Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 19 February 2014

Public Authority: Medicines and Healthcare Products Regulatory Agency

Address: 151 Buckingham Palace Road Victoria, London, SW1W 9SZ

Decision (including any steps ordered)

1. The complainant has requested legal advice obtained by the Medicines and Healthcare Products Regulatory Agency (MHRA) related to the licensing of nicotine containing products (NCP[1]) and nicotine replacement therapies (NRT[2]) as medicines.

2. The Commissioner's decision is that MHRA has correctly applied section 42(1) of the FOIA to the withheld information.

3. The Commissioner does not require the public authority to take any steps as a result of this decision notice.

Request and response

4. On 28 June 2013, the complainant wrote to MHRA and requested information in the following terms:

"You have refused, again, to disclose the legal advice relied on by MHRA and referred to above in this letter. You claim that "the Government" will not release its legal advice, and that "advice privilege and litigation privilege apply".

[1] NCP – nicotine products not making medicinal claims and not requiring a Marketing Authority (MA)

[2] NRT – nicotine products making medicinal claims and requiring/holding MAs

We do not believe that any litigation was underway or reasonably in contemplation at the time the pre-March 2010 legal advice was given. The supporting documents make reference to advice obtained in 2009 in the context of MHRA's decision to extend the use of licensed NRT products to include harm reduction. That does not sound like litigation-privileged advice given in contemplation of court proceedings. If we are wrong, please explain what litigation was underway or in reasonable contemplation at the time. Even if litigation or general legal advice privilege did apply, MHRA has waived this by openly and expressly referring to the legal advice several times in a number of publicly disclosed MLX364 documents which seek to explain MHRA's position."

5. MHRA responded on 24 July 2013 and refused to provide the requested information, citing section 42 of the FOIA as its basis for doing so.

6. Following an internal review MHRA wrote to the complainant on 17 September 2013 upholding its original position.

7. In its submission to the Commissioner, MHRA also stated that it wished to apply section 35(1)(a) of the FOIA.

8. Full details of the correspondence are contained in an Annexe at the end of this decision notice. This provides a more detailed background and context regarding the request.

Scope of the case

9. The complainant contacted the Commissioner on 25 October 2013 to complain about the way his request for information had been handled.

10. The Commissioner considers the scope of this case to be to determine if MHRA has correctly applied the exemptions it has cited to the withheld information.

Reasons for decision

11. Section 42(1) provides that*: 'Information in respect of which a claim to legal professional privilege or, in Scotland, to confidentiality of communications could be maintained in legal proceedings is exempt information.'*

12. Legal Professional Privilege (LPP) protects the confidentiality of communications between a lawyer and client. It has been described by the Information Tribunal (in the case of Bellamy v the Information

Commissioner and the DTI EA/2005/0023) as: *"a set of rules or principles which are designed to protect the confidentiality of legal or legally related communications and exchanges between the client and his, her or its lawyers, as well as exchanges which contain or refer to legal advice which might be imparted to the client, and even exchanges between the clients and their parties if such communication or exchanges come into being for the purpose of preparing for litigation." (paragraph. 9)*

13. There are two types of privilege: litigation privilege and legal advice privilege. Litigation privilege will be available in connection with confidential communications made for the purpose of providing or obtaining legal advice in relation to proposed or contemplated litigation. Advice privilege will apply where no litigation is in progress or being contemplated. In these cases, the communications must be confidential, made between a client and professional legal adviser acting in their professional capacity and made for the sole or dominant purpose of obtaining legal advice. Communications made between adviser and client in a relevant legal context will attract privilege.

14. The Commissioner's view is that for LPP to apply, information must have been created or brought together for the dominant purpose of litigation or for the provision of legal advice. With regard to 'advice privilege' the information must have been passed to or emanate from a professional legal adviser for the sole or dominant purpose of seeking or providing legal advice.

15. Having reviewed the withheld information the Commissioner is satisfied that it is indeed communications between a client (MHRA) and its legal adviser for the dominant purpose of obtaining legal advice. The section 42 exemption is therefore engaged.

16. MHRA made five references to 'legal advice received' and the complainant submits this constitutes waiver of all LPP. MHRA argue that it is established that the test for waiver of privilege is whether the contents of the documents are being relied on.

17. Although partial disclosure of privileged material may give rise to implied waiver of the whole in litigation cases, such 'collateral waiver' has no application outside litigation.

    "outside litigation, a party is entitled, provided, of course, he does not falsify, to advance his case in public debate to the best advantage; if so advised, by selective quotation. If he does so, an alert opponent will see what he is doing and demand disclosure of the whole advice, if he is to be persuaded. Such is the cut and thrust of public debate. Even a public authority, whose advice is funded by the taxpayer, is entitled to declare

the final upshot of the advice received without running the risk of revealing every last counterargument of which it has been warned."[3]

18. The Commissioner has not found any evidence to support the complainant's view that privilege in respect of this advice has been waived.

19. The exemption given at section 42 is a qualified exemption. This means that even where the exemption is engaged, information is only exempt from release if the public interest in maintaining the exemption outweighs the public interest in disclosing the requested information.

Public interest in favour of disclosing the requested information

20. Some weight must always be attached to the general principles of achieving accountability and transparency. This in turn can help to increase public understanding, trust and participation in the decisions taken by public authorities.

Complainant's arguments in favour of disclosure

21. The complainant contends that MHRA did not apply the public interest test (PIT) correctly. Under the Commissioner's guidance on the PIT the MHRA must decide whether the public interest is better served by withholding the information or by disclosing it.

22. The complainant stated that under section 2(2)(b) of the FOIA, when the MHRA applies the public interest test, it can **only** withhold the legal advice if the public interest in maintaining the exemption outweighs the public interest in disclosure.

23. The MHRA states that it 'does not consider any of the arguments advanced by [redacted] are sufficient to outweigh the public interest in maintaining the confidentiality of the Agency's correspondence with its lawyers in relation to the NCPs at this point in time. The MHRA should, however, have considered whether the arguments for withholding the information were sufficient to outweigh the public interest in disclosing the advice, this is a different test. It is not for [redacted] to argue that the legal advice should be disclosed. Instead the MHRA must demonstrate that the legal advice should be withheld, and that the

[3] http://www.informationtribunal.gov.uk/DBFiles/Decision/i153/FCO%20v%20IC%20(EA-2007-0092)%20Decision%2029-04-08%20(w).pdf (para 22).

public interest lies in not disclosing it. The MHRA has approached the test "the wrong way round".

24. The MHRA has not put forward any arguments in favour of withholding the advice it has merely asserted that the arguments put forward are not sufficient. It has not however explained ***why*** it believes the arguments are insufficient.

25. The complainant went on to present the further arguments below;

    a) there is widespread concern about the consequences of the Announcement, including the forced removal of products from the market, the impact on businesses manufacturing/importing products and the impact on public health of products being removed and consumers who use e-cigarettes returning to smoking conventional tobacco cigarettes;

    b) the large amount of money involved (the loss of sales and revenues caused by the Announcement if implemented, will run into millions of pounds);

    c) the large number of people affected (millions of e-cigarette consumers and potentially thousands of people employed in or supporting the e-cigarette section);

    d) an apparent lack of transparency in the MHRA's Consultation and its Announcement as a result of it failing to publish the legal advice which seems to have underpinned the whole consultation process;

    e) the public interest, given the importance of and implications of the Announcement, in establishing whether the actions undertaken by the MHRA did indeed 'follow' what the legal advice actually stated;

    f) the public interest in establishing whether in citing the legal advice in support of the position it took, the MHRA followed the advice correctly, had not misunderstood or misconstrued it, or took the relevant passages cited out of proper context.

    g) there is a clear public interest in the disclosure of this legal advice, given that it is fundamental to the decisions MHRA took prior to launching the MLX364 consultation in 2010 and at its conclusion in 2013. The legal advice does not relate to confidential commercial interests, it relates to an important matter in the public interest which has been widely reported on, and which is causing considerable concern amongst electronic cigarette consumers, manufacturers, retailers and respected academics and experts.

Public interest arguments in favour of maintaining the exemption

26. The Commissioner has taken into account the inbuilt public interest in the concept of legal professional privilege, as well as what the particular factors in this case suggest about the balance of public interest. This includes what harm may result, and what benefit to the public interest may result, through disclosure of the information in question. The inbuilt public interest in legal professional privilege was noted by the Information Tribunal in the case Bellamy and Secretary of State for Trade and Industry (EA/2005/0023):

"…there is a strong element of public interest inbuilt in to the privilege itself. At least equally strong countervailing considerations would need to be adduced to override that inbuilt interest…it is important that public authorities be allowed to conduct a free exchange of views as to their legal rights and obligations with those advising them without fear of intrusion, save in the most clear case…" (paragraph 35).

27. It is very important that public authorities should be able to consult with their lawyers in confidence and to obtain legal advice. Any fear of doing so resulting from a disclosure could affect the free and frank nature of future legal exchanges or it may deter them from seeking legal advice. The Commissioner's published guidance on legal professional privilege states the following:

"Legal professional privilege is intended to provide confidentiality between professional legal advisers and clients to ensure openness between them and safeguard access to fully informed, realistic and frank legal argument, including potential weaknesses and counter arguments. This in turn ensures the administration of justice".

28. However, in DBERR v Dermod O'Brien (EWHC 164 (QB)) the High Court noted that the inbuilt public interest in legal professional privilege should not mean that section 42(1) is in effect, elevated to an absolute exemption.

Balancing the public interest arguments

29. The Commissioner accepts that there is a public interest in disclosing information which will lead to greater openness and accountability. However in balancing the opposing public interest arguments in this case, the Commissioner is mindful of the Information Tribunal's decision in Bellamy.

30. The Commissioner recognises that the general public interest inherent in the exemption will always be strong due to the importance of the

principle behind LPP: safeguarding openness in all communications between client and lawyer to ensure access to full and frank legal advice, which in turn is fundamental to the administration of justice. However it is not an absolute exemption and where there are equal or weightier countervailing factors, then the public interest in maintaining the exemption does not outweigh the public interest in disclosing the information.

31. In considering the balance of the public interest, the Commissioner accepts that there is a strong element of public interest inbuilt into legal professional privilege in order to protect the confidentiality of communications between lawyers and their clients. However, he does not accept that the factors in favour of disclosure need to be exceptional for the public interest to favour disclosure.

32. The MHRA also accepts there is an inherent public interest in ensuring that public authorities are transparent in the decisions they make in order to promote accountability and improve the quality of decision making.

33. In this case, disclosure of the withheld information would assist the public in understanding any legal issues associated with the stance by the MHRA that NCPs and NRTs should be licensed as medicines and regulated accordingly. The Commissioner considers that these are issues which could potentially affect many members of the public.

34. In order to determine where the public interest lies in this case, the Commissioner has considered the circumstances of this particular case and the content of the withheld information. He has also considered whether the advice is likely to affect a significant number of people, the timing of the request and the status of the advice.

35. The Commissioner considers that there is a very strong public interest in promoting openness, transparency and accountability in the decision-making processes of government departments such as the MHRA. In this particular case, disclosure of the legal advice would provide a greater degree of transparency in relation to the reasoning behind MHRA's proposal for regulation and licensing.

36. The Commissioner notes that, at the time of the request, no definitive decision had been taken about whether or not to regulate NCPs and NRTs. It is still the case that there has been no such decision to date. As such, the legal advice was still very much "live" at the time of the request and cannot be considered to be no longer of great relevance or to have served its purpose. The Commissioner considers this adds significant weight to the arguments in favour of maintaining the exemption.

37. Although the MHRA has adopted an approach of 'no need to wait', it is the Commissioner's understanding that any changes regarding regulation and licensing of NRTs and NCPs, is subject to EU law to create a Europe-wide legal position on NCPs as medicines through the revision of the Tobacco Products Directive. The European Commission has said it expects the new legislation to be adopted in 2014 and for it to come into effect in the UK from 2016.

38. The Commissioner accepts there is a very strong public interest in the MHRA being able to obtain full and thorough legal advice to enable it to make legally sound, well thought out and balanced decisions without fear that this legal advice may be disclosed into the public domain. The Commissioner considers that disclosure may have a negative impact upon the frankness of legal advice provided and might even have a limited impact upon the extent to which legal advice is sought. This in turn may have a negative impact upon the quality of decisions made by the MHRA which would not be in the public interest.

39. The Commissioner has considered the withheld information, the potential harm which might arise from disclosure and the wider context that informs the public interest in transparency and accountability. For the reasons set out above, whilst this is a finely balanced judgement, the Commissioner considers that in all the circumstances of the case, the public interest in maintaining the section 42 exemption outweighs the public interest in disclosure. This being the case he has not gone on to consider the application of section 35(1)(a).

Right of appeal

40. 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: GRC@hmcts.gsi.gov.uk
    Website: www.justice.gov.uk/tribunals/general-regulatory-chamber

41. 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.

42. 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 .....

Pamela Clements
Group Manager, Complaints Resolution
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Annexe 1

On 28 June 2013 the complainant wrote to the MHRA stating:

We write further to our recent correspondence, and in light of MHRA's classification decision of 12 June 2013.

The MLX364 Consultation

In March 2010, MHRA announced a consultation on whether to classify and regulate NCPs (which includes e-cigarettes) as "medicinal products" under the Medicinal Products for Human Use and Directive 2001 (Medicinal Products Directive). MHRA proposed three options:

i. *Option 1: classify NCPs as medicinal by function and remove all unlicensed NCPs from the market within 21 days*

ii. *Option 2: classify NCPs as medicinal by function and give notice that all unlicensed NCPs be removed from the market after a certain date.*

iii. *Option 3: do nothing and allow supposedly 'unregulated' products to remain on the market*

MHRA expressed the view, prior to starting the consultation that it preferred Option 1. Option 3 was clearly not a credible option at all in MHRA's eyes. In March 2011, MHRA acknowledged that its consultation had highlighted uncertainty around the levels of nicotine that have a significant pharmacological effect and there was a need for further information on the impact of regulation on public health and business. It undertook to engage in a period of scientific and market research, over a period of 18 months, before it made a final decision on which of the options to adopt "in spring 2013".

Classification decision of 12 June 2013

On 12 June 2013, MHRA announces that *"the UK Government has decided that [MHRA] will regulate all NCPs as medicines".* Furthermore, it said that *"the UK Government will press for EU law to create a Europe-wide legal position on NCPs as medicines through the revision of the Tobacco Products Directive. The European Commission has said it expects the new legislation to be adopted in 2014 and for it to come into effect in the UK from 2016."*

The announcement continued *"From that point [ie 2016], all NCPs will*

require a medicine licence. This will allow manufacturers to ensure that their products meet the safety, quality and efficacy requirements of medicine. Until that law is in place, the MHRA would encourage those manufacturers with unlicensed products currently on the market to apply for a medicine licence".

Requests for clarification

So that [complainant] fully understands what MHRA is actually proposing, the implications for its business and its customers, and the legal basis for both MHRA's decision and its recommendation that [complainant] should now embark on the process of obtaining a licence for its products, we require an urgent and full response to the matters raised below:

1. Please confirm whether MHRA's position as announced is conditional on, and subject to, the proposed EU Tobacco Products Directive first passing into law, and if so, in the form proposed by the EU Commission in December 2012.

2. The MLX364 consultation was premised on MHRA having received legal advice (which you refuse to disclose) that NCPs could be classified as "medicinal by function" under existing legislation, namely the Medicinal Products Directive 2001. If, by apparently making its decision conditional on new legislation coming into force, MHRA is now of the view that it cannot *at this time* classify NCPs as medicines under that legislation (which would be consistent with case law in other EU states, the recent draft opinion of the EU Parliament's JURI Committee, and any sensible reading of the Medicinal Products Directive), the please confirm that this is the case, so that we have clarity and certainty on the point.

3. Some of the 1,200 or so amendments to the draft Tobacco Products Directive tabled by MEPs. Including those proposed by no less than the Chair of the ENVI Committee (The Committee on the Environment, Public Health and Food Safety[4]) responsible for the passage of the draft Directive into law, would expressly require our client's products **not** to be classified as medicinal products by member states, and provide for an alternative regulatory regime (or even the status quo). If the Directive passes into law including

[4] http://www.eppgroup.eu/ENVI

the amendments proposed by the ENVI Committee Chair or including other tabled amendments having similar effect, this would render unlawful any unilateral attempt by MHRA to classify NCPs as medicines (by function) under the Medicinal Products Directive. *Does MHRA agree? If you disagree, please explain why.*

4. In any event, no part of the draft Tobacco Products Directive does anything to alter the scope or meaning of the Medicinal Products Directive. Article 18, as drafted by the Commissioner simple states that NCPs over a certain nicotine threshold shall require authorisation under the Medicinal Products Directive. We question the effect of that when there is a body of European legal opinion and national court case law which states that NCPs should not be regulated as medicines under that legislation, other than "by presentation" on the part of the manufacturer.

5. In light of points 1-4, we do not understand how MHRA can be in a position to announce at this particular point in time, that it **will** implement in 2016 a regime of medicinal regulation under either the existing Medicinal Products Directive (on which it consulted) or under the draft Directive currently being debated by EU legislators.

6. It is unclear from MHRA's announcement whether the proposed new medicinal licensing regime will apply **all** nicotine containing products ("nicotine containing products" being the exact working used in the announcement, and also in recent medical appearances by Mr Mean), or only to those nicotine containing products which do not also contain tobacco. Please confirm the position.

7. If tobacco-based NCPs have indeed been exempted from the new medicinal licensing regime, please explain why favourable treatment has been given to tobacco-based nicotine products.

8. The announcement says that "*the UK Government* has decided that MHRA will regulate all NCPs as medicines" and that "*the UK Government* will press for EU law to create a Europe-wide legal position on NCPs as medicines through the revision of the Tobacco Products Directive".

   Is it therefore correct to conclude that, rather than being the culmination of the MLX364 consultation process undertaken by MHRA in its own name, the 12 June 2013 decision is in fact a political decision taken by Ministers but announced through MHRA under the pretext of its long awaited MLX364 consultation decision?

9. Without knowing whether the EU Directive will ever become law, or what form, MHRA has nevertheless advised manufacturers that they should embark upon the prohibitively expensive and time consuming process of obtaining medicines licences, ahead of the 2016 "deadline". MHRA's Q&A document says: *"there is no need to wait – the MHRA welcomes applications from manufacturers for product licences. We hope that the first licences will be granted within a year".*

10. [Redacted] is clearly confused, given that:

    a. without revision to the Medicinal Products Directive, the only lawful basis upon which [redacted] products can be considered 'medicinal' is if they are marketed as such by presentation, which our client has no intention of doing, not least because it would mislead consumers

    b. there are comments in the MHRA supporting documents (see for example in the Impact Assessment) which suggest that the success or otherwise of the Government's policy will very much depend on whether MHRA require full human and/or clinical trials for NCPs or something less onerous, and that is for MHRA to decide what form of medicines licensing it requires for NCPs. Indeed, MHRA's 12 June summary document states (para 9): *"the UK Government will encourage applications for medicines licences for NCPs and will make best use of the flexibilities within the existing framework to enable licensed products to be available".* However, [redacted] has not seen any announcements from MHRA introducing a less onerous of more "flexible" regime for the medicines licensing of NCPs.

11. In light of the above, and given that we are told that 'there is no need to wait', please confirm what the relaxed or more flexible licensing requirements now are for e-cigarettes, and exactly what [redacted] needs to do should it decide to immediately start the process of obtaining "a product licence" for each of its products from MHRA "within a year".

12. We assume that MHRA/the Government will not indemnify any e-cigarette manufacturer that embarks upon a medicines licensing route which proves in due course to have been totally unnecessary because the EU Directive fails to pass into law in its Commission-endorsed draft for, or at all, and MHRA then no longer requires a medicines authorisation as a result. However, we would be grateful if you would confirm the position in your response.

On 24 July 2013 MHRA responded:

> In response to the questions you pose on your letter in numbered paragraphs;
>
> > 1. The Government's position is to press for a requirement for licensing through EU legislation and the MHRA's position will need to take account of the final form of the legislation. Pending the adoption of a directive the MHRA will continue to encourage companies voluntarily to license NCPs on the basis of presentation and will continue to decide whether products are medicinal products on a case by case basis.
> >
> > 2. The Government has not changed its position that nicotine containing products could be classified as medicinal by function. The MHRA takes decisions on the application of medicines legislation on a case by case basis, taking account of all the characteristics of the product in particular its composition, its pharmacological, immunological or metabolic properties, to the extent to which they can be established in the present state of scientific knowledge, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail.
> >
> > 3/4. As noted above, the Government's position is related to the draft EU Tobacco Products Directive and will need to take account of the final form of the legislation. The legal status of NCPs following the coming into effect of a Tobacco Products Directive can only be assessed on the basis of the legislation adopted and in particular its interaction with Directive 2001/83/EC.
> >
> > 5. The MHRA's press release reported the European Commission's estimate of when the draft legislation could be in force in the member states rather than the Government and this could change depending on the final form of the legislation.
> >
> > 6/7. The MHRA's press related to NCPs (but not tobacco products), which are the subject matter of the relevant provisions of the draft Tobacco Products Directive. The MHRA has not made a determination that products containing tobacco are not, as a class, medicinal products. The MHRA in considering products continues to decide on a case by case basis whether a product meets the definition of medicinal product under Directive 2001/83/EC.
> >
> > 8. The MHRA's consultation (MLX368) concluded in 2010 and the outcome is published on the MHRA's website. The MHRA

> announced the Government's position on the regulation of NCPs as it relates to the draft EU Tobacco Products Directive.
>
> 9/10. The Government's decision to encourage companies voluntarily to license NCPs on the basis of presentation, and to press for a requirement through EU legislation, is intended to ensure that consumers have available high quality products to help them cut down their smoking and to quit. Consumers will benefit from consistent high standards of quality, safety and efficacy through this approach.
>
> 11/12. As noted in your letter, the MHRA has been clear that it will make use of flexibilities within the existing framework. The Commission on Human Medicines advised on this issue and the paper it considered is available on the MHRA's website. It remains a matter for those wanting to market NCPs whether it is appropriate or necessary to apply for marketing authorisation under the current legal framework governing medicinal products, pending any relevant provisions in a Tobacco Products Directive.

We have taken the section of your letter under the heading "Your letter of 13 June 2013" to be a formal request under the Freedom of Information Act 2000 notwithstanding that you have made that same request along with requests for extensive other information in other FOI requests. We can confirm that we hold information of the type you have requested. But we rely on the exemption in section 42 of the Freedom of Information Act 2000. We do not consider that legal professional privilege in respect of the legal advice given and received in relation to NCPs has been lost by virtue of the references to that legal advice by the MHRA in the consultation exercise. That advice remains confidential and has not been disclosed to the public.

Accordingly we have gone on to consider whether the public interest in maintaining the exemption is outweighed by the public interest in disclosure. In that regard we have particularly considered the reasons you advance that there is a clear public disclosure of the legal advice. The reason for the section 42 exemption is that safeguarding the openness in all communications between lawyer and client, so ensuring full and frank advice, is strongly in the public interest. We do not consider that you have advanced sufficiently strong countervailing considerations to show that the public interest in disclosure outweighs the public interest in maintaining confidentiality of legal advice. In particular the reasons you advance seem to be reasons which are generally applicable when government is making policy decisions do not sufficiently outweigh the public interest in maintaining legal professional privilege.

On 16 August 2013 the complainant wrote to MHRA:

We write in response to MHRA's letter dated 24 July 2013. In the final 4 paragraphs of that letter, the MHRA stated that it has treated the request in our letter of 28 June 2013 for a copy of the legal advice obtained in 2009 as "a formal request for information under the Freedom of Information Act 2000".

The MHRA has refused to provide this requested information on the basis that, although the information is held by the MHRA, it is exempt from disclosure pursuant to section 42 of the FOIA, namely that it is legally privileged.

We do not agree that the MHRA has valid grounds for refusing the request on the basis of this exemption.

Nature of the request

[Redacted] has requested information from the MHRA, namely information which sets out the legal advice which MHRA admits it received in 2009 the effect of which is said to be that NCPs may come within the scope of medicines legislation because of their supposed pharmacological effect. The legal advice is expressly referred to by MHRA in some of the MLX364 documents MHRA published at the outset of the MLX64 consultation process in February 2010[5], in the "outcome" documentation MHRA published on March 2011[6], and in the documentation MHRA uploaded to its website in June 2013 in support of its 12 June 2013 announcement[7].

We note from the documents published in June 2013 (see the CHM paper referred to in at footnote 5) that the context in which the legal advice was obtained was "when MHRA extended the indication of NRT [nicotine replacement therapies] to include harm reduction" which took place in 2009.

MHRA's letter of 24 July 2013 confirms that this legal advice exists. The letter asserts that the advice "remains confidential and has not been disclosed to the public". Nowhere in the letter does MHRA take issue with our assumption that the legal advice must exist in documentary form. That it exists in documentary form is apparent from the the fact that the MHRA has expressly and specifically referred to it, and summarised the gist of it in its

[5] Eg see para 14 of 1 February 2010 consultation letter.

[6] Eg seen penultimate para of March 2011 "outcome" document; anser to Q2 in the March 2011 "FAQs" document

[7] Eg see the second para on page 7 of the "Commission of Human Medicines Working Group on NCPs paper "CHMWG2013/1st" uploaded to MHRA's website in June 2013

consultation documents and in the documents disclosed in support its 12 June 2013 announcement.

It is therefore clear from the above that the legal advice exists and that is recorded in documentary form.

MHRA asserts that the legal advice in question is legally privileged and exempt from disclosure pursuant to s42 FOIA. MHRA takes issue with our previous suggestion that even if that was the case (which is not admitted), then legal privilege has been waived by the repeated and specific references to legal advice in the documents which MHRA has put in the public domain, throughout the consultation documents in 2010 and 2011 and in the material published by MHRA which is said to support its 12 June 2013 announcement.

It may be true that the advice when it was given in 2009, was provided on a "confidential" basis and that the MHRA has never publically released it (if it had, then there would of course not need to request it under FOIA). However, although the entirety of the legal advice itself has never been published or disclosed as part of the consultation exercise, the ***nature*** of the advice has now been summarised by MHRA and that has been disclosed by MHRA to the world at large.

Crucially, the MHRA's own documents (see for example those referred to in footnotes 3-5) confirm that the legal advice was provided in 2009 for the different purpose of considering an extension of the indication of nicotine replacement therapies to include harm reduction. It was not provided to the MHRA for the purpose of the MHRA considering whether electronic cigarettes and other NCPs could conceivably fall within the scope of the Medical Products Directive 2001 and therefore be classified as "medicines".

In light of the above, we consider that any legal privilege that may have existed over the advice, and/or the inherently confidential nature of it, has now been lost.