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Your ref: [REDACTED]
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18 April 2024

Dear Sir/Madam,

(1) Imperial Brands PLC, (2) Imperial Tobacco Limited, (3) Fontem Ventures BV v Secretary of State for Health and Social Care

1. We write in response to your pre action letter dated 4 April 2024. The proposed claim is related to the 'Creating a smokefree generation and tackling youth vaping Consultation' ('the Consultation').
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. In line with Article 5.3, the Department of Health and Social Care will be publishing both your correspondence and this response, this will also apply to any future correspondence in relation to this matter.
3. In summary, the 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.

Background

4. Smoking is the UK's biggest preventable killer, causing around 1 in 4 cancer deaths and approximately 80,000 deaths, 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. The government and public health sector recognise that vapes can be an effective tool in supporting smoking cessation, but the number of children using vapes has tripled in the past 3 years. Due to nicotine content, vaping carries risk of harm and addiction for children. Not all the risks from vapes have been fully investigated, including inhaling additives for flavours, and the

[REDACTED] - Head of Division

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long-term effects of vaping are yet unknown. There has been a recent and highly concerning surge in the number of children vaping and the evidence shows that vaping products are regularly promoted in a way that appeals to children, through flavours and descriptions, cheap convenient products and in-store marketing - despite the risks of nicotine addiction. The government has consistently said that vapes should not be used by children and that it is concerned about the rise in youth vaping.

6. The use of disposable vaping products (sometimes referred to as single use vapes) has increased substantially in recent years, particularly among young people. The Action on Smoking and Health (ASH) *Use of e-cigarettes among young people in Great Britain* report found that in 2021, only 7.7% of current vape users aged 11 to 17 used disposable vapes, which increased to 52% in 2022 and 69% in 2023.
7. Disposable vapes are neither rechargeable nor refillable and are discarded when they run out of charge or e-liquid, which represents an inefficient use of the finite resources used in their manufacture. These devices are also inherently difficult to recycle and usually must be manually disassembled. Disposable vapes are frequently disposed of incorrectly. Littering causes a range of environmental and animal health risks. Disposal outside specialist recycling poses a fire risk.

Proposed Claimant

8. The proposed Claimants are (1) Imperial Brands PLC, (2) Imperial Tobacco Limited, (3) Fontem Ventures BV. They are referred to collectively in this letter as 'Imperial Tobacco'.

Proposed Defendant

9. The Secretary of State for Health and Social Care ('the Secretary of State') is the correct Defendant, and is represented by the Government Legal Department.

The Consultation

10. The Consultation covered a range of areas. Your letter indicated a particular interest in the areas of disposable vapes and reusable vapes. The Consultation included a number of questions on whether there should be restrictions on the sale and supply of disposable vapes, whether restrictions should take the form of prohibiting their sale and supply, the length of an implementation period, and any other measures. The Consultation included a range of other questions on the regulation of vapes. Prior to the Consultation, the government also held a call for evidence on youth vaping, the results of which were published on 4 October 2023¹.
11. The Consultation closed on 6 December 2023². There were approximately 28,000 valid responses. In relation to disposable vapes, 79.6% of respondents agreed that there should be restrictions on the sale and supply of disposable vapes, and 69% agreed that these restrictions should take the form of prohibiting their sale and supply. For those with links to the tobacco industry, the figures were 64% and 54%. The feedback from the Consultation also shows support for policies to regulate vape flavours, point of sale displays, and packaging and product presentation.
12. A thorough and proportionate approach was adopted to the review and analysis of the very large number of responses to the Consultation. DHSC can confirm that your client's response was read in full. Conscientious consideration was given to all the submissions including the response from Imperial Tobacco.

The Consultation Response – the subject of the proposed challenge

¹ <https://www.gov.uk/government/calls-for-evidence/youth-vaping-call-for-evidence>

² <https://www.gov.uk/government/news/plans-progressed-to-create-a-smokefree-generation>

13. Your proposed challenge is to a specific element of ‘Creating a smokefree generation and tackling youth vaping consultation: government response’ (‘the Response’)³, published on 29 January 2024. The DHSC also published ‘Creating a smokefree generation and tackling youth vaping: your views’ on 12 October 2023.

14. The Response sets out a summary and analysis of responses to the Consultation, and the government’s response. It sets out the decision to bring forward legislation, including in relation to vaping, as follows:

“After considering the responses to this consultation, the UK Government will work with the devolved administrations to bring forward legislation.

[...]

To tackle the rise in youth vaping, the UK Government will take powers to make regulations to:

- restrict vape flavours*
- restrict how vapes are displayed in stores*
- restrict packaging and product presentation for vapes*
- apply the above restrictions to non-nicotine vapes and other consumer nicotine products such as nicotine pouches*

The UK Government intends these measures to be taken forward in secondary legislation which will be subject to further consultation.

The UK Government thinks there is a strong case to take action to reduce the affordability of vapes and is continuing to consider options, including a new duty, to achieve this.

To assist in enforcement, the UK Government will introduce new FPNs for England and Wales set at £100 for breaches of age of sale and free distribution legislation for tobacco and vapes (nicotine and non-nicotine) and regulate to extend these provisions to other consumer nicotine products.

The UK Government, the Scottish Government and the Welsh Government intend to introduce legislation to implement a ban on the sale and supply of disposable vapes. The UK Government will work with the devolved administrations to explore an import ban.”

15. Your letter indicates that the proposed challenge would be to a particular part of the Response, which states (underlining added):

“The UK is a party to the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC) and so has an obligation to protect the development of public health policy from the vested interests of the tobacco industry.

To meet this obligation, there was a mandatory question where we asked all respondents to disclose whether they have any direct or indirect links to, or receive funding from, the tobacco industry.

In total, we received 307 responses from respondents who disclosed links to the tobacco industry. We analysed these alongside other responses using the methodology above.

In line with the requirements of article 5.3 of the FCTC, throughout this consultation response we summarise the views of respondents with disclosed links to the tobacco industry. But we

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

have not considered these views when determining our policy response due to the vested interests of the tobacco industry.

We did not ask directly if respondents were affiliated with the vaping industry. However, we have received a number of responses from the vaping industry, including vape retailers.”

16. Your letter refers to this as the ‘Refusal to Consider Decision’.

The FCTC

17. The UK is a party to the World Health Organization (WHO) Framework Convention on Tobacco Control (‘the FCTC’). The FCTC was adopted by the World Health Assembly on 21 May 2003 and ratified by the UK in 2004. The FCTC entered into effect in 2005 and today over 180 countries are parties to the treaty. The FCTC is the world’s first public health treaty. The UK government was one of the first signatories of the FCTC and takes its obligations under the FCTC very seriously.

18. As a world leader in tobacco control, the UK government is fully committed to application of the FCTC with particular consideration to the requirements under Article 5.3. Article 5.3 states: *“In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law.”*

19. Article 5.3 applies across government, and DHSC produced guidance⁴ (‘the Guidance’) to support other departments. The Guidance states that *“There is a fundamental and irreconcilable conflict between the tobacco industry’s interests and public health policy interests. Government officials should exercise caution during interactions with the tobacco industry, in all cases.”*

20. You assert that *“Article 5.3 does not require representations by the tobacco industry to be discounted”*. We disagree with this. WHO Guidelines for Implementation of Article 5.3 FCTC contains the guiding principle that *“[t]here is a fundamental and irreconcilable conflict between the tobacco industry’s interests and public health policy interests”* and that *“Parties should not accept, support or endorse any offer for assistance or proposed tobacco control legislation or policy drafted by or in collaboration with the tobacco industry”*. It also recommends that: *“Parties are strongly urged to implement measures beyond those recommended in these guidelines when adapting them to their specific circumstances”*.

21. The WHO has advised that countries should either regulate or ban vapes. The UK has chosen to regulate as vapes can be an effective tool to support smokers to quit.

22. As set out in the Guidance, the UK considers that organisations owned by the tobacco industry (including companies producing vapes or nicotine pouches) are within the scope of Article 5.3, but a vape organisation with no tobacco industry links is not in the scope of Article 5.3.

23. At the Sixth Conference of the Parties to the WHO FCTC⁵, Parties were invited to consider taking measures to *“protect tobacco-control activities from all commercial and other vested interests related to ENDS/ENNDS, including interests of the tobacco industry”*. The Decision of the Conference of the Parties defined ENDS and ENNDS as follows: *“Electronic nicotine delivery systems (ENDS), of which electronic cigarettes are the most common prototype, are devices that vaporize a solution, which may include nicotine, or not, the user then inhales”,* and *“Electronic non-nicotine delivery systems (ENNDS)”*.

24. Article 18 of the FCTC covers Protection of the Environment. The Convention states: *“In carrying out their obligations under this Convention, the Parties agree to have due regard to the*

⁴ <https://www.gov.uk/government/publications/protocol-for-engagement-with-stakeholders-with-links-to-the-tobacco-industry/guidance-for-government-engagement-with-the-tobacco-industry>

⁵ [https://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6\(9\)-en.pdf](https://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6(9)-en.pdf)

protection of the environment and the health of persons in relation to the environment in respect of tobacco cultivation and manufacture within their respective territories.”

25. The link between the FCTC and the environment was further strengthened through a decision⁶ made at the Tenth Conference of the Parties to the FCTC in February 2024. The Decision states that the Conference of the Parties, to which the UK was represented, “*Decides...to urge Parties to take into account the environmental impacts from cultivation, manufacture, consumption and waste disposal of tobacco products and related electronic devices, and to strengthen the implementation of Article 18 of the WHO FCTC, including through national policies related to tobacco and/or protection of the environment*”
26. It is correct that the Guidance does not mandate that government departments should refuse to consider consultation responses submitted by entities with links to the tobacco industry when conducting public consultations – neither does it exclude departments from doing so. It does not cover the consideration of consultation responses. It only covers the design of the consultation questions, setting out that “*When undertaking a consultation on tobacco policy, respondents should be asked to declare any direct or indirect links to, or funding received from, the tobacco industry.*” What approach to take to responses from the tobacco industry is not covered by the Guidance and is left to the discretion of individual departments.

The Tobacco and Vapes Bill

27. The government introduced the Tobacco and Vapes Bill⁷, Bill 189 of 2023-24 (‘the Bill’)⁸ to Parliament on 20 March 2024. Its Second Reading was on 16 April 2024. Additionally, the government has committed to ban the sale and supply of disposable vapes from April 2025 under separate environmental legislation as set out below.
28. As set out in the Consultation Response, the Bill will grant the government powers to make regulations to restrict vape flavours, restrict how vapes are displayed in stores, restrict packaging and product presentation for vapes, and apply the above restrictions to non-nicotine vapes and other consumer products. These measures will be taken forward in secondary legislation which will be subject to further consultation. The government aims for this secondary legislation to be laid in Parliament in 2025.
29. No decisions have been made on specifics of this secondary legislation. No restrictions on vapes have been included on the face of the Bill, other than to make it illegal in the future to give free samples of vapes to under 18s and to introduce an age of sale for non-nicotine vapes.

The draft SI

30. DEFRA published a draft Statutory Instrument (SI), Impact Assessment and Explanatory Memorandum on 11 March 2024: The Environmental Protection (Single-use Vapes) (England) Regulations 2024 draft SI. Alongside this publication, DEFRA started an informal 2-week engagement period where they asked for views or comments on the draft regulations.
31. Your letter indicates no challenge to this draft regulation, and indeed any challenge would be premature.

Details of the matter being challenged

32. Your letter alleges that the ‘Refusal to Consider Decision’ was unlawful on the grounds that it was contrary to basic common law requirements of fair consultation and/or procedural fairness and/or Imperial Tobacco’s procedural legitimate expectation.

⁶ <https://storage.googleapis.com/who-fctc-cop10-source/Decisions/fctc-cop-10-14-en.pdf>

⁷ <https://www.gov.uk/government/news/smokefree-generation-one-step-closer-as-bill-introduced>

⁸ <https://bills.parliament.uk/bills/3703>

33. For the following reasons, 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.

Response to the proposed claim

Jurisdiction

34. 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*".
35. 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.
36. The proposed challenge to the Consultation Response would be precisely such a challenge, and is therefore impermissible. Your pre-action letter fails to address this fundamental issue.
37. 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 "vitiating" 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 "vitiating" 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".

38. 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.”

39. For this reason, the proposed claim would have no realistic prospect of success and would be dismissed.

Grounds in any event lack merit and are unarguable

40. Without prejudice to the above, the proposed grounds are plainly without merit and wholly unarguable for the following reasons. These reasons are given briefly, as the subject matter of the challenge is now within the scope of the Bill and is being considered by Parliament.
41. Your letter appears to be based on a misapprehension, arising from the use of the term ‘considered’. The views of respondents with links to the tobacco industry were not ignored or omitted. They were read, analysed and summarised. The Secretary of State was aware of them. The Secretary of State took account of and acknowledged the content of tobacco industry responses and shared the summary in the published government Response. They were, in summary, given the conscientious consideration required by *Gunning* along with all other responses.
42. When it came to the determining the policy response, a lawful decision was made to then discount the known views of respondents linked to the tobacco industry in order to comply with the UK’s obligations under the FCTC to protect public health policy from the commercial and other vested interests of the tobacco industry. *Gunning* does not require that a public body’s decision be influenced or determined by every (or any) consultation response.
43. None of the correspondence cited in your letter contains any promise that Imperial Tobacco’s response (or the responses from the tobacco industry in general) would influence or determine the ultimate decisions. No possible legitimate expectation could arise.
44. The same approach was taken in the Youth vaping call for evidence analysis⁹ which was published on 4 October 2023, and which said:

“Tobacco industry declaration

The UK is a party to the World Health Organization Framework Convention on Tobacco Control (FCTC) and so has an obligation to protect the development of public health policy from the vested interests of the tobacco industry. To meet this obligation, we asked all respondents to disclose whether they have any direct or indirect links to, or receive funding from, the tobacco industry. In line with Article 5.3 of the FCTC, we have documented tobacco industry comments as part of this analysis. However, we will not consider these comments when formulating actions to reduce the number of children vaping.”

45. It was entirely reasonable, rational, lawful and procedurally fair for the Secretary of State, having carefully taken into account the full range of Consultation responses including those from the tobacco industry, to decide that the final decisions ought not to be influenced by the views of the tobacco industry.

⁹ <https://www.gov.uk/government/calls-for-evidence/youth-vaping-call-for-evidence/outcome/youth-vaping-call-for-evidence-analysis>

46. Further, the Court of Appeal in *R (Eveleigh) v Secretary of State for Work and Pensions* [2023] EWCA Civ 810, [2023] 1 WLR 3599 did not determine whether or not a voluntary consultation necessarily attracts the full requirements of *Gunning* (because the Court of Appeal allowed the government's appeal on another ground), and expressly stated that this question would have to be determined in another case. The Secretary of State would reserve the right to test this same point in any proceedings before the Court of Appeal.

Response to requests for information and documents

47. Aside from the information provided in this letter, no further information or documentation will be provided because your client's proposed claim is outside the Court's jurisdiction and the duty of candour therefore does not arise. In any event, sufficient information has been provided in this letter to enable your client to determine whether to bring judicial review proceedings.

ADR proposals

48. Imperial Tobacco may contribute to any future consultation which will be launched ahead of the introduction of specific regulations on the sale of vapes.

49. However, the government does not intend to enter into any negotiations regarding the scope of the proposed legislation, which is a matter for Parliament.

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

Address for further correspondence and service of court documents

51. Any subsequent documents served by email must be served on the relevant case officer who is [REDACTED] (quoting reference number [REDACTED]).

Yours sincerely



[REDACTED]
For the Treasury Solicitor

D [REDACTED]
E [REDACTED]