



Government Legal Department

██████████
Reed Smith LLP
The Broadgate Tower
20 Primrose Tower
London
EC2A 2RS

Litigation Group
102 Petty France
Westminster
London
SW1H 9GL

T ██████████

██████████ Westminster 12 www.gov.uk/gld

Your ref: ██████████
Our ref: ██████████

11 December 2023

Dear Mr ██████████,

Philip Morris Limited v Secretary of State for Health and Social Care

1. We write in response to your pre action letter dated 27 November 2023, which sets out your client's proposed challenge to the 'Creating a smokefree generation and tackling youth vaping Consultation' ('the Consultation') on three grounds.
2. As you will be aware, the UK government is required, under Article 5.3 of the WHO Framework Convention on Tobacco Control, to protect public policy from the commercial and other vested interests of tobacco companies. As such, we will be publishing both your correspondence and this response.
3. The Consultation closed on 6 December 2023¹. (Your client has since issued its claim and served it on 7 December 2023). There were approximately 28,000 responses.
4. Smoking is the UK's biggest preventable killer, causing around 1 in 4 cancer deaths and approximately 80,000 deaths in the United Kingdom alone, costing the economy and wider society £17 billion each year. No other consumer product kills up to two-thirds of its lifelong users and the government's plans will save tens of thousands of lives and save the NHS billions of pounds. Four in five smokers have started by the time they are 20 and although the vast majority try to quit, many fail to do so due to the addictive nature of tobacco.
5. Your letter demanded a response by 1 December, and suggested the matter was urgent because the Consultation was still open. First, the pre-action protocol provides for 14 days for responses. Second, it is important that Government gives careful consideration to pre-action letters, and a full response was not feasible within the extremely short timescale proposed. Third, it is not clear why the closing date of the Consultation could render the matter urgent. Fourth, your client has considerable resources, and there is no explanation in your letter as to why your client could not have raised these issues earlier – the Consultation opened on 12

¹ <https://www.gov.uk/government/news/plans-progressed-to-create-a-smokefree-generation>

██████████ - Head of Division

██████████ - Deputy Director, Team Leader Constitutional & Social Care Public Law



October 2023. Your client issued a claim on 6 December 2023, without waiting for a substantive response, and despite the preliminary response provided on 1 December 2023.

I. The Claimant

6. Philip Morris Limited

II. From

7. The Secretary of State for Department of Health and Social Care c/o The Treasury Solicitor, 102 Petty France, London, SW1H 9GL.

III. Reference details

8. All correspondence should quote reference [REDACTED]. The lawyers dealing with this claim is [REDACTED] and [REDACTED].

IV. Details of the matter being challenged

9. Your pre action letter makes a number of claims about heated tobacco products and alleges that the Consultation is unfair and unlawful. It proposes three grounds on which your client intends to apply for permission to bring judicial review proceedings:
 - a. A failure to give adequate information or reasons to enable consultees to provide intelligent, considered responses.
 - b. That the design of the consultation deprives consultees of the opportunity to provide a proper response.
 - c. That aspects of the policy that is the subject of the Consultation appear to have been pre-determined.
10. For the following reasons, the Secretary of State for Health and Social Care ('the Secretary of State') considers that your proposed claim is outside the Court's jurisdiction, misguided, and wholly without merit. The proposed challenge would be an unjustified attempt to delay or derail important legislative change.
11. Further, for the reasons set out below it is considered that the claims made in your pre-action letter are selective and misleading and do not demonstrate compliance with the claimant's duty of candour within judicial review proceedings.

V. Response to the proposed claim

Jurisdiction

12. Article 9 of the 1689 Bill of Rights provides: "*That the freedom of speech, and debates or proceedings in Parliament, ought not to be impeached or questioned in any court or place out of Parliament*".
13. In *R (on the application of A and others) v Secretary of State for the Home Department* [2022] EWHC 360 (Admin), Mr Justice Fordham considered a proposed challenge to a consultation on a proposal which would require primary legislation and found that the proposed challenge

was “clearly, and beyond reasonable argument” outside the Court’s jurisdiction and that the claim must be dismissed.

14. The proposed challenge to the Consultation would be precisely such a challenge, and is therefore impermissible. Your pre-action letter fails to address this fundamental issue. Your Statement of Facts and Grounds argues that A is wrongly decided, but does refer to the need to avoid causing “*undue disruption to any legislative process*”.

15. As summarised in *A and others* at paragraph 10:

“(1) There is a principle of non-justiciability, rooted in the Bill of Rights (a constitutional statute), and reflected in the case-law. (2) It would offend that principle of non-justiciability for the Courts to entertain a challenge, or express any reasoning, involving: (i) any “vitiation” of a decision to lay a Bill before Parliament; or (ii) any “interference” with the laying of a Bill of primary legislation before Parliament. (3) Impermissible “vitiation” would be exemplified by a legal challenge whose target, or subject matter, involved impugning a decision as to the design of primary legislation, including where that decision has been arrived at following a process of consultation and engagement. (4) Impermissible “interference” would be exemplified by a legal challenge whose substantive content, or claimed remedy, involved impeding or delaying the introduction of a Bill or primary legislation into Parliament (or conversely which involved dictating that a Bill, or the design of a Bill, be introduced into Parliament). ... (7) Nor could the Gunning principles, as to legally adequate consultation, be invoked to impugn such a substantive decision”.

16. Mr Justice Fordham comprehensively and correctly set out the reason why a Court is bound to dismiss such a challenge:

“24. The justiciability question in the present case is this: does the Court's supervisory jurisdiction on judicial review extend to the Court policing the Gunning standards, in the context of a consultation which was concerned with “delivering effective legislative change”, and whose culminating substantive decision necessarily entails the design of a Bill of primary legislation to be introduced into Parliament? In my judgment, the answer to that question – based on the authorities – is clearly, and beyond reasonable argument, “no”. In the first place, the “vitiating” consequence of breach of the Gunning standards – as seen throughout public law wherever those standards are policed by the judicial review Court – can have no place in the present context. [...]

“25. It is not possible, in my judgment, to treat the Gunning standards as being legally applicable to “process decisions” about ‘the design of the decision-making process’, in a manner which is distinct from and insulated from the substantive decision-making as to the design of the Bill. Consultation is really about “participation in” a “decision-making” process. [...]”

*“26. A declaration that an applicable legal standard was breached, in the consultation and engagement process culminating in the operative decisions as to the design of the Bill to introduce into Parliament, would, in my judgment, clearly constitute a breach of Parliamentary privilege and the constitutional separation of powers, as these are clearly described by the Divisional Court in the *Adiatu* case. A declaration from a judicial review Court, declaring that the consultation which preceded the Bill and informed its design was unlawful would – even if the Court bent over backwards to make very clear that that was the scope and extent of its judgment and its declaration – clearly raise questions about whether some step ought to be taken in light of that conclusion of law by the Court. [...]*”

“27. In conclusion, it is not – in my judgment – arguable, with a realistic prospect of success, that the Gunning standards are legal standards engaging the supervisory jurisdiction of the judicial review Court in these following circumstances: where Government has chosen to undertake a “consultation and engagement process”, for the purposes of “delivering effective legislative change”, where the outcome would necessarily be substantive decisions as to the design of a Bill to be introduced into Parliament.”

17. For this reason, the proposed claim would have no realistic prospect of success and would be dismissed.
18. Further, insofar as your client makes criticisms of the command paper ‘Stopping the start: our new plan to create a smokefree generation’², to do so in legal proceedings would also constitute a breach of Article 9.

The grounds are misguided

19. Without prejudice to the above, the proposed grounds are plainly without merit for the following reasons.
20. On 4 October 2023, the Department of Health and Social Care (DHSC) presented to Parliament a command paper ‘Stopping the start: our new plan to create a smokefree generation’ setting out proposed action to protect future generations from the harms of smoking by creating the first smokefree generation, and also tackle youth vaping. The Consultation was launched on 12 October 2023³.
21. One key element of the proposed action is the introduction of primary legislation which would make it an offence for anyone born on or after 1 January 2009 to be sold tobacco products (and in Scotland, also an offence for anyone born on or after 1 January 2009 to purchase tobacco products). Setting this date will mean the change in the law would come into effect in 3 to 4 years’ time from January 2027, when this group of children turns 18. This would effectively raise the smoking age by one year, every year, until it applies to the whole population.
22. The UK Government, and the Scottish and Welsh devolved administrations, also propose to make it an offence for anyone at or over the legal age to purchase tobacco products on behalf of someone born on or after 1 January 2009 (‘proxy purchasing’).
23. The Consultation covered a number of topics including (but not limited to) the scope of the proposed primary legislation.
24. The Consultation included the following questions (among others) on the scope of proposed changes to age of sale legislation:

“Do you agree or disagree that the age of sale for tobacco products should be changed so that anyone born on or after 1 January 2009 will never be legally sold (and also in Scotland, never legally purchase) tobacco products?”

“The following products would be in scope of the new legislation:

cigarettes

cigarette papers

hand rolled tobacco

cigars

cigarillos

pipe tobacco

waterpipe tobacco products (for example shisha)

² <https://www.gov.uk/government/publications/stopping-the-start-our-new-plan-to-create-a-smokefree-generation/stopping-the-start-our-new-plan-to-create-a-smokefree-generation>

³ <https://www.gov.uk/government/consultations/creating-a-smokefree-generation-and-tackling-youth-vaping>

chewing tobacco

heated tobacco

nasal tobacco (snuff)

herbal smoking products

This mirrors the current scope of age of sale legislation in England and Wales. Existing age of sale requirements in Scotland currently cover products consisting wholly or partly of tobacco and which are intended to be smoked, sniffed, sucked or chewed. Insofar as the products listed would not be within the scope of the existing restrictions, it is proposed that the scope of the Scottish legislation be expanded to include them.

Do you agree or disagree that all tobacco products, cigarette papers and herbal smoking products should be covered in the new legislation?"

25. The Consultation also included questions on proposals to introduce legislation to permit local authorities to issue fixed penalty notices (FPNs) to enforce breaches of age of sale legislation of tobacco products and vapes in England and Wales.
26. The Consultation was voluntary. As such, the question of the applicable legal standards remains open to determination by the Court of Appeal (*Secretary of State for Work and Pensions v Eveleigh & Ors* [2023] EWCA Civ 810; [2023] 1 WLR 3599) and the Secretary of State would reserve the right to raise this point on appeal. For the purposes of this letter only, it is assumed that the Gunning principles apply, rather than rationality. The 'Gunning principles' are set out in *R v. North East Devon Health Authority, ex p. Coughlan* [2001] QB 213.

Ground 1

27. The second Gunning principle is that a consultation must include sufficient reasons for particular proposals to allow those consulted to give intelligent consideration and response.
28. Your proposed challenge is limited to the proposal to include a specific tobacco product, heated tobacco, within a date of birth limit for the sale of tobacco products.
29. The reason for the proposal to include heated tobacco products within the scope of the proposed age of sale legislation was clearly stated in the consultation: because this would mirror existing age of sale legislation for tobacco products.
30. That was a clear and sufficient reason for the proposal.
31. In fact, if the proposal had not covered all tobacco products that would have been contrary to 90 years of age of sale legislation and would have required far more explanation. As your client will be well aware, the regulation of 'tobacco products' as a whole is longstanding.
32. See, for example, s. 7(1) of the Children and Young Persons Act 1933 which created the offence of selling "any tobacco or cigarette papers" to persons under 18; where tobacco is defined inclusively (not exclusively) in s. 7(5) as "*includes cigarettes any product containing tobacco and intended for oral or nasal use and smoking mixtures intended as a substitute for tobacco*". Other examples include the Tobacco Advertising and Promotion Act 2002, and the Children and Families Act 2014.
33. Heated tobacco products are tobacco products. They are products containing tobacco intended for oral use, and so fall well within the definition. That the tobacco is heated (to, for example, 400 degrees Celsius) rather than combusted as in cigarettes does not take heated tobacco outside the s. 7(5) definition.
34. Section 94 of the Children and Families Act 2014 permits the Secretary of State to create regulations "*if the Secretary of State considers that the regulations may contribute at any time*

to reducing the risk of harm to, or promoting, the health or welfare of people under the age of 18". In doing so, Parliament legislated that:

"(4) Regulations under subsection (6) or (8) are to be treated for the purposes of subsection (1) or (2) as capable of contributing to reducing the risk of harm to, or promoting, people's health or welfare if (for example) they may contribute to any of the following—

(a) discouraging people from starting to use tobacco products;

(b) encouraging people to give up using tobacco products;

(c) helping people who have given up, or are trying to give up, using tobacco products not to start using them again;

(d) reducing the appeal or attractiveness of tobacco products;

(e) reducing the potential for elements of the packaging of tobacco products other than health warnings to detract from the effectiveness of those warnings;

(f) reducing opportunities for the packaging of tobacco products to mislead consumers about the effects of using them;

(g) reducing opportunities for the packaging of tobacco products to create false perceptions about the nature of such products;

(h) having an effect on attitudes, beliefs, intentions and behaviours relating to the reduction in use of tobacco products.

(5) Regulations under subsection (6) or (8) are to be treated for the purposes of subsection (1) as capable of contributing to reducing the risk of harm to, or promoting, the health or welfare of people under the age of 18 if—

(a) they may contribute to reducing activities by such people which risk harming their health or welfare after they reach the age of 18, or

(b) they may benefit such people by reducing the use of tobacco products among people aged 18 or over."

35. Section 95 defines a tobacco product as *"a product consisting wholly or partly of tobacco and intended to be smoked, sniffed, sucked or chewed"*. Section 91 (prohibiting the purchase of tobacco and cigarette papers on behalf of children), defines "tobacco" in s. 95(7) as follows:

"(7) Tobacco" has the same meaning in this section as in section 7 of the Children and Young Persons Act 1933 (offence of selling tobacco to children)."

36. Section 1(b) of the Tobacco Advertising and Promotion Act 2002 contains a similar definition:

"tobacco product" means a product consisting wholly or partly of tobacco and intended to be smoked, sniffed, sucked or chewed."

37. Under this ground it is alleged that *"the Consultation appears to proceed on the basis of the New Zealand case study. However, the New Zealand comparator is flawed vis-à-vis HTP, which were specifically excluded from the legislation enacted in that jurisdiction"*. However, the Command Paper and Consultation are clear about the scope of New Zealand's plans.

38. Finally, much of the argument made under this proposed ground is an attack on the rationality of the proposal (e.g. *"the elision of combustible tobacco products and HTP does not withstand scrutiny and/or is arbitrary and irrational"*). The second Gunning principle is an aspect of procedural fairness. It is not a backdoor to a challenge to the Government's decision to put a proposal to the public. The Government is entitled to propose raising the age of sale for all

tobacco products, including heated tobacco products in line with 90 years of primary legislation by Parliament. Any challenge to a proposal, rather than the eventual decision, would be premature.

39. One of the reasons for a public body to consult voluntarily is to gather information about alternatives to the proposals consulted on, as well as the level of support for proposals. There was no requirement in this case to include alternatives in the Consultation document.

Ground 2

40. This proposed ground objects to the design of the Consultation, which utilises multiple choice questions together with accompanying boxes to allow consultees to explain their answers or provide further comments in up to 300 words. There are 27 specific questions with 27 free text boxes, in other words overall consultees could include up to 8,100 words in their response. This is a standard way in which consultations are designed. The Government is entitled to design a consultation in this way. There was nothing even arguably unlawful in doing so.

41. Further, your letter fails to recognise that the Consultation permitted professionals and organisations to submit documents:

“If you’re responding as an individual sharing your professional views or on behalf of an organisation, you may upload a document to support your response at the end of the survey. Please do not upload information that could identify an individual or member of the public.”

42. Your client in fact submitted a response via the online portal and submission to the email mailbox which included a document running to 18 pages.

43. The third Gunning principle is that adequate time must be permitted for a response. The Government received approximately 28,000 responses during the eight weeks consultation period, including your client’s response. Your client is a large multinational tobacco company with very significant resources. The issues in the Consultation would not have been new or surprising to your client.

44. The letter asserts but does not explain why eight weeks would not be sufficient for consultees. The government’s guidance consultation principles state that: *“Consultations should last for a proportionate amount of time on the basis of legal advice and taking into account the nature and impact of the proposal. Consulting for too long will unnecessarily delay policy development. Consulting too quickly will not give enough time for consideration and will reduce the quality of responses.”* There is no principle in law that 12 weeks is a starting point for consultation periods, and there is no reason in the present case why 8 weeks would not be a sufficient period of time. Your client has not explained what it would have done differently with a further four weeks.

45. The duration of the consultation is consistent with this guidance. There will be further opportunities to scrutinise any proposal which the government decides to take forward following the Consultation, as part of the parliamentary process.

Ground 3

46. The first Gunning principle is that consultation must be undertaken at a time when proposals are still at a formative stage. In *R (Spurrier) v. Secretary for State for Transport* [2019] EWHC 1070 (Admin); [2020] PTSR 240 the Divisional Court noted that it was important to distinguish between actual or apparent pre-determination on the one hand, and pre-disposition on the other. The latter is not unlawful. The Divisional Court stated: *“[A]s is so often the case in policy-making, the policy-maker does not have to be—and, usually, is patently not—detached or disinterested as between the possible policy options”* (at [510]); see also *R (Sardar) v. Watford Borough Council* [2006] EWHC 1590 (Admin) per Wilkie J at [29].

47. This proposed ground relies on an unrealistic misreading of the Consultation. The first substantive question in the Consultation is *“Do you agree or disagree that the age of sale for*

tobacco products should be changed so that anyone born on or after 1 January 2009 will never be legally sold (and also in Scotland, never legally purchase) tobacco products?" Reading the Consultation as a whole it is plain that the Government has not predetermined the issue.

48. As regards impact assessments, it is not clear how your client thinks that not publishing impact assessments alongside the Consultation could constitute predetermination. In any event, the impact assessment for the Tobacco and Vapes Bill will be published in due course. Parliament will have further opportunity to scrutinise the Government's approach, including the impact assessment, as the Bill progresses.

Assertions made regarding heated tobacco products

49. The pre-action letter contains a number of claims about heated tobacco products and suggests that there is "*a clear and growing body of evidence that suggests that HTP are significantly less harmful than combustible tobacco products, and that they can assist in encouraging current smokers to move to smokeless alternatives*". These claims and arguments are in effect an attempt to challenge the proposal which was put to consultation, rather than a challenge to the Consultation itself. Any challenge to the decision, which is yet to be made, would be premature. In any event, for clarity (and without prejudice to any future response to a challenge) some of the ways in which the claims made in the pre-action letter are selective and misleading are set out below.
50. The scope of the draft primary legislation to be put to Parliament is a matter for the Secretary of State now that the Consultation has closed. None of the below indicates any predetermination of that decision. However, it is important to be clear that your client's suggestion that including heated tobacco products in the scope of the proposal put to Consultation was in some way irrational or requiring detailed explanation is entirely wrong. It is beyond doubt that the Secretary of State was entitled to include these products within the proposal.
51. Combustible tobacco products are the most lethal consumer product available, killing up to two out of three lifelong users. To describe a product as "less harmful" than that is not necessarily a significant claim. If cigarettes were 50% less lethal, they would still be causing in the region of 40,000 deaths per year (approximately 100 deaths per day) in the UK. The range of heated tobacco products are diverse, and there is differing evidence on the health harms of these products.
52. Given the very well known, multiple and serious harms of tobacco taken in by many routes (inhaled, nasal, chewed etc), the evidence of toxicity in laboratory studies and the well-known addiction due to exposure to nicotine; and in the absence of an established and uncontested body of independent research to international medical standards; it would be entirely rational and lawful for any government to proceed on the basis that this well-known carcinogen within 'heated tobacco products' will also pose risks to long-term to health like every other tobacco product.
53. Whether heated tobacco products are "less harmful" than combustible tobacco or may be used as an aid to quit cigarettes is far less relevant when considering a proposal which would only affect those who are currently 14 years of age and younger and cannot currently legally be sold tobacco products as they are under 18. If heated tobacco products were able to be sold to adults in the future who by reason of their date of birth were never able to legally buy tobacco products such as cigarettes then the relevant harm profile would be comparing the harm of heated tobacco against no tobacco harm - as it would be being sold to someone who has never legally been sold any other tobacco product. Those who are currently adults and who have established smoking habits will not be affected. In any event, as set out in the quote of the Khan Review at paragraph 59 there is "little evidence" to conclude that heated tobacco products make

a contribution to smoking cessation, and other tobacco-free quit aids which are less harmful will remain available (e.g. nicotine patches, nicotine vapes).

54. Further, these claims are based on selective quotations, and do not refer to the full range of available evidence. Some claims (e.g. *"in reality, they have a harm profile more akin to vapes"*) are highly subjective and lack supporting independent evidence (much of the available evidence concerning heated tobacco products is industry funded and not independent).
55. It is important to note that the UK has signed up to the **WHO Framework Convention on Tobacco Control**. Article 4(2)(b), for example, refers to *"the need to take measures to prevent the initiation, to promote and support cessation, and to decrease the consumption of tobacco products in any form"*. This forms part of the UK's obligations in international law.
56. Further, the **2015 Regional Committee for Europe roadmap**⁴ makes recommendations including that member states:

"41. Ensure that comprehensive tobacco control measures, such as taxation, warnings, protection from environmental tobacco smoke and cessation treatment, apply to all tobacco products [Article 4.4 (1)]."

42. Develop appropriate policies that prevent and reduce tobacco consumption, exposure to tobacco smoke and nicotine addiction, with particular attention to young people, non-smokers and vulnerable groups [Article 5.2(b) (1)]."

43. Establish regulations to prohibit or to restrict ingredients aimed at increasing the palatability and attractiveness of all tobacco products [Articles and partial guidelines 9 and 10 (1)]."

44. Adopt and implement effective measures that prohibit the sale and supply of all tobacco and nicotine delivery products to persons under 18 years, including by prohibiting access of minors to self-service vending machines [Article 16 (1)]."

57. Your client will also be aware of the '**Report on the scientific basis of tobacco product regulation: eighth report of a WHO study group**', Geneva: World Health Organization; 2021 (WHO Technical Report Series, No. 1029)⁵. The main recommendations are summarised at 13.1 and include:

"to ensure continued focus on evidence-based measures to reduce tobacco use as outlined in the WHO FCTC and seek to avoid being distracted from tobacco industry actions to promote novel and emerging tobacco products, such as heated tobacco products"

"to use existing regulations for tobacco products to regulate heated tobacco products (including the device) and consider broadening the scope of existing regulations in which regulatory loopholes may be exploited by the tobacco industry, including in countries in which heated tobacco products are currently not legally available"

"to apply the most restrictive tobacco control regulations to heated tobacco products (including the device), as appropriate within national laws, taking into account a high level of protection for human health"

"to prohibit all manufacturers and associated groups from making claims about reduced harm of heated tobacco products, as compared with other products, or portraying heated tobacco products as an appropriate approach for cessation of use of any tobacco product and to ban their use in public spaces unless robust independent evidence emerges to support a change in policy"

⁴ <https://iris.who.int/bitstream/handle/10665/341113/9789240022720-eng.pdf?sequence=1>

⁵ <https://www.who.int/publications/i/item/9789240022720>

58. The recent 2023 policy brief addresses the same points⁶.
59. Your letter refers to the **Khan Review**. The full quotation from the Khan Review⁷ regarding heated tobacco products is as follows:

“A note on heated tobacco products

Although all tobacco products can cause harm, it is important to recognise that smoked tobacco is by far the most harmful (reference 89). There are now newer tobacco products on the market that claim to reduce harm by modifying this process, such as heated tobacco products (HTP). These products heat tobacco through a device but do not ignite it. Like all tobacco products, HTPs are covered under UK tobacco regulations. In practice, these products are quite diverse and there is differing evidence on the health harms related to them. Some evidence (reference 90) associates particular HTPs produced in the US with very high levels of carbon monoxide. Other evidence (reference 91) suggests considerable reductions in exposure to harmful chemicals for people who switch from cigarettes. A recent Cochrane Review (reference 92) found little evidence so far to conclude that they make a contribution to smoking cessation. As with snus, I have come to the conclusion that with such an array of tobacco-free alternatives already available (vapes, patches and gum) the primary distinction in government policy-making and regulation should be between nicotine products that do or do not contain tobacco. However, I do ask that the government supports further independent research into HTPs, and that manufacturers should be made to pay for independent toxicological testing of their products. The government should track the patterns of HTP use and population effects. Based on this research, the government should ensure the regulatory framework is appropriate for these products.”

(underlining added)

60. The Khan Review also says “*Some tobacco accessories have a long track record of egregious promotion that would never be permitted for cigarettes. Other tobacco companies have exploited the same loophole by shifting to promote devices used for heated tobacco rather than the tobacco itself.*”
61. For the avoidance of doubt, voluntarily consulting on the scope of its proposals did not require the Government to consult on its response to the Khan Review. Your letter contains no proposed ground regarding any breach of any alleged duty to consult.
62. Your letter also refers to the **UK Committee on Toxicity’s 2017 statement**⁸. The quotation provided omits the end of the sentence and to present it as the conclusion is misleading by omission. The full context of the statement is as follows:

“28. Tobacco smoking and smokeless tobacco for oral or nasal use are carcinogenic to humans, and have been classified by IARC as Group 1 carcinogens.

29. The aerosol generated by heat-not-burn tobacco products contains a number of compounds of concern, some of which are carcinogens, and there will be a risk to the health of anyone using these products.

30. For non-smokers who start to use these products, this will be an increase in risk, compared to if the products were not used. The Committees were particularly concerned for young people, who do not smoke, starting to use these products, due to the potential for longer exposure over the remainder of their lives compared to adults and to possible differences in sensitivity.

⁶ <https://www.who.int/publications/i/item/9789240042490>

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https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1081366/khan-review-making-smoking-obsolete.pdf

⁸ https://cot.food.gov.uk/sites/default/files/heat_not_burn_tobacco_statement.pdf and https://cot.food.gov.uk/sites/default/files/heat_not_burn_tobacco_summary.pdf

31. *As the exposure to compounds of concern in the aerosol is reduced compared to conventional cigarette smoke, it is likely that there is a reduction in risk, though not to zero, to health for smokers who switch completely to heat-not-burn tobacco products.*

32. *The risks associated with use of heat-not-burn tobacco products cannot be quantified due to gaps in the information available and uncertainties in the dose response relationship of the chemicals and potential adverse health outcomes. In addition, the levels of the different compounds in the aerosol vary compared to the levels in smoke from conventional cigarettes and therefore it is not possible to extrapolate from epidemiological data on smoking risks, particularly given the complexity of the interactions that occur between these compounds in producing adverse health effects.*

33. *As these products contain nicotine and are designed to deliver similar levels of nicotine to conventional cigarettes, their use will not reduce nicotine exposure or its risk to health and possibility of addiction from nicotine.*

34. *Most of the data on heat-not-burn tobacco products has been provided by the product manufacturers. To date there has been limited independent confirmation of the manufacturers' findings, and for public health reassurance the Committees consider it important to obtain independent verification of the manufacturers results.*

35. *Further information on the population impact of availability of these products should be collected, including uptake of these products by smokers and nonsmokers and their age profile, whether product switching or dual use occurs including with e-cigarettes, uptake of smoking as a result of use of these products by non-smokers, and overall population exposure, including bystanders, to compounds of concern.*

36. *In addition to the requested comparison of novel heat-not-burn tobacco products with conventional cigarettes, it is of interest to compare the risks from these products to those from e-cigarettes. This will be borne in mind when the COT considers e-cigarettes, but is not possible to address based on the data presented to the Committees as part of the current evaluation.*

37. *Overall, the Committees conclude that while there is a likely reduction in risk for smokers switching to heat-not-burn tobacco products, there will be a residual risk and it would be more beneficial for smokers to quit smoking entirely. This should form part of any long-term strategy to minimise risk from tobacco use”*

(underlining added)

63. Your letter refers to a **2018 evidence review by Public Health England** on e-cigarettes and heated tobacco products⁹. Again, the quotation is selective and misleading. The full sentence reads: “*On that basis, it concluded that “heated tobacco products may be considerably less harmful than tobacco cigarettes and more harmful than EC (e-cigarettes)”* (underlining added).

64. Your letter refers to decisions by the **U.S. Food and Drug Administration** (the FDA). The FDA operates in a different regulatory environment and the US tobacco market differs from the UK market. The UK Government is not obliged to follow the regulatory decisions of foreign countries.

65. Your letter refers to a study in Japan. However, Japan is not a comparable case study to the UK as users in Japan do not have easy access to non-tobacco nicotine vapes as a cessation tool as nicotine containing e-liquid is categorised as a pharmaceutical ingredient and is strictly controlled. As regards two studies in Japan, a Cochrane Review¹⁰ stated:

“Data from two time-series studies showed that the rate of decline in cigarette sales accelerated following the introduction of heated tobacco to market in Japan. This evidence was of very low-

⁹ https://assets.publishing.service.gov.uk/media/5a981c6740f0b67aa27253cc/Evidence_review_of_e-cigarettes_and_heated_tobacco_products_2018.pdf

¹⁰ <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD013790.pub2/full>

certainty as there was risk of bias, including possible confounding, and cigarette sales are an indirect measure of smoking prevalence.”

“The rate of decline in cigarette sales accelerated after the introduction of heated tobacco to market in Japan but, as data were observational, it is possible other factors caused these changes. Moreover, falls in cigarette sales may not translate to declining smoking prevalence, and changes in Japan may not generalise elsewhere. To clarify the impact of rising heated tobacco use on smoking prevalence, there is a need for time-series studies that examine this association.”

“Conversely, both time-series studies used data from a single country (Japan), which limits the generalisability of conclusions. For instance, Japan differs from many countries because it is illegal to sell nicotine e-cigarettes unless they are registered as a pharmaceutical product. This may have left a gap in the market for heated tobacco.”

66. The Cochrane Review considered these studies to have a GRADE Working Group grades of evidence of ‘very low’ certainty, which means *“we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.”*

VI. Response to requests for information and documents

67. The Government takes its duty of candour of obligations extremely seriously. Aside from the information provided in this letter, no further information or documentation will be provided because:

- a. Your client’s proposed claim is outside the Court’s jurisdiction and the duty of candour therefore does not arise.
- b. In any event, the proposed claim concerns a challenge to the Consultation on the basis of the Gunning principles. Such a challenge will be largely based on the Consultation documents themselves. Should a claim be issued, no further disclosure would be needed to resolve the matter fairly and justly.

68. You are reminded that **claimants in judicial review equally owe a duty of candour**. Your presentation of evidence regarding heated tobacco products and claims about heated tobacco products are selective and misleading, and are not in accordance with the duty of candour.

6. ADR Proposals

69. The Government does not intend to enter into any negotiations with the tobacco industry concerning the smokefree generation proposals, and will not as you propose *“discuss, on an urgent basis, the potential removal of HTP from the scope of the proposed legislation”*. The scope of the proposed legislation will in due course be a matter for Parliament.

70. As set out above, the proposed claim has no merit and your client is urged to reconsider its intention to pursue the claim.

VII. Address for further correspondence and service of court documents

71. We note that proceedings have been filed at the High Court, once proceedings have been issued by the court and validly served, any subsequent documents served by email must be served on the relevant case officers, who are: [REDACTED] [REDACTED]

[redacted] and [redacted] [redacted]
(quoting reference [redacted]).

Yours sincerely

GLD

[redacted]
For the Treasury Solicitor

E [redacted]