Serono till June 2012 and her husband has a consulting contract with Merck-Serono for 2016. There were other reasons why the EMA’s policy was not correctly applied. As we stated under item B7 above, we could not find any conflicts of interest declarations for two core members of the SAG on the EMA’s website when we checked it in May 2016.”

It is grossly misleading that McKenna after all this detailed documentation that the EMA did not adhere to its own rules wrote: “Nordic Cochrane concluded, without explaining how it came to the conclusion or how the quoted extract supports it: "This demonstrates that the EMA 's policy was NOT correctly applied." For all the reasons outlined above, Prime Time was correct to take the view that Professor Gøtzsche and Nordic Cochrane's unsubstantiated complaint that the rules were not followed in relation to Professor Pollard did not merit inclusion in the broadcast report.”

McKenna demonstrates here without leaving a trace of doubt that the RTÉ did not report on the issues in an accurate, fair, impartial and objective manner. Indeed, it has not even done so after having been challenged by my complaint, which gave the RTÉ the opportunity of setting the record straight. We DID explain - in much detail - how we arrived at the conclusion that the EMA did not apply its own policy correctly, and our remarks about Pollard WERE substantiated.

McKenna: “Prime Time examined the claim that members of the EMA's Scientific Advisory Committee could not discuss disagreements in public and found it has been rebutted elsewhere.”

This is plain wrong. We wrote in our complaint to the Ombudsman:

“In the EMA’s 256-page internal report (4), there is a **“Confidentiality Reminder**” on page 2:[13]
“As an EMA expert you are bound to life-long duty of confidentiality. The duty of confidentiality applies to all information of the kind covered by the obligation of professional secrecy. This includes, for example, the fact that there is a meeting, that you have been nominated to participate, the agenda of the meeting, the product or company concerned, the participants, any part of the discussions and outcome. All documentation (correspondence, reports, minutes, etc.) must be kept as confidential and stored in a secure place or destroyed. The duty of confidentiality stops only if information has been made public and only to the extent that has been released into the public domain.””

When we pointed this out in our complaint to the EMA, the EMA post hoc tried to escape from this clear message by saying that, “The need for life-long confidentiality can by no means be compared to an imposition

of life-long secrecy as it does not prevent experts who disagree with a collegial decision to discuss their disagreements in public, provided that they shall make clear that the views expressed are their own and not those of the concerned scientific committee, and that they do not disclose commercially confidential information."

We wrote to the Ombudsman about p2 in the internal EMA report: "This is not a permission to discuss disagreements in public; it amounts to a gagging clause. According to information we have, the members of one of the EMA's committees clearly felt that this amounted to a life-long prohibition to speak in public about disagreements. We have also been told that a person who posed critical questions was reminded of the life-long confidentiality."

The RTÉ knew about our complaint to the Ombudsman, and I have no doubt that the RTÉ has read it, as the RTÉ refers to it. It is therefore outrageous that McKenna now postulates that: "Prime Time examined the claim that members of the EMA's Scientific Advisory Committee could not discuss disagreements in public and found it has been rebutted elsewhere."

McKenna writes: "But the more damaging claim is the one of financial conflicts of interest. The basis for this claim was hearsay: "We have been informed, however, by one of the persons who participating in meetings at the EMA, that some of the SAG members have financial conflicts of interest in relation to companies that sell an HPV vaccine, which means they are not independent"."

As I have explained above, this was not hearsay. For instance, Pollard has financial conflicts of interest in relation to companies that sell HPV vaccines (see his Declaration at the end of my letter). Being a principal investigator for a drug compay always involves money, in one form or another.

McKenna: "Aside from its apparent conflation of a declaration of interest with a conflict of interest, in its complaint to the Ombudsman, Nordic Cochrane did not advance any argument as to how Dr Alteri is conflicted because of her past employment with Merck-Serono or how she could be seen as having rendered herself liable to a restriction on her involvement."

We do not conflate declaration of interest with a conflict of interest. These terms are used interchangeably in the scientific literature and express the same. It is also wrong that we did not advance any argument as to why Alteri was conflicted. First of all, people are by definition conflicted when they have something to declare. Second, I explained in my complaint to the RTÉ 1 December: "Research has shown that conflicts of interest in relation to the drug industry are important, whether or not they are directly related to the product that is being evaluated."

This has been abundantly documented, and it is true even if the conflict is not related to the company whose product is being assessed. I have written a lot about this in my book about the drug industry (Gøtzsche PC. Deadly medicines and organised crime: How big pharma has corrupted health care. London: Radcliffe Publishing; 2013, which in 2014 was Winner of the British Medical Association's Annual Book Award in the category Basis of Medicine). People who are conflicted in relation to one or more drug companies tend to dismiss harms of drugs and to vote for keeping dangerous drugs on the market when they serve as experts in drug agency committees, compared to experts without such conflicts.

McKenna postulates that we devise our "own set of rules and then claim that they have been broken," despite the fact that I had already explained that according to the rules, it is a conflict of interest to work for a drug company, whether or not that company sells the product that is under investigation, and despite the fact that people working for the EMA, e.g. Alteri and Pollard, had declared such conflicts.

McKenna nonetheless tries to argue that we should be incorrect: “The rules are contained in the document, Staff Regulations 2014, which applied at the time of the EMA HPV vaccine review (included in the attached Appendix). The basic premise of the rule is summed up on the EMA's website in its statement that it: " ... takes care to ensure that its scientific experts, staff and Management Board do not have any financial or other interests that could affect their impartiality." That is based on Article 63(2) of Regulation (EC) No 726/2004 which: " ... requires that members of the Management Board, members of the committees, rapporteurs and experts shall not have financial or other interests in the pharmaceutical industry which could affect their impartiality, [and] that they shall undertake to act in the public interest and in an independent manner."

All this legalese, which continues in subsequent sentences in McKenna’s letter, cannot change the fact that the EMA so clearly violated what McKenna himself quoted: " ... takes care to ensure that its scientific experts, staff and Management Board do not have any financial or other interests that could affect their impartiality."

McKenna: “Nordic Cochrane appears to believe that the declaration of an interest means a conflict of interest arises. The rules, however, do not support that view.”

This is plain wrong, according to all international standards. I explained above, declaration of interest and conflict of interest are terms that are used interchangeably in the scientific literature and express the same.

McKenna: “The rules also recognise that an absence of conflicts of interest should be balanced with the needs of the Agency for staff members having the appropriate competencies and expertise. Nordic Cochrane has been unable to demonstrate a real conflict of interest under EMA rules for any of the people it has made allegations against - Professor Pollard, Dr Julie Williams, Professor Guido Rasi or Dr Enrica Alteri. Its approach to the issue has been partial and has been demonstrated to contain erroneous allegations. Prime Time was fair, accurate, objective and impartial in its reporting of the issue. It was also in the public interest to report, not only the concerns of Nordic Cochrane, but the limitations of its complaint of conflicts of interest, given the importance that had been attached to that complaint by campaigners against the vaccine in Ireland in the group, Regret.”

It is not a valid excuse that one cannot find qualified experts without conflicts of interest. This is simply not true, both in general and in relation to the concrete case. There are always good experts available without conflicts of interest. It is outright nonsense when McKenna claims that we were unable to “demonstrate a real conflict of interest under EMA rules.” The conflicts of interest declared by Pollard and Alteri are real and so are the conflicts of interest that Rasi failed to declare. What the EMA rules say are pretty irrelevant. Firstly, the EMA did not adhere to its own rules. Second, these rules are highly flexible, which does not install public confidence in what goes on. Third, the EMA is not accountable to itself but to the citizens in the European Union, among which are millions of scientists who know perfectly well that it would not be accepted by a respected medical journal if people did not declare that they were inventors of patents or had financial ties to drug companies. <u>These conflicts are real.</u>

By the end of his letter, McKenna argues that “the Prime Time reporting” was “accurate, fair, impartial and objective.”

It surely was not. And the treatment I have received was not fair or impartial either. McKenna adds insult to injury in his letter to the BAI by denying the obvious facts in the case. Furthermore, the RTÉ has prevented me from defending myself in a fair way. McKenna writes, for example:

“Given that the professor wrongly claimed in his initial complaint to the broadcaster that the reporter was "very aggressive" in her interview with him and came with "a personal agenda", and that that false allegation is included in the complaint referral to the BAI, RTE wishes to note that it has no doubt that the interview with Professor Gøtzsche was rigorous, as interviews with Prime Time regularly are, but is satisfied that it was not

'aggressive' and that the reporter came to it with no agenda ether than establishing the truth on a matter of very considerable public interest."

I have asked the RTÉ for a copy of the tapes that contain the interview with me. The RTÉ has refused to give me access to the tapes (see its letter at the end), which would have revealed that I am absolutely correct when I say that the reporter was very aggressive. She was so aggressive that I cannot remember having ever been exposed to such aggressiveness in my entire life, although I get interviewed several times a week and have collaborated with the media for about 30 years in many countries. It is pathetic that McKenna says that the reporter was not aggressive when there exists objective evidence that she was, which the RTÉ has denied me to access. Instead, the RTÉ evaluates itself and says that the reporter was not aggressive. What a conflict of interest!

Sincerely,

Peter C Gøtzsche, DrMedSci, MSc
Director of the Nordic Cochrane Centre, Rigshospitalet
Professor, University of Copenhagen

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Public Declaration of Interests and Confidentiality Undertaking of European Medicines Agency (EMA), Scientific Committee members and experts

Public declaration of interests

I, **Andrew Pollard**

Organisation/Company: University of Oxford

Country: United Kingdom

do hereby declare on my honour that, to the best of my knowledge, the only direct or indirect interests I have in the pharmaceutical industry are those listed below:

2.1 Employment

No interest declared

2.2 Consultancy

No interest declared

2.3 Strategic advisory role

No interest declared

2.4 Financial interests

No interest declared

2.5 Principal investigator

Period	Company	Products	Therapeutic Indication
05/2013-12/2013	Okairos	Observational study on RSV disease	N/A
04/2012-02/2014	GlaxoSmithKline	Synflorix	12 month booster
12/2011-06/2014	Funded by Wellcome Trust and in collaboration with Emergent	Vivotif, Typhella	Travel Vaccine
07/2010-12/2013	GlaxoSmithKline	Menitorix	Primary Immunisation
04/2013-12/2014	Okairos	PanAd3 - RSV, MVA - RSV	Prevention

10/2012-12/2013	Novartis	Bexsero	Prevention
11/2013-08/2015	Pfizer	Observational study on pneumococcal carriage	Pneumonia and meningitis

2.6 Investigator

Period	Company	Products	Therapeutic Indication
03/2012-12/2013	Sanofi	D TaP-IPV-Hib - HBs (Vaxelis)	Primary Immunisation
09/2012-05/2013	GSK	Flu D-QIV	Prevention
09/2013-05/2015	Pfizer	TruMenBA	Meningitis

2.7 Grant / Funding to organisation /institution

No interest declared

2.8 Close family member interest

No interest declared

2.9 Any other interests or facts

Chair of the Department of Health's Joint Committee on Vaccination and Immunisation.

I have not initiated any new projects with funding from vaccine manufacturers since 2013.

The following are academic trials or publicly funded research where the research is not funded by pharmaceutical companies:

European Commission grant (EBOVAC) to study an Ebola vaccine which has been developed by Janssen (2015-current).
European Commission grant (EUCLIDS; funding 2011-2016) to study the cause of fever with Bexsero (vaccine provided for the study under a supply agreement with University by Novartis/GSK).
Grant from the Bill and Melinda Gates Foundation to study the efficacy of a typhoid vaccine (Tybar-CV) produced by Bharat Biotech, India (2013-2016).
European Commission grant (ADITEC, 2011-2016) to study the genes expressed in children when they receive an adjuvanted influenza vaccine (FluAd, Novartis).
Grant from the National Institute for Health Research (2015-2020) to study treatment of encephalitis in children with intravenous immunoglobulin (supply agreement with CSL Behring).
Grant from the Global Alliance for Vaccines and Immunisation to study the infant pneumococcal vaccine schedule in Nepal (2013-2017).

Other investigators in the same academic department as me undertake research funded by vaccine manufacturers.

CONFIDENTIALITY UNDERTAKING

In view of the following definitions:

"EMA Activities" encompass any meeting (including meeting preparation and follow-up, associated discussion or any other related activity) of the European Medicines Agency's Management Board, Committees, Working Parties, Expert Groups, or any other such meeting; work as an expert on assessments; work as an expert on guidance development.

"Confidential Information" means all information, facts, data and any other matters of which I acquire knowledge,

either directly or indirectly, as a result of my EMA Activities.

"Confidential Documents" mean all drafts, preparatory information, documents and any other material, together with any information contained therein, to which I have access, either directly or indirectly, as a result of my participation in EMA Activities. Furthermore, any records or notes made by me relating to Confidential Information or Confidential Documents shall be treated as Confidential Documents.

I understand that I may be invited to participate either directly or indirectly in certain EMA activities and hereby undertake:

- To treat all Confidential Information and Confidential Documents under conditions of strict confidentiality.
- Not to disclose (or authorise any other person to disclose) in any way to any third party any Confidential Information or Confidential Document.
- Not to use (or authorise any other person to use) any Confidential Information or Confidential Document other than for the purposes of my work in connection with EMA activities.
- To dispose of Confidential Documents as confidential material as soon as I have no further use for them.

This undertaking shall not be limited in time, but shall not apply to any document or information that I can reasonably prove was known to me before the date of this undertaking or which becomes public knowledge other than as a result of a breach of any of the above undertakings.

I confirm the information declared on this form is accurate to the best of my knowledge and I acknowledge that my information will be stored electronically and published on the EMA website.

Full Name:	Andrew Pollard
Date:	2015-12-31

For Definitions of activities etc, refer to Policy on Handling of Conflicts of Interest / Electronic DOI template

RTÉ

Mr Peter C Gøtzsche
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20 January 2017

Re: Freedom of Information (FOI) request

RTÉ reference: FOI 2016/165

Dear Professor Gøtzsche,

I refer to your Freedom of Information ("FOI") request received by RTÉ on the 20 December 2016 and to our acknowledgement letter sent to you on 20 December 2016. As you are aware, the Freedom of Information Act 2014 (the "Act") provides for the right of access, on request, to records held by a public body. Certain records are exempt from release under the Act, which are set out in detail in Part 4 of the Act.

Your Request

I note that you have requested the following:

> *"a copy of the whole interview journalist Rita O'Reilly made with me in my office in Copenhagen on 14 November, for use in a programme that aired on 24 November. I I request, under Section 12 of the Irish Freedom of Information Act 2014, to get a copy".*

RTÉ response

I am sorry but I must refuse your request.

This refusal is based on the following grounds:

Freedom of Information (FOI) Act 1997 (Prescribed Bodies) (No. 2) Regulations, 2000

RTÉ is subject to the Acts in relation to its functions with the exception of its programme related function. This is provided for in the Freedom of Information Act, 1997 (Prescribed Bodies) (No. 2) Regulations, 2000 (the "**SI 115 of 2000**").

Schedule 2 of SI 115 of 2000 lists RTÉ's functions to which the FOI Act apply. These functions are management, administration, finance, commercial, communications and the making of contracts of or for service with any person, company or other body.

Relevant to determining whether records fall within these functions, is the High Court judgment in *Raidió Teilifís Éireann v Information Commissioner*[1] in which it was determined that even if a

1 http://m.oic.gov.ie/en/Decisions/Appeals-to-the-Courts-/High-Court-Judgments/Radio-Telef%C3%ADs-%C3%89ireann-v-the-Information-Commissioner/

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record relates to a function of management, administration, finance, commercial or communications, if the record relates to RTÉ's editorial and programme-making function, then the record, or a part thereof, ought to be excluded from the application of the FOI Act.

In the Explanatory Note it is stated that RTÉ is subject to FOI only for its non-programme related functions. The full Statutory Instrument (S.I. 115/2000) is available on the Office of the Information Commissioner website (www.oic.ie).

Schedule 3 of SI 115 of 2000 lists the kinds of records which are exempt. Paragraph one relates to the gathering and recording of news, information, data, opinions, on or off the record quotes or views from any person or body or source, for journalistic or programme content purposes. Paragraph two relates to source information or material. Paragraph three relates to the editing or storing of material for the purpose of programme origination. Paragraphs four and five refer to the making of editorial decisions and the reviewing of programming after transmission.

It therefore follows that any FOI request containing information relating to the matters referred to above ought to be excluded from release. It is my contention that a copy of the interview on 14th November 2016 at your office in Copenhagen, by journalist Rita O'Reilly, for use in an RTÉ 'Prime Time' programme broadcast on 24th November 2016, is directly concerned with RTÉ content and comprises an integral part of the editorial processes within RTÉ.

It is relevant to note that there is no requirement to take public interest considerations into account when refusing a request on the basis of the editorial programme-making exemptions contained in Schedule 3 to the Regulations.

Appeal

In the event that you are not happy with the above decision you may seek a review of the decision. The designated Internal Reviewer for RTÉ is Cillian de Paor, Group Secretary, RTÉ. You have four weeks from receipt of this letter to apply to Mr de Paor for a review. He, in turn, has three weeks from the date of receipt of your request to respond. There is a €30 fee for handling internal reviews. If, after Mr de Paor's response, you wish to seek a further review, you are entitled to seek a review to be conducted by the Office of the Information Commissioner at 18, Lower Leeson Street, Dublin 2. You have six months from the date of receipt of the internal review decision to request the Information Commissioner to carry out a review of the initial and internal review decisions.

Yours sincerely,

Dr. Anne O'Connor,

Head of Statutory Compliance and FOI Decision Maker, RTÉ, Donnybrook, Dublin 4.