# Freedom of Information Act 2000 (FOIA)

# Decision notice

**Date:** 9 November 2011

**Public Authority:** Medicines and Healthcare Products Regulation Agency

**Address:** 151 Buckingham Palace Road
London
SW1W 9SZ

## Decision (including any steps ordered)

1. The complainant has requested minutes of various meetings where the Pluserix MMR vaccine was discussed. The Medicines and Healthcare Products Regulation Agency (the "MHRA") provided some information, but withheld some under the health and safety exemption (section 38); the third party information exemption (section 40); and the confidential information exemption (section 41). Subsequently, the complainant made an additional request for information on the status of attendees at a specific meeting, and whether they were MHRA employees.

2. The Commissioner's decision is that the MHRA has correctly relied upon the health and safety exemption, and the third party personal information exemption to withhold some information. He has also decided some of the information was exempt under the confidential information exemption. However, he has also decided that some information was not exempt under sections 38 and 40, and should therefore be disclosed. The Commissioner has also decided that the MHRA should respond to the complainant's additional request.

3. The Commissioner requires the MHRA to take the following steps to ensure compliance with the legislation:

   - It should disclose an unredacted version of the minutes of the ARGOS meeting on 4 September 1992.

   - It should also respond to the complainant's additional request for it to confirm whether the individuals, whose names have been redacted from the above minutes, were MHRA officials.

4. The MHRA must take these steps within 35 calendar days of the date of this Decision Notice. Failure to comply may result in the Commissioner making written certification of this fact to the High Court (or the Court of Session in Scotland) pursuant to section 54 of the Act and may be dealt with as a contempt of court.

## Request and response

5. On 13 September 2010, the complainant wrote to the MHRA and made the following request:

> *"Could you please supply the Minutes from the meetings of the CSM Sub Committee on the Safety Efficacy and Adverse Reactions (SEAR) between 1/9/90 and 31/12/90."*

6. On 14 September 2010, the complainant wrote to the MHRA again and made the following additional request:

> *"Could you please supply me with a copy of the Minutes from the meeting on the 4th September 1992 by SEARS (Sub Committee CSM ... Safety Efficacy and Adverse Reactions) and ARGOS (Adverse Reactions Group of SEARS)."*

7. For ease of reference these will be referred to as requests (1) and (2).

8. The MHRA responded on 21 September 2010. It noted that the requested minutes were very lengthy, and asked the complainant to clarify what she was seeking from within these minutes. It reiterated this in an email dated 27 September 2010, and also made reference to section 12 of the FOIA.

9. Following an exchange of correspondence, on 5 October 2010 the MHRA contacted the complainant and informed her that it had now located the minutes of the SEAR meetings in question. However, it was unable to locate minutes of an ARGOS meeting on the date in question.

10. On 6 October 2010 the complainant pointed out that request (2) had been for the minutes of a joint SEAR/ARGOS meeting, and noted that it was still unclear whether it had found the minutes of this joint meeting.

11. On 7 October 2010 the MHRA confirmed that it had no record of a joint SEAR/ARGOS meeting on the date in question, although it had a record of separate SEAR and ARGOS meetings held on 5 September 1992.

12. On 21 October 2010 the complainant asked the MHRA to confirm whether it held the ARGOS minutes. On the same day the MHRA

confirmed that it was unable to locate ARGOS minutes, and asked the complainant to refine her request in relation to the SEAR minutes.

13. In light of this, on 27 October 2010 the complainant refined her requests as follows:

> Request (1): *"Could you please supply copies of the Minutes from the SEARS committee meetings between September and December 1991 where the Pluserix MMR vaccine is discussed. Please include reference to any adverse reactions, licensing information, problems, manufacturers advice, literature from overseas, and reports/papers tabled on the Pluserix vaccine."*
>
> Request (2): *"…I should like to request all material in connection with the Pluserix MMR vaccine included in the meeting of SEAR on 5th September 1992."*

14. On 16 November 2010 the MHRA confirmed that it had now located the SEAR minutes in question, and was now reviewing those minutes.

15. On 30 December 2010 the MHRA issued a substantive response. In relation to request (1) it stated that there had been no SEAR meeting in December 1991. In relation to the SEAR meetings in September, October and November 1991 it confirmed that the Pluserix vaccine had not been discussed. In relation to the refined version of request (2) it confirmed that the Pluserix vaccine had not been discussed at the SEAR meeting on 5 September 1992.

16. However, in relation to the original version of request (2), it informed the complainant that it had now located minutes for the ARGOS meeting on 4 September 1992 – which did discuss the Pluserix vaccine (the "ARGOS minutes"). It disclosed a redacted version of these minutes, together with a paper entitled "Neurological adverse events after MMR "that had been discussed at a meeting of the Committee on Safety of Medicines (the "CSM") on 4 September 1992. It noted that the information that had been redacted was being withheld under the third party information exemption.

17. On 19 January 2011 the complainant requested an internal review. In particular, she queried the handling of her requests and the use of the third party information exemption to redact the ARGOS minutes.

18. Following an internal review the MHRA wrote to the complainant on 7 February 2011. In relation to the SEAR meetings, it confirmed that the Pluserix vaccine had not been discussed at the meetings in question. In relation to the information that had been redacted from the ARGOS minutes, it upheld its previous use of the third party information

exemption. In addition to this, it stated that it believed that this information was also exempt under the health and safety exemption.

19. On the same day the complainant contacted the MHRA again. She noted that when upholding its use of the third party information exemption, it had referred to an 'Agency Policy'. She asked for a copy of this policy. She also asked it to confirm whether the individuals whose names had been redacted under this exemption were all officials of the MHRA. The MHRA responded on 14 February 2011 and provided a copy of the policy in question. However, it did not refer to her request for it to confirm whether the individuals in question were MHRA officials or not.

## Scope of the case

20. The complainant contacted the Commissioner to complain about the way her request for information had been handled.

21. On 12 July 2011 the Commissioner wrote to the complainant to clarify the scope of her complaint. He noted that the substantive part of the complaint appeared to be the use of the health and safety exemption, and the third party information exemption, to withhold certain information from the ARGOS minutes. If information had also been redacted from the CSM paper, he would also consider these redactions. He asked the complainant to confirm whether there were any other substantive issues she felt should be considered in this case.

22. Additionally, the Commissioner noted that the original version of request (1) referred to dates in 1990. However, much of the later correspondence between her and the MHRA (including the refined request) referred to SEAR minutes in 1991, rather than 1990. He would progress on the basis that this aspect of her request was focused on 1991, rather than 1990.

23. The complainant responded on 21 July 2011, and provided further clarification as to the scope of her complaint. In particular, she referred the Commissioner to her request to the MHRA (on 7 February 2011) for information as to whether the individuals in question were MHRA officials or not.

24. Following this, on 2 August 2011 the Commissioner wrote to the complainant and confirmed that the scope of this case would be to consider:

    - The use of the health and safety exemption and the third party information exemption to redact information from the ARGOS

minutes – together with any redactions that had been made from the CSM paper that had been disclosed to her.

- The lack of response to her additional request for confirmation as to whether the names redacted from the ARGOS minutes were officials of the MHRA.

25. During the investigation of the case the MHRA confirmed that it had withheld information from the CSM paper under the health and safety exemption, the third party information exemption, and the confidential information exemption.

26. Therefore the scope of this case has been to consider the following:

- the use of the health and safety exemption and the third party information exemption to redact information from the ARGOS minutes;

- the use of the health and safety exemption, the third party information exemption, and the confidential information exemption to redact information from the paper presented to the CSM meeting (the "CSM paper"); and

- the MHRA's failure to respond to the complainant's additional request for it to confirm whether the individuals, whose names had been redacted from the ARGOS minutes, were MHRA officials (the "additional request").

27. During the investigation of the case the Commissioner drew the MHRA's attention to the complainant's additional request, and asked it to confirm whether it held this information and, if so, whether it was prepared to disclose it to the complainant. The MHRA responded and indicated that it was content for the Commissioner to respond on its behalf. However, the Commissioner does not consider that this would be appropriate, and therefore he considers that the MHRA should respond to this additional request.

## Background

28. This notice has references to the CSM, SEAR and ARGOS. By way of background, the Adverse Reactions Group of SEAR (ARGOS) was a sub-group of the Sub-committee on Safety, Efficacy and Adverse Reactions (SEAR). This was a sub-committee of the Committee on the Safety of Medicines (CSM). The CSM provided advice to the UK licensing authority – which, at the time of the request, was the Medicines Control Agency.

This Agency merged with the Medical Devices Agency in 2003 to become the MHRA.

## Reasons for decision

29. In this case the MHRA has applied the health and safety exemption, the third party information exemption, and the confidential information exemption. The Commissioner has considered the application of each of these exemptions in turn.

### The health and safety exemption

30. In this case the MHRA has relied upon section 38(1)(b) to withhold names from the ARGOS minutes, together with the names of some of its officials shown in the CSM paper.

31. Section 38(1)(b) states that information is exempt if its disclosure would, or would be likely to, endanger the safety of any individual.

32. At internal review the MHRA applied the health and safety exemption on the grounds that, *"…officials of the MHRA who take part in and advise on decisions concerning the licensing of medicines are potentially vulnerable if they can be identified with particular decisions which the MHRA goes on to take."*

33. During the investigation of the case the MHRA expanded on the risks to personal safety apparently facing its employees and advisors. It described examples of incidents involving MHRA staff and the particular risks posed by animal rights activists – which the Commissioner considers is compelling evidence of MHRA staff being targeted. It also explained that a core responsibility of the MHRA is the assessment of applications for Marketing Authorisations (licences to supply a product in the UK market). Before a licence is granted the MHRA must be satisfied that the product meets stringent criteria relating to efficacy, safety and quality. MHRA assessors are routinely involved in assessing products that have been tested on animals, and many may have undertaken such experimentation in a professional capacity before they joined the MHRA. It therefore considers that it is a clear target for animal rights activists who oppose animal testing. This targeting is not limited to those directly involved in animal experimentation but may also extend to those organisations or individuals who supply or have dealings with such sites.

34. Therefore it has explained that,

> *"…there is a very real risk that disclosing the names of assessors in such a way as to link them to specific products would constitute a*

*potential threat to those of its staff who have, or be construed by activists to have, dealing with animal testing or the sites in which these activities occur."*

35. It has gone on to state that the nature of some activists has led it to conclude that they would be unlikely to discriminate between its staff who had a greater or lesser involvement in a particular assessment report, and that therefore all would be potentially vulnerable.

36. The Commissioner considers that the term 'endanger' under this exemption should be interpreted in the same way as the term 'prejudice' in other FOIA exemptions. Therefore, in order to engage this exemption a public authority must demonstrate that disclosure of the information in question would or would be likely to have a detrimental effect upon the physical or mental health of any individual, or the safety of any individual, that is more than trivial or insignificant.[1]

37. In this instance, the Commissioner notes that the MHRA has not specified whether disclosure of this information would or would be likely to cause the prejudicial effects it has set out. In cases where a public authority has failed to specify the level of prejudice at which an exemption has been engaged the Commissioner considers that lower threshold of 'likely to prejudice' should be applied, unless there is clear evidence that it should be the higher level.[2]

38. Bearing in mind the arguments made by the MHRA, the Commissioner considers that the most appropriate threshold to consider in relation to this exemption it the lower threshold of likely to prejudice.

39. In reaching a view on the application of this exemption the Commissioner has first considered whether the potential prejudice argued by the MHRA relates to the interest identified in this exemption – i.e. if the prejudice were to occur, would this prejudice relate to the safety of individuals?

40. Having considered the MHRA's arguments, as set out above, the Commissioner is satisfied that the potential prejudicial effects do relate to the safety of individuals.

41. In addition to this, bearing in mind the above arguments, the Commissioner is satisfied that there is a causal relationship between the potential disclosure of the withheld information and endangerment to

---

[1] *Ministry of Defence v ICO & R Evans* [EA/2006/0027].
[2] *McIntyre v ICO & the Ministry of Defence* [EA/2007/0068]

the safety of individuals. Furthermore, he is satisfied that the resultant endangerment would (if it were to occur) be real and of substance.

42. Next the Commissioner has gone on to consider whether the disclosure of this information would be likely to endanger the safety of individuals.

43. In reaching a decision on the question of the likelihood of prejudice the Commissioner considers that the expression 'likely to prejudice' means that the chance of prejudice being suffered should be more than a hypothetical possibility – there must be a real and significant risk.[3]

44. As noted above, this exemption has been applied to two different sections of the withheld information – names from the ARGOS minutes, and the names of some MHRA officials shown in the CSM paper.

45. The Commissioner has considered the question of the likelihood of prejudice in relation to each of these groups of withheld information in turn.

46. In relation to the names from the ARGOS minutes, the Commissioner notes that these show the identities of who attended this meeting, together with names attributing certain comments to certain individuals.

47. Given the potential repercussions on the individuals concerned, were the argued prejudice to occur, the Commissioner has considered the MHRA's arguments in relation to this information carefully. However, having done so he does not find these arguments particularly compelling.

48. The MHRA's arguments focus primarily on individual members of its staff being linked to certain products, and (primarily) the assessment and approval of those products. These arguments were previously made to the Commissioner in the consideration of a previous complaint, in which he upheld the use of this exemption.[4] However, the Commissioner notes that this previous case focused on a request for assessments and approvals of a specific drug, and he considers that the circumstances of that previous case are different to those in this case. In particular, the Commissioner notes that this information shows the attendees at a specified meeting of the ARGOS committee. After reading through the redacted version of the minutes disclosed to the complainant, the Commissioner notes that this meeting does not appear to have been called specifically to discuss the Pluserix vaccine – nor has the MHRA made this point.

---

[3] *John Connor Press Associates Limited v ICO* [EA/2005/0005], para 15.
[4] Case Ref. FS50072939.

49. In addition to this, the MHRA has not identified any particular piece of information within the ARGOS minutes, nor has it provided any specific argument in relation to any specific topics of discussion which took place at this meeting.

50. The Commissioner also notes that the minutes of some of the CSM meetings have been published on the MHRA website.[5] Some of these published minutes do show the attendees at the meetings of the CSM, and also attribute comments to specific individuals. The Commissioner also notes that these published minutes do list at least some individuals who are (or were) MHRA assessors. The MHRA has not provided any evidence that there has been an increase in the levels of threats or attacks on these attendees since the publication of these minutes on its website.

51. Therefore, although the Commissioner recognises that the regulation of medicinal products (and in particular, vaccines) is at times a controversial field, he has not been provided with any compelling evidence by the MHRA that the disclosure of the information withheld from the ARGOS minutes would be likely to endanger safety of any individual. Therefore, he does not consider that the health and safety exemption is engaged in relation to the names shown in the ARGOS minutes.

52. The Commissioner has gone on to consider the likelihood of prejudice to the second group of information – namely, the names of MHRA officials shown in the CSM paper.

53. The MHRA's arguments in relation to this information are the same as those referred to above.

54. In relation to this information, the Commissioner notes that the names are linked to a specific product (the Pluserix vaccine). Bearing in mind the arguments made by the MHRA in relation to the identification of specific individuals with specific products, and the evidence that it has supplied, the Commissioner is satisfied that the disclosure of this information would be likely to endanger the health and safety of the individuals concerned. The Commissioner is satisfied that disclosing the names of staff in a manner which links them to a specific product, investigation or inspection would be likely to endanger their health or

---

5 http://www.mhra.gov.uk/Committees/Medicinesadvisorybodies/CommitteeonSafetyofMedicines/Minutes/index.htm

safety. Therefore the health and safety exemption is engaged in relation to this information.

55. The health and safety exemption is a qualified exemption. This means that the information in question should only be withheld where the public interest in maintaining the exemption outweighs the public interest in disclosure.

56. In respect of the public interest in disclosure the Commissioner considers that there is a public interest in openness and accountability. In the circumstances of this case, he considers that the regulation of medicines is clearly a matter of significant public interest and scrutiny – especially in relation to the use of a vaccine that was used in a national programme of vaccination. In particular there is a significant public interest in increasing the transparency into the decision making process which went into the official decision to withdraw the use of the Pluserix vaccine (together with another MMR vaccine), and instead use a different MMR vaccine, whilst at the same time not withdrawing the manufacturer's licence.

57. As regards the public interest in maintaining the exemption the Commissioner has been mindful of his conclusions that disclosure of the withheld information would be likely to endanger the safety of individuals. He considers that there is a significant public interest in avoiding the endangerment of the safety of individuals.

58. In balancing the public interest arguments in this case the Commissioner finds the public interest avoiding the endangerment of the safety of individuals particularly weighty. Bearing this in mind, the Commissioner has decided that the public interest in disclosure is outweighed by the public interest in maintaining this exemption. Therefore the names of MHRA officials shown in the CSM paper are exempt from disclosure under the health and safety exemption and should not be disclosed.

59. The Commissioner has gone on to consider the application of the third party information exemption.

**The third party information exemption**

60. Section 40(2) provides an exemption for information which is the personal data of an individual other than the applicant, and where one of the conditions listed in sections 40(3) or 40(4) is satisfied.

61. In this case the relevant condition is contained in section 40(3)(a)(i), which applies where the disclosure of the information to any member of the public would contravene any of the data protection principles. This is an absolute exemption, and is therefore not subject to a public interest test.

62. The MHRA has sought to rely upon this exemption to withhold:

    - names from the ARGOS minutes,
    - the names of non-MHRA employees shown in the CSM paper, and
    - 'patient identifier' information, contained in the CSM paper.

63. The MHRA has argued that the disclosure of this information would be unfair and therefore in breach of the first principle of the Data Protection Act 1998 (the "DPA"). In addition to this, it has also argued that the disclosure of the information listed at the second and third bullet points would also breach the second principle of the DPA.

64. In order to establish whether this exemption has been correctly applied the Commissioner has first considered whether the withheld information is the personal data of third parties.

65. Section 1 of the DPA defines personal data as data which relate to a living individual, who can be identified:

    - from that data, or
    - from that data and other information which is in the possession of, or is likely to come into the possession of, the data controller.

66. In this case, the information listed at the first two bullet points above shows the names of attendees at the ARGOS meeting, or the names of individuals who were recorded as having some dealings with the MHRA. Bearing this in mind, the Commissioner is satisfied that this withheld information is the personal data of third parties.

67. In relation to the third bullet point, the 'patient identifier' information shows:

    - patient initials and their age,
    - geographical locators (i.e. names of countries, cities and towns),
    - vaccination numbers, and
    - patient identification numbers.

68. Having considered this information the Commissioner notes that some of it relates to patients who have died (marked in the documents as 'succumbed'). This information cannot be personal data, as it does not relate to living individuals. Therefore this exemption does not apply to this information. This information can be found on the pages marked as 40, 53 and 54 of the copy of the CSM paper, provided to the

Commissioner during the course of the investigation. Although the Commissioner has decided that this exemption cannot apply to this information, given the sensitivity of this information he has gone on to consider whether it is exempt under the confidential information exemption. This is discussed in detail from paragraph 105 onwards.

69. However, in relation to the remaining information there is no evidence to suggest that this relates to deceased individuals. Therefore the Commissioner has proceeded on the basis that this information relates to living individuals.

70. In relation to patient initials and their age, the Commissioner is satisfied that it would be possible for individuals to be identified from this information – especially when combined with other information contained in the paper. Therefore, the Commissioner considers that this information is the personal data of third parties.

71. In order to consider whether a living individual could be identified from the geographical locators, vaccination numbers and patient identification numbers, the Commissioner has to consider whether the individuals would be identifiable by members of the public, not armed with the further information held by the MHRA, if this information were disclosed.[6]

72. The MHRA has stated that this information might assist in the identification of individual patients. However, it has not provided any additional arguments as to how this might occur.

73. After considering this information and the other information contained in the CSM paper, the Commissioner is not satisfied that individuals can be identified from this information. Whilst the Commissioner accepts that some of this information relates to specific geographical locations, and a relatively small number of individuals, he does not consider that the disclosure of this information would lead to the identification of those individuals. Therefore he does not accept that this information is personal data. As such, the Commissioner finds that this exemption is not engaged in relation to the geographical locators, vaccination numbers and patient identification numbers contained in the CSM paper. Therefore he considers that this information should be disclosed.

74. In relation to the information which is personal data – the names from the ARGOS minutes of the ARGOS meeting in question, the names of

[6] *Department of Health v Information Commissioner [2011] EWHC 1430 (Admin.)* Para's 39 - 54

non-MHRA employees and patient initials and their age – the Commissioner has gone on to consider whether the disclosure of this information would be in breach of the first principle of the DPA.

75. The first principle requires that personal data is:

- processed fairly and lawfully, and
- that one of the conditions in schedule 2 is met.

76. The Commissioner has first considered whether the disclosure of the withheld information would be fair.

77. In considering whether disclosure of this information would be fair the Commissioner has taken the following factors into account:

- whether disclosure would cause any unnecessary or unjustified damage or distress to the individual concerned;
- the individual's reasonable expectations of what would happen to their information; and
- are the legitimate interests of the public sufficient to justify any negative impact to the rights and freedoms of the data subjects.

The non-MHRA employees shown in the CSM paper

78. This information can be found on the pages marked as 23, 24, 27 and 33 of the copy of the CSM paper, provided to the Commissioner during the course of the investigation.

79. The MHRA has stated that its usual policy is to withhold information about individuals who are not its employees, as disclosure would be in breach of the first principle. In this instance the information relates to two employees of a pharmaceutical company, and the name of a medical professional working in another country.

80. The MHRA has not provided any specific arguments as to how the disclosure of this information would cause any unnecessary or unjustified damage or distress to these individuals. However, the Commissioner notes that the use of MMR vaccines, and the problems associated with the Pluserix vaccine, was an issue of public concern and criticism. Bearing these points in mind, the Commissioner considers that were this information to be disclosed, the individuals named would potentially suffer criticism or reputational damage.

81. In relation to the reasonable expectations of the employees of the pharmaceutical company, the Commissioner considers that given the issue under debate in these documents, and as they were private sector

employees, they would have no reasonable expectation that their names would be disclosed under the FOIA. In relation to the medical professional, the Commissioner notes that their identity is only recorded as a passing reference, recording their activities in obtaining medical information in another country. Bearing this in mind, the Commissioner is satisfied that they would have no reasonable expectation that their name would be disclosed under the FOIA.

82. Finally, the Commissioner does not consider that the legitimate interests of the public in relation to this information are particularly weighty. Whilst there are interests in openness and transparency, especially in understanding how the decisions were made in relation to the Pluserix vaccine, the Commissioner considers that these interests are satisfied by the disclosure of the contents of the CSM paper, even in its redacted form. As these individuals did not have any active role in the actual decision making process in relation to this vaccine, he is not satisfied that the legitimate interests of the public are sufficient to justify any negative impact to the rights and freedoms of the individuals concerned.

83. Therefore, he considers that the disclosure of this information would be unfair. As such, he considers that this information is exempt from disclosure under this exemption.

Patient identifying information

84. This information relates to details of adverse reactions following the administration of the MMR vaccine. The Commissioner has first considered whether this information constitutes the sensitive personal data of these patients. Sensitive personal data is defined in section 2 of the DPA as, amongst other things, personal data relating to the physical health or condition of an individual. Bearing this in mind, and after considering the withheld information, the Commissioner is satisfied that it constitutes the sensitive personal data of these patients.

85. The Commissioner's approach is that where information constitutes sensitive personal data disclosure of that information will in most circumstances be unfair. By its very nature, sensitive personal data has been deemed to be information that individuals regard as the most private information about themselves. Further, the Commissioner considers that disclosure of this type of information is likely to have a detrimental or distressing effect on the subjects of this information (i.e. the patients).

86. Bearing in mind the nature of this information, which relates to the medical history of children, the Commissioner considers that the disclosure of this information would be unfair. Therefore he considers that this information is exempt from disclosure under this exemption.

The individuals identified in the ARGOS minutes

87. In regard to the names from the ARGOS minutes the MHRA has argued that by publishing assessors names linked to a particular product, the impression would be given that those individuals incorrectly and individually exercised their judgement when assessing the original licence application. In its view this impression is wrong and therefore unfair. It also noted that it has examples of staff being subjected to persistent, and sometimes abusive, correspondence from members of the public, who perceive a regulatory decision in relation to a particular medicinal product or range of products to have been incorrect and hold individual MHRA staff personally responsible for that decision. In addition to the potential threat of harassment, the MHRA has also argued that there was also a threat of attacks on its assessors' professional credibility. In addition to this, it has also referred the Commissioner to the arguments it has made in relation to the engagement of the health and safety exemption (see paragraphs 32 to 35), and specifically to the potential endangering of the safety of its employees.

88. Although the Commissioner notes the potentially serious consequences argued by the MHRA, he notes that no specific arguments have been made in relation to the ARGOS minutes in question. The MHRA's arguments focus on the potentially serious consequences, should its assessors' names be linked to a particular product. However, as noted at paragraphs 48 and 49 above, the Commissioner does not consider that the names redacted from the ARGOS minutes would be linked to a particular product, as the meeting does not appear to have been called specifically to discuss the Pluserix vaccine.

89. Although the Commissioner is not convinced that the disclosure of this information would have the serious consequences argued by the MHRA, he is aware that the decisions made at this meeting in relation to the Pluserix vaccine are of potential sensitivity or controversy. At the time of the meeting, growing concerns over the potential side effects of this, and another, MMR vaccine led to a decision to discontinue the use of these vaccines, and instead switch to a different MMR vaccine. However, the ARGOS committee (at this meeting) decided not to revoke the manufacturer's licence, "*…in the light of international and supply considerations*." Although this is not an argument made by the MHRA, the Commissioner considers that the decision not to revoke the manufacturer's licence was a potentially controversial one, which could potentially leave those at the meeting open to criticism.

90. In relation to the reasonable expectations of the individuals who attended the ARGOS meeting the Commissioner notes that the minutes of the meeting are marked as 'Commercial in Confidence' and 'Not for

Publication', and accepts that at the time the meeting was held in 1992, these individuals would have had a reasonable expectation that their identities and comments would not have been put into the public domain. However, the Commissioner considers that he has to consider the reasonable expectations of these individuals at the time of the request, in 2010.

91. The MHRA has argued that it would not have been in the expectations of these individuals for their names to be disclosed, stating that it is, and always has been, the *"tacit understanding"* of all assessors involved in this type of work, that their identities will not be disclosed.

92. In reaching a view on the reasonableness of this expectation the Commissioner has noted the seniority of the individuals concerned. The MHRA has informed him that the individuals involved in this type of work are generally at Senior Civil Service level, or an equivalent grade, although it has noted that grades from middle management upwards may also be involved in the process. Bearing this in mind, and given the nature of the topics discussed at this ARGOS meeting in question, the Commissioner is satisfied that the individuals were of a relatively senior rank.

93. Although this meeting did not involve decisions on how public money was spent, the Commissioner notes that the decisions were being made in relation to the safety and efficacy of medicines. Therefore, given the potential impact on human health of these decisions, he considers that there would be a reasonable expectation of accountability and transparency.

94. The Commissioner again notes that the MHRA does publish the minutes of the CSM meetings, and that these do show the attendees at these meetings, attribute comments to specific individuals, and list at least some individuals who are (or were) MHRA Assessors (see paragraph 50).

95. Bearing these points in mind, the Commissioner is not convinced by the MHRA's arguments about the reasonable expectations of the attendees of the ARGOS meeting in question.

96. In relation to the legitimate interests of the public, the Commissioner considers that these are:

- Furthering the public's understanding and participation in debates of the day on issues of public importance such as, in this case, matters regarding public health. In particular, the decisions to suspend the use of the Pluserix vaccine and to not revoke the manufacturer's licence were of note. The ARGOS minutes

disclosed to the complainant show that this decision was made by the members present. Therefore the Commissioner considers that there is a legitimate public interest in knowing who attended that meeting, and therefore who contributed to this decision.

- Increasing the public's understanding of the development of Government policy on issues regarding public vaccination especially regarding the use of the combined MMR vaccine which was introduced in 1988 and has generated a significant amount of public debate and some controversy since it was introduced.

- The public gaining a better understanding of the actions taken by an expert group, whose actions have helped shape government policy in areas where that policy still affects the public in a fundamental way, i.e. through the health of the nation.

- Increasing the transparency of the actions of this expert group.

- Increasing public confidence in the actions of this expert group, and allowing the public to gain an appreciation of whether their advice and actions were appropriate and effective.

- Increasing public confidence in official decisions taken in matters regarding public health.

97. Taking these factors into account, the Commissioner considers that the legitimate interests of the public are sufficient to justify any negative impact to the rights and freedoms of the data subjects. Therefore he considers that the disclosure of this information would be fair.

98. Having decided that disclosure of the names of the individuals identified in the ARGOS minutes would be fair, the Commissioner has gone on to consider whether the disclosure of this information would be lawful. In this case, the Commissioner is not aware of any duty of confidence or statutory bar protecting this information. Therefore he is satisfied that the disclosure would be lawful.

99. The Commissioner has gone on to consider whether any of the conditions in schedule 2 of the DPA can be met for the disclosure of this information.

100. The Commissioner considers that the most applicable condition in this case is likely to be condition 6 which gives a condition for processing personal data where the processing is necessary for the purposes of legitimate interests pursued by the data controller or by the third party or parties to whom the data are disclosed, except where the processing is unwarranted in any particular case by reason of prejudice to the rights and freedoms or legitimate interests of the data subject.

101. In order to consider whether this condition is met the Commissioner believes that disclosure must satisfy a three part test:

- there must be a legitimate interest in disclosing the information;
- the disclosure must be necessary for that legitimate interest; and
- even where the disclosure is necessary, it nevertheless must not cause unwarranted interference (or prejudice) to the rights, freedoms and legitimate interests of the data subject.

102. The Commissioner has detailed the legitimate interests in the disclosure of this information at paragraph 96 above. The Commissioner considers that the disclosure of this information is necessary for these legitimate interests.

103. Having already established that the processing is fair, the Commissioner is also satisfied that the release of this information would not cause any unnecessary interference with the rights, freedoms and legitimate interests of the data subjects. Therefore he is satisfied that this schedule 2 condition is met.

104. Therefore the Commissioner considers that the disclosure of the names of the individuals shown in the ARGOS minutes would not be in breach of the first principle of the DPA. As such he does not consider that this information is exempt under this exemption. Therefore this information should be disclosed.

**The confidential information exemption**

105. Section 41(1) states that information is exempt information if:

- it was obtained by the public authority from any other person (including another public authority, and
- the disclosure of the information to the public (other than under the FOIA) by the public authority would constitute a breach of confidence by that or any other person.

106. The MHRA has sought to rely upon this exemption to withhold information detailing the deaths of several patients. In addition to this, the Commissioner has also considered the application of this exemption to the patient identifier information relating to deceased patients – referred to at paragraph 68 above.

107. In considering whether disclosure of information constitutes an actionable breach of confidence the Commissioner will consider if:

- the information has the necessary quality of confidence;
- the information was imparted in circumstances importing an obligation of confidence; and
- disclosure would be an unauthorised use of the information and to the detriment of the confider.

108. However, it is the Commissioner's view that information on personal matters can still be protected under the law of confidence, even if disclosure may not be detrimental in terms of any tangible loss.

109. If these parts of the test are satisfied, the Commissioner will then consider whether there would be a defence to a claim for breach of confidence based on the public interest in disclosure of the information.

110. Whilst taking into account the particular circumstances of this case, the Commissioner has also been mindful of the decision of the Tribunal in *Bluck v ICO & Epsom and St Helier University Hospital NHS Trust* [EA/2006/0090] (the "Bluck case"). In that case a request had been received for a deceased person's medical records from an individual who was not the deceased person's personal representative. The Tribunal upheld the Commissioner's decision that the requested information was exempt from disclosure under section 41 of the FOIA. Whilst the Commissioner accepts that the request in this case was not for the deceased patients' medical records, given that the information directly relates to details of the medical history of these patients, he is satisfied that this Tribunal judgment is relevant to this case.

Was the information obtained from a third party?

111. The Commissioner has first considered whether this information was obtained from a third party.

112. This information was provided to the MHRA by a pharmaceutical company. Therefore, the Commissioner is satisfied that it was provided by a third party.

113. In addition to this, the Commissioner is satisfied that this information was drawn from the medical records of these patients. Whilst this information is not in the form of medical records, the Commissioner considers that it is of the same sensitivity and relevance to the deceased patients as their medical records, and has been obtained in connection with the provision of health services to those patients.

114. Therefore the Commissioner is satisfied that the information in question was obtained from a third party – both provided by the pharmaceutical company to the MHRA, and, in regard to the information obtained from

the patients' medical records, by the patient to the relevant health care provider.

115. The Commissioner has gone on to consider whether disclosure would constitute an actionable breach of confidence. He has first considered whether this information has the necessary quality of confidence.

Necessary quality of confidence?

116. The Commissioner considers that information will have the necessary quality of confidence if it is not otherwise accessible, and if it is more than trivial.

117. In this instance, the Commissioner has not been provided with any evidence to suggest that this information has been put into the public domain. Furthermore, given the events that this information relates to, the Commissioner would not expect details of these events to generally be put into the public domain (although he is aware that in some circumstances they might be). Bearing this in mind, and given the lack of evidence that any details are in the public domain, the Commissioner is satisfied that this information is not generally accessible.

118. Furthermore, given the seriousness of the issues that this information is about, the Commissioner is satisfied that it is not trivial.

119. Therefore the Commissioner is satisfied that the information in question has the necessary quality of confidence.

120. The Commissioner has gone on to consider whether the information was imparted in circumstances importing an obligation of confidence.

Imparted in confidence?

121. The MHRA has not provided the Commissioner with any details of how this information was provided to it by the pharmaceutical company. However, the Commissioner notes that this information is contained in a paper which was provided to the MHRA's predecessor by a pharmaceutical company, in relation to discussing adverse events following the use of an MMR vaccine. This appears to have been provided to the MHRA in 1992. Given the topic of the information, and the fact that the FOIA was not in existence in 1992, the Commissioner is satisfied that this information was provided to with an expectation of confidence.

122. Furthermore, the Commissioner is satisfied that the information was imparted in circumstances importing an obligation of confidence, as it was provided in confidence by the patients to their health care providers. When patients submit to treatment from doctors and other

medical professionals, they do so with the expectation that information would not be disclosed to third parties without their consent. He is satisfied that an obligation of confidence is created by the very nature of the doctor / patient relationship and the duty is therefore implicit. This is further supported by the oath which doctors take guaranteeing to protect doctor / patient confidentiality.

Would disclosure be to the detriment of the confider?

123. The Commissioner considers that as medical records constitute 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. He also considers that the loss of privacy can be a detriment in its own right.[7]

124. Bearing this in mind, the Commissioner does not consider that it would be necessary for disclosure of this information to cause detriment in order for the disclosure of this category of information to be actionable.

Would there be a defence to disclosure in the public interest?

125. In the Commissioner's view disclosure will not constitute an actionable breach of confidence if there is a public interest in disclosure which outweighs the public interest in keeping the information confidential, i.e. that there is a public interest defence for a breach of confidence.

126. In this instance the Commissioner considers that there is a considerable public interest in increasing the understanding of any risks associated with the use of a particular drug. However, he also considers that this interest has been somewhat met by the information that the MHRA has already disclosed as a result of this request.

127. In weighing this against the public interest in keeping the information confidential, the Commissioner has been mindful of the wider public interest in preserving the principle of confidentiality.

128. The consequence of any disclosure of confidential information will, to some degree, undermine the principle of confidentiality which is really to do with the relationship of trust between confider and confidant. People would be discouraged from confiding in public authorities if they did not have a degree of certainty that such confidences would be respected. In particular the Commissioner considers that it is in the public interest that patients have confidence that medical staff will not disclose

[7] EA/2006/0090, para 15

sensitive medical information 'or' divulge full details of their medical history and lifestyle**.** Without that assurance patients may be deterred from seeking medical advice and without adequate information doctors cannot properly diagnose or treat patients. This would not be in the public interest.

129. Bearing all these points in mind, despite the tragic nature of the events that lie behind this information, the Commissioner does not consider that the public interest in disclosure is sufficient to outweigh the considerable public interest in maintaining the confidentiality of the information in question. Therefore, he considers that the MHRA would not have a public interest defence for breaching its duty of confidence in this case.

130. Finally, the Commissioner has considered the question of whether the duty of confidence can survive the death of the individual to whom the duty is owed. In reaching a view on this, the Commissioner has been guided by the views of the Tribunal in the Bluck case, which considered this question and concluded that a duty of confidence is capable of surviving death of the confider.[8] The Commissioner is aware that the requested information in this case is not the medical records of the deceased patients. However, and as noted at paragraph 113 above, the Commissioner considers that this information has been drawn from the deceased patients' medical records. As such he considers that this information is of the same sensitivity and relevance to the deceased patients as their medical records.

131. Therefore in relation to this information, the Commissioner considers that the duty of confidence owed to the patients would survive their death, and that therefore the disclosure of this information by the MHRA would be a breach of the duty of confidence. Furthermore, in relation to this information it is the Commissioner's view that in determining whether disclosure would constitute an actionable breach of confidence, it is not necessary to establish whether, as a matter of fact, the deceased person has a personal representative who would take action.

132. Therefore the Commissioner considers that this information is exempt from disclosure under the exemption for information provided in confidence.

[8] EA/2006/0090, para 21

## Other matters

133. In relation to the information that has been withheld under the confidential information exemption, given the sensitivity of the information (about deceased patients) the Commissioner is deeply concerned about the MHRA's failure to provide any detailed arguments to support its use of this exemption.

134. Additionally, in relation to the information relating to deceased individuals that the MHRA sought to withhold under section 40 – taking into account that this information is about the medical treatment and deaths of children – the Commissioner is deeply concerned that it sought to apply this exemption to information that was clearly about deceased individuals. He considers that this shows a lack of care in relation to this information. Furthermore, he also considers that this is indicative of a somewhat blanket approach to the application of section 40 in this case.

135. Although it did not form part of the complaint, the Commissioner is also concerned to note the references to section 12 by the MHRA in its correspondence with the complainant (see paragraph 8 above). It appears that the minutes initially requested by the complainant were locatable by the MHRA. However, he notes that MHRA's position, as set out in an email to the complainant dated 27 September 2010, advising her that as these minutes were very lengthy "*it would be necessary to redact the minutes for each product and send to each marketing authorisation holder for their review…*" This would be very time consuming – meaning that they would need to refuse the request under section 12 of the FOIA. The Commissioner considers that this shows that the MHRA was seeking to take into account the cost of establishing whether information was exempt from disclosure when estimating the cost of dealing with these requests. The Commissioner does not consider that this is an appropriate factor to take into account when establishing the cost of dealing with a request, and would refer the MHRA to his guidance note on section 12 entitled "Using the Fees Regulations".[9] This states:

> *"Once the documentation containing the information has been located and retrieved, a public authority cannot take into account the time taken, or likely to be taken, to consider whether any of the*

9 http://www.ico.gov.uk/for_organisations/guidance_index/freedom_of_information_and_environmental_information.aspx

*requested information is exempt. Nor can it take into account the time taken, or likely to be taken, to remove the exempt information in order to leave the information that is to be disclosed in response to the request."*

136. As this was not part of the complainant's complaint to the Commissioner, he has not made a formal finding on this issue. However, he would advise the MHRA to take this guidance into account when handling future requests.

## Right of appeal

137. Either party has the right to appeal against this Decision Notice to the First-tier Tribunal (Information Rights). Information about the appeals process may be obtained from:

First-tier Tribunal (Information Rights)
GRC & GRP Tribunals,
PO Box 9300,
LEICESTER,
LE1 8DJ

Tel: 0300 1234504
Fax: 0116 249 4253
Email: informationtribunal@hmcts.gsi.gov.uk
Website: www.justice.gov.uk/guidance/courts-and-tribunals/tribunals/information-rights/index.htm

138. If you wish to appeal against a Decision Notice, you can obtain information on how to appeal along with the relevant forms from the Information Tribunal website.

139. Any Notice of Appeal should be served on the Tribunal within 28 (calendar) days of the date on which this Decision Notice is sent.

**Signed ……**

**Gerrard Tracey**
**Principal Policy Advisor**
**Information Commissioner's Office**
**Wycliffe House**
**Water Lane**
**Wilmslow**
**Cheshire**
**SK9 5AF**