Review of FOI Request 14/100

Review completed on 11 July 2014

Purpose Of Internal Review

The purpose of this internal review is to determine whether the Medicines and Healthcare Products Regulatory Agency ('the agency') dealt properly with the applicant's request under the Freedom of Information Act (FOIA).

The terms of reference of this review are:

- To read all correspondence between the applicant and the agency, and other relevant correspondence;
- To form an opinion on the handling of the correspondence by the agency;
- To advise whether the actions taken by the agency in reaching their decisions is justified under the FOIA;
- To make recommendations for further action by the agency if appropriate; and
- To prepare a report of the review for the agency and the requester.

Introduction

Brief facts of case

On 10 March, Mr Granito made a Freedom Of Information (FOI) request to the Medicines and Healthcare Products Regulatory Agency (MHRA), containing a number of questions related to the physical and chemical/metal/alloy properties of Mercury Amalgam used by the NHS in 1996.The MHRA responded on 7 April, answering question 3 "Dental amalgams are classified as Class IIa medical devices" and question 7 "The MHRA has not received any medically confirmed adverse acute or chronic ill health associated with mercury amalgams and/or any other dental medical materials and substances." but stating that the agency did not hold the information to answer Mr Granito's eight other questions.

Mr Granito wrote back on 5 May asking what agency did hold the information (if not HSE who sent him to the MHRA), whether the Minister signed off all medicines in order for them to be "deemed safe and tested for public use" and "How the Agency knew the toxic materials are impacting on public health if the Agency did not have a national register such as the one being put in place by Dr Poulter and Jeremy Hunt after faulty breast implants caused chronic ill health in a number of women in the UK".

The agency replied on 19 May, advising that they were unable to assist with his enquiry and directing him to the General Dental Council (GDC).

Mr Granito then responded on 18 June, stating that he had already contacted the GDC and was unsatisfied with their response (see below).

Although not specifically requested as such, Mr Granito's latest communication has been treated as a request for an internal review.

Background

I am not aware of any relevant background communication between the agency and Mr Granito prior to the FOI request on 10 March 2014.

On receiving Mr Granito's email of 18 June, I contacted relevant colleagues in MHRA Devices Division, who had handled the original request, on 19 June to investigate the facts of the case and challenge the original conclusions. My conclusions below are a result of those findings.

Correspondence

First contact, Mr Granito to MHRA, 10 March 2014

"-----Original Message-----
From: Granito [mailto:request-201261-7c79bfe6@whatdotheyknow.com]
Sent: 10 March 2014 13:39
To: MHRA Customer Services
Subject: Freedom of Information request - Please include data about NHS use of biocides as sealer's when mercury amalgam was used in 1996

Dear Medicines and Healthcare products Regulatory Agency,

Please provide details about the physical and chemical/metal/alloy properties of Mercury amalgam used by the NHS in 1996 as a restorative material in dental surgical procedures.

Please include data about NHS use of biocides as sealer's when mercury amalgam was used in 1996:

1.The name of manufacturer(s)
2.The name of each substance in the product including the name of it's active substance and the amount of each substance as a percentage of the whole.
3.The classification of the biocidal/heavy metal/alloy product.
4.Particulars of any likely direct or indirect adverse side effects.
5.Procedures to be followed and measures to be taken in the case of spillage or leakage of the biocidal product and the active substance contained in that biocidal product.
6. Safety data sheets for mercury amalgams and biocidal/paraformaldehyde based sealer's.
7. Data and registry of recorded adverse acute and chronic ill health associated with mercury amalgams and/or any other dental medical materials and substances.
8. Please list all biocides and heavy metals and alloys used today in the NHS as dental restorative materials and sealer's.

Kind regards

Granito"

MHRA original response, 7 April 2014

"Dear Granito,

Enquiry under the Freedom of Information Act (2000) – MHRA Ref: FOI 14/100

Please see below our response to your specific questions:

Please provide details about the physical and chemical/metal/alloy properties of Mercury amalgam

used by the NHS in 1996 as a restorative material in dental surgical procedures.
The MHRA does not hold this information

Please include data about NHS use of biocides as sealer's when mercury amalgam was used in 1996:

1.The name of manufacturer(s)
The MHRA does not hold this information.

2.The name of each substance in the product including the name of it's active substance and the amount of each substance as a percentage of the whole.
The MHRA does not hold this information.

3.The classification of the biocidal/heavy metal/alloy product.
Dental amalgams are classified as Class IIa medical devices.

4.Particulars of any likely direct or indirect adverse side effects.
The MHRA does not hold this information.

5.Procedures to be followed and measures to be taken in the case of spillage or leakage of the biocidal product and the active substance contained in that biocidal product.
The MHRA does not hold this information.

6. Safety data sheets for mercury amalgams and biocidal/paraformaldehyde based sealer's.
The MHRA does not hold this information.

7. Data and registry of recorded adverse acute and chronic ill health associated with mercury amalgams and/or any other dental medical materials and substances.
The MHRA has not received any medically confirmed adverse acute or chronic ill health associated with mercury amalgams and/or any other dental medical materials and substances.

8. Please list all biocides and heavy metals and alloys used today in the NHS as dental restorative materials and sealer's.
The MHRA does not hold this information."

First follow up, Mr Granito to MHRA, 5 May 2014

"-----Original Message-----
From: Granito [mailto:request-201261-7c79bfe6@whatdotheyknow.com]
Sent: 05 May 2014 11:30
To: MHRA Customer Services
Subject: RE: FOI 14/100

Dear MHRA Customer Services,

1. Who or what agency does have the information requested by me?

2. If it is not the HSE then what other agency because they sent me to you?

3. Are not Government ministers supposed to legally sign off all drug and medicine licenses in order for them to be deemed safe and tested for public use?

4. How do you know how these toxic materials are impacting on public health if you do have a national register such the 1 now being put in place by Dr Poulter & Jeremy Hunt after faulty breast implants caused chronic ill health in a number of women in the UK?

Thank you for your time

Granito

Yours sincerely,

Granito"

MHRA response to follow up, 19 May April 2014

"Dear Granito,

Thank you for your email of 5 May 2014.

We are sorry we are unable to assist with your enquiry and would suggest that you contact the General Dental Council (GDC) who may be able to assist or signpost you. Their contact details are below:

Email: information@gdc-uk.org
Tel: +44 20 7887 3800

Yours Sincerely,

Customer Services"

"-----Original Message-----
From: Granito [mailto:request-201261-7c79bfe6@whatdotheyknow.com]
Sent: 18 June 2014 18:08
To: MHRA Customer Services
Subject: RE: FOI 14/100

Dear MHRA Customer Services,

Thank you for your reply. However, the General Dental Council was the first agency I contacted in 2011. It's supposed 'investigations' were pathetically lacking and i was informed that if i wanted data about medical devices used by a previous NHS dentist I would have to take civil action to get it! Now that is not right is it?

The GDC relied on incomplete record keeping of vital data and my dental records were refused until the GDC got involved at my request. Although, it was a complete waste of time and the only people they are protecting is the dentists. It seems that when the public [myself]wish to hold government to account they [[me] are treated with contempt. So it appears my concerns have come full circle, which is no surprise as this is a common way of denying the public data which is currently secret [if it exists at all]. Why should I have to take out civil action in court to find out what 'medical devices' (mercury/a highly toxic hazardous material) was used to treat me? In light of the Minamata Treaty, which states:

'Significantly, this treaty includes a specific article related to human health (Article 16) with measures and activities that can be undertaken to assess and protect human health from

mercury. It outlines an important requirement that information related to mercury and human health must not be kept confidential thereby underscoring the public Right To Know about mercury impacts on their health.'

The related health clause under Article 17 which concludes, "For the purposes of this Convention, information on the health and safety of humans and the environment shall not be regarded as confidential" may provide leverage for those who wish to seek information from government on known sources and impacts of mercury on men, women and children in the UK. Information that has previously been classified may be released and publicised, raising awareness about mercury pollution in communities.

The hazards associated with mercury added products cannot be underestimated. The potential for mercury to be released at every stage from manufacture through useful life and disposal phase means that the potential for exposure during daily use of these products is high.

Thank you for your time,

Granito"

Consideration Of The Issues

The issues under consideration are:

- Has the agency answered the request?
- Have any exemptions been properly applied?
- Has the agency fulfilled its general obligation to be helpful?

Has the agency answered the request?

In part. Most of the information was indeed not held by the agency, which I was able to confirm from questioning the drafters of the original response. However the original response to question 7 should have been clearer. It originally stated that there had been "..no **medically confirmed** adverse acute or chronic ill health associated with mercury amalgams and/or any other dental medical materials and substances." This should have been clarified to state that a "medically confirmed" case was where it had been reported by a Health care Professional but that the MHRA had received two reports from patients that were not clinically confirmed by a healthcare professional to have any association with dental materials. The text of these reports is below but all identifying details have been removed under section 40 of the FOIA 2000 as to leave them in would infringe the patients' right to privacy under the Data Protection Act 1998:

1. 'I am writing to you to raise your awareness regarding chronic mercury poisoning from amalgam mercury poison silver fillings, which is a more correct description of the poison product. I am sure you know that mercury is a grade two-listed toxic poison and that it is neurotoxic, genotoxic and nephrotoxic even in minute and miniscule amounts.
   The latest WHO policy and Mercury in Health Care clearly states that –recent studies suggest that mercury may have no threshold below which some adverse effects do not occur – therefore the risk involved is not a risk worth taking considering the high risk of harm from any medical use of this horrific

poison.
My amalgam silver fillings which are made of 50% mercury have been leaking into my body and also releasing methyl mercury vapors [sic] for over the past 30 years, consequently I am now suffering from hypersensitivity to mercury and I am slowly dieing [sic] of chronic mercury poisoning.'

2. 'The mercury fillings in my mouth are leaking mercury vapour at a constant rate under normal conditions. Mercury vapour leaks at normal body temperature, More mercury vapour leaks when a hot drink is taken and in addition chewing,
grinding or any normal abrasion to the teeth results in a much higher level of mercury vapour rising from my teeth. The mercury is depositing itself within the organs of my body. This Knowledge is based upon high quality scientific studies of Mercury fillings. I have been poisoned by the NHS since childhood. I have many Mercury based fillings .'

Have any exemptions been properly applied?

Not applicable. No exemptions under the FOI Act 2000 were used in this case.

Has the agency fulfilled its general obligation to be helpful?

Not entirely. On reflection the agency should have identified in the original reply that some of the information might be held by the officially accredited Notified Bodies in the EU and explained that these are the Competent Authorities in the EU (including the UK) for assessing class IIb and III medical devices for compliance with the EU Medical Devices Directive and awarding a CE mark (class I and IIa are the lowest risk class of device and can be self-certified by the manufacturer). Under the general obligation to provide advice and assistance contained in section 16 of the FOI Act 2000, the agency could have provided a list of the Notified Bodies in the EU which Mr Granito could then have contacted. This list is now attached and I apologise to Mr Granito that this was not included with the original response on 7 April or in the agency's second response on 19 May. It is important to note that this does ***not signify*** that the Notified Bodies necessarily hold the information, or would be willing to release it if they did, merely that it is another place where the information ***could*** reasonably be expected to be held and therefore worth trying (as they are not public authorities, Notified Bodies are not subject to the FOIA).

Conclusion and recommendations
In light of the above I find that the agency did answer the request correctly, in that the information was indeed not held by the agency. However I find partly against the agency on procedural grounds as the agency failed in their general obligation to be helpful and have committed a minor breach of section 16 of the Act.

There are no recommendations arising from my review.

If Mr Granito remains dissatisfied, he may ask the Information Commissioner (ICO) to make a decision on whether or not we have interpreted the FOIA correctly in dealing with the request and subsequent internal review. The ICO address is listed below:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Matthew Garland
Policy Division
Medicines and Healthcare Products Regulatory Agency